

Using Intellectual Property Rights to  
Stimulate Pharmaceutical Production  
in Developing Countries:  
**A REFERENCE GUIDE**



**United Nations Conference on Trade and Development**

**Using Intellectual Property Rights  
to Stimulate Pharmaceutical Production  
in Developing Countries: A Reference Guide**

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# Preface

Over the past few years, intellectual property rights (IPRs) have become a major economic, trade and investment issue, as illustrated by considerable increases in royalty payments and licensing fees in most areas of the world and the inclusion of intellectual property (IP) provisions in regional and bilateral trade and investment agreements. At the same time, concerns have been raised in many countries as to whether the IP system still serves its original purpose, i.e. the promotion of innovation and the transfer and dissemination of technology to the benefit of society, or whether exclusive rights are increasingly being used to defend selective private interests and prevent effective competition.

This debate has been particularly intense in the context of countries' public health policies. Patents and the protection of pharmaceutical test data are frequently mentioned in discussions regarding access to medicines in developing countries. The United Nations Millennium Development Goals (MDGs) put considerable emphasis on access to medicines. Based on its expertise in the interrelated areas of investment, IP and technology transfer, the United Nations Conference on Trade and Development is committed to making its contribution to this important issue.

The present Guide has been prepared by the UNCTAD secretariat (Division on Investment and Enterprise (DIAE)) as part of its technical assistance activities in the area of IPRs and the promotion of pharmaceutical production and supply capacities in developing countries.

These activities respond to a 2005 recommendation by UNCTAD's Commission on Investment, Technology and Related Financial Issues that:

“UNCTAD should, within its work programme on investment, technology transfer and intellectual property, assess ways in which developing countries can develop their domestic productive capability in the supply of essential drugs in cooperation with pharmaceutical companies.”<sup>1</sup>

In the pursuit of this mandate, UNCTAD established in 2006 a pilot programme on local pharmaceutical production and the implementation of regulatory frameworks for access to medicines with the financial support of Germany and the United Kingdom. The overall objective of the programme, implemented by the UNCTAD/DIAE Intellectual Property Unit, is to assist developing countries, and least developed countries (LDCs) in particular, to (a) establish domestic intellectual property regimes that facilitate increased access to affordable medicines; and (b) where feasible, create local or regional pharmaceutical production and supply capacities, with the possibility of cooperative arrangements with investors.

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<sup>1</sup> See [http://www.unctad.org/en/docs/c2122\\_en.pdf](http://www.unctad.org/en/docs/c2122_en.pdf) (paragraph 9(c) of the 2005 Agreed Recommendations).

The objective of the present Guide is to provide concise and practical information on ways to promote local pharmaceutical production and improve access to medicines through a variety of policy tools, focusing on the flexibilities provided under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the interfaces between IP, investment, drugs regulation and procurement strategies. The Guide will be an important tool for training activities for stakeholders from selected developing countries, in an effort to build capacities for the creation of domestic legal frameworks conducive to the promotion of pharmaceutical production and supply capacities.



Supachai Panitchpakdi  
Secretary-General of UNCTAD

## Acknowledgments

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UNCTAD gratefully acknowledges extensive comments on earlier versions of this Guide from experts from intergovernmental organizations, governments, civil society organizations and academia, *inter alia* at informal consultations convened by the UNCTAD secretariat on 11 October 2007 at the Palais des Nations, Geneva, as well as the invaluable contributions by Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development (ICTSD), and Melanie Jones (Duke University School of Law). Mineko Mohri and Erin Close provided very helpful inputs for the finalization of this document. The UNCTAD secretariat is solely responsible for the contents and policy options provided in this Guide.

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## Abbreviations

ACP	African, Caribbean, and Pacific Group of States
AIPPI	Association for the Protection of Intellectual Property
ALRC	Australian Law Reform Commission
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
BGH	Bundesgerichtshof (Federal Court of Justice, Germany)
BIT	bilateral investment treaty
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (Federal Ministry for Economic Cooperation and Development, Germany)
CAFC	Court of Appeal for the Federal Circuit (United States)
CAFTA	Central American Free Trade Agreement
CAMR	Canada's Access to Medicines Regime
CARIFORUM	Caribbean Forum
CBD	Convention on Biological Diversity
CCPA	Court of Customs and Patent Appeals (United States)
CGIAR	Consultative Group on International Agricultural Research
CIEL	Center for International Environmental Law
CIPRH	Commission on Intellectual Property Rights, Innovation and Public Health
DIAE	Division on Investment and Enterprise (UNCTAD)
DFID	Department for International Development (United Kingdom)
DRA	Drug Regulatory Authority
EAC	East African Community
EC	European Community(ies) (now European Union)
ECJ	European Court of Justice
EGC	European General Court (formerly European Court of First Instance)
EFTA	European Free Trade Association
EML	Essential Medicines List
EMR	Exclusive Marketing Right
EPA	European Partnership Agreement
EPC	European Patent Convention
EPO	European Patent Office
EST	Expressed Sequence Tag
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (United States)
FDC	fixed dose combination
FDI	foreign direct investment
FIFRA	Federal Insecticide Fungicide and Rodenticide Act (United States)
FTA	free trade agreement
GAO	Government Accountability Office (United States)
GATT	General Agreement on Tariffs and Trade
GDP	gross domestic product

GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit (German Federal Agency for Technical Cooperation)
HAI	Health Action International
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
ICTSD	International Centre for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IP	intellectual property
IPRs	intellectual property rights
IP Watch	Intellectual Property Watch (Monthly Edition and online publication)
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture (FAO)
JPO	Japanese Patent Office
KEI	Knowledge Ecology International
LDC	least developed countries
MDGs	Millennium Development Goals
MFN	most favoured nation
MSF	Médecins Sans Frontières
NAFTA	North American Free Trade Association
NGO	non-governmental organization
OAPI	Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization)
OECD	Organization for Economic Cooperation and Development
PCT	Patent Cooperation Treaty
R&D	research and development
RPSC	regional pharmaceutical supply center
RTA	regional trade agreement
SNP	Single Nucleotide Polymorphisms
SPLT	Substantive Patent Law Treaty
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRM	Tiered Royalty Method
UNDP	United Nations Development Programme
U.S.C.	United States Code
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## **PART ONE**

### **Stimulating the Local Production of Pharmaceuticals in Developing Countries: Introductory remarks**

At the September 2005 United Nations General Assembly, the Heads of State and Government of the United Nations Member States reiterated their determination to ensure the timely and full realization of the Millennium Development Goals (MDGs) by 2015. Despite this commitment, the MDGs are far from being realized. In particular, large populations in developing countries still lack regular access to essential medicines.<sup>2</sup> One third of the global population lacks access to needed medicines, and the situation is worse in poor countries, where as much as 50 per cent of the population lacks access.<sup>3</sup>

#### **A. Underlying premises of this Guide**

Effective promotion of affordable access to medicines in developing countries depends on a multitude of different factors. Access is made difficult by insufficient distribution infrastructure, lack of medical personnel, trade and fiscal barriers, inadequate health care systems and prices that are unaffordable to citizens of developing countries. There have been important initiatives on the part of the pharmaceutical industry to donate medicines, but the magnitude of the health crisis faced by developing countries requires more sustainable, long-term solutions.<sup>4</sup> Particular difficulties arise in the case of diseases that disproportionately affect developing countries, such as tuberculosis and malaria, due to the fact that market mechanisms have failed to provide the pharmaceutical industry with incentives to rapidly develop effective cures.

One possible means of addressing the lack of access to medicines in developing countries is the creation of local pharmaceutical production and supply capacities. This could make developing countries less dependent on the importation of pharmaceutical products, which are often high-priced. The potential importance of local production has been recognized in World Health Assembly (WHA) Resolution 61.21, “Global strategy and plan of action on public health, innovation and intellectual property”, Element 4.1 of which calls upon member States

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<sup>2</sup> Access to medicines plays an important role in the realization of the United Nations Millennium Development Goals (MDGs). See Goal 6 (Combat HIV/AIDS, malaria and other diseases) and Goal 8, target 17 (In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries) available at: [http://www.who.int/topics/millennium\\_development\\_goals/about/en/index.html](http://www.who.int/topics/millennium_development_goals/about/en/index.html).

<sup>3</sup> World Health Organization and Health Action International, “Measuring Medicine Prices, Availability, Affordability and Price Components,” 2nd edition, 2008, p. 1.

<sup>4</sup> This is the view expressed by the former CEO of Merck. See “Public health, innovation and intellectual property rights”, Report of the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health, Geneva, April 2006, pp. 131/132 [hereinafter CIPIH Report]. (available at: <http://www.who.int/intellectualproperty/report/en/index.html>).

to promote the “transfer of technology and the production of health products in developing countries”.<sup>5</sup>

The Organization for Economic Cooperation and Development (OECD) High Level Forum on Medicines for Neglected and Emerging Infectious Diseases in June 2007 recommended:

“[...] 3. Supporting developing countries-led efforts in strengthening their own health, local production and research systems [...]. In particular: [...] Taking steps to strengthen the capability of developing countries to manage issues of intellectual property, including using available flexibilities to the fullest extent, and to build sustainable networks and capacity for global research.”<sup>6</sup>

The European Parliament has urged the European Union (EU) and its member States to:

“take additional measures [...] to facilitate and increase the production of pharmaceutical products by the developing countries themselves [...] [and] to provide concrete financial support for [...] local production of pharmaceuticals in all developing countries, especially LDCs [...]”<sup>7</sup>

Based on the work undertaken by UNCTAD on IPRs and development,<sup>8</sup> this Guide is meant to provide concise and practical information on the ways international IPR rules may be used as tools for the promotion of local pharmaceutical production in developing countries and LDCs. Additionally, many of the measures discussed in this Guide would contribute to strengthening developing countries’ and LDCs’ capacities to purchase patented medicines at affordable prices, irrespective of their local production capacities. The Guide is mainly addressed to developing country government officials and policymakers, producers of generic pharmaceutical products and their legal counsels, as well as civil society stakeholders. The Guide does not attempt to provide a comprehensive treatment of the access to medicines issue, nor does it explore contextual issues of local production, such as infrastructure and governance challenges. In order for the options available under the TRIPS Agreement to be fully implemented, a combination of political will, good lawyering and sufficient resources is required.<sup>9</sup> This Guide deals with the question of good lawyering, with a view to enabling those countries with a political will to increase both access to needed medicines and local pharmaceutical production.<sup>10</sup>

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<sup>5</sup> Sixty-first World Health Assembly, WHA61.21 of 24 May 2008, Element 4.1, para. 32, p. 41 (available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA61-REC1/A61\\_REC1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA61-REC1/A61_REC1-en.pdf)).

<sup>6</sup> See OECD, “Noordwijk Medicines Agenda”, 21 June 2007, (available at: <http://www.oecd.org/dataoecd/62/11/38845838.pdf>).

<sup>7</sup> See Nos. 3 and 4 of the Resolution P6\_TA-PROV (2007) 0353 of 12 July 2007 (available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN>).

<sup>8</sup> See the UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development (available at: <http://www.unctad.org/ddip>).

<sup>9</sup> See F. Abbott, J.H. Reichman, “The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions,” *Journal of International Economic Law*, Vol. 10, 2007, pp. 921 ff. [hereinafter Abbott/Reichman] (available at [http://eprints.law.duke.edu/1838/1/Reichman10\\_J.Int'l\\_Econ\\_L.921-987\\_2007.pdf](http://eprints.law.duke.edu/1838/1/Reichman10_J.Int'l_Econ_L.921-987_2007.pdf)).

<sup>10</sup> There have been some indications of enhanced collaboration among African nations. The African Union’s Conference of Ministers of Health decided to “pursue, with the support of our partners, the local production of generic medicines on the continent and to making full use of the flexibilities within the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health.” See the “Gaborone Declaration”, Doc. CAMH/Decl.1 (II), 10-14 October 2005, p. 3.

UNCTAD's work on the IP aspects of local pharmaceutical production is part of a larger German-sponsored initiative to promote local pharmaceutical producers in the developing world.<sup>11</sup> In addition, UNCTAD, with the support of the United Kingdom's Department for International Development (DFID) provided technical assistance to developing countries in the implementation of regulatory frameworks for access to medicines.

IPRs may provide important incentives for innovation in the pharmaceutical sector<sup>12</sup> but may also create obstacles to future innovation and impediments to the diffusion of both knowledge and research results in addition to high prices that reduce access to needed medicines.<sup>13</sup> Experts have highlighted that exclusive rights are one of the important factors influencing the prices of pharmaceutical products.<sup>14</sup> This premise was also acknowledged in the World Trade Organization (WTO) Declaration on the TRIPS Agreement and Public Health, whose paragraph 3 states:

“3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.”<sup>15</sup>

The high prices of patented products result from the need for the pharmaceutical industry to recoup the research and development (R&D) costs as well other expenditures, such as marketing costs. Questions arise, however, when the pricing policies of some companies result in medicines being marketed by way of a low-volume, high margin strategy in

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<sup>11</sup> The German initiative originates in the Federal Ministry of Economic Cooperation and Development (BMZ) and involves other stakeholders such as the United Nations Industrial Development Organization (UNIDO), the German Agency for Technical Cooperation (GTZ), the German Bank for Reconstruction (KfW), and Capacity Building International, Germany (InWEnt). The involvement of a broad range of stakeholders reflects the multi-faceted aspects of promoting local pharmaceutical production, i.e. the need to provide technical assistance regarding a domestic legal framework on IP and investment; macro-and micro economic analysis and assistance for governments and companies; training of local producers in production and quality issues; and the financing of training activities. It is important to note that this initiative is not seeking to introduce pharmaceutical production in every developing country or LDC, but only in those where this seems economically feasible and sustainable.

<sup>12</sup> See, e.g., J. Straus, “The Impact of the New World Order on Economic Development: The Role of the Intellectual Property Rights System”, *European Review*, Vol. 15, Issue 01, 2007, pp. 47 ff., referring also to other sectors of industry.

<sup>13</sup> See, e.g., C. Correa, “Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?”, in *International Public Goods and Transfer of Technology under A Globalized Intellectual Property Regime*, editors K. Maskus and J.H. Reichman, Cambridge University Press, 2005 [hereinafter Maskus/Reichman], pp. 227 ff (229–32); J.H. Reichman, R. Cooper Dreyfuss, “Harmonization Without Consensus: Critical Reflections on Drafting A Substantive Patent Law Treaty”, *Duke Law Journal*, 2007, pp. 85 ff. [hereinafter Reichman/Cooper Dreyfus].

<sup>14</sup> See Commission on Intellectual Property Rights, “Integrating Intellectual Property Rights and Development Policy”, London, 2002, p. 36 [hereinafter Commission on Intellectual Property Rights] (available at [www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)); and the United Kingdom Department for International Development, “Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry”, March 2005, p. 20 [hereinafter DFID] (available at <http://www.aidsportal.org/store/909.pdf>). The view that patents affect drugs prices is not uncontroversial. For the opposing opinion, see T. Jones in the CIPIH Report, p. 225, referring to non-IPR-related obstacles. See also E. Noehrenberg, “The realities of TRIPS, patents and access to medicines in developing countries”, in *The Intellectual Property Debate. Perspectives from Law, Economics and Political Economy*, editor M.P. Pugatch, Cheltenham, Northampton, 2006, pp. 170 ff. [hereinafter Noehrenberg], arguing that patents confer much less pricing power than usually thought.

<sup>15</sup> Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN(01)/DEC/W/2, of 14 November 2001 (available at: <http://www.who.int/medicines/areas/policy/tripshealth.pdf>).

developing countries, particularly considering that R&D costs are typically recuperated through sales in OECD countries.<sup>16</sup>

In the absence of exclusive rights on pharmaceutical products, prices for drugs may be kept at a more affordable level than under a patent regime. An example is India, which had the lowest prices for pharmaceutical products in the world prior to patent protection being introduced in 2005.<sup>17</sup> Existing studies estimate that the introduction of patent regimes in lower and middle income developing countries will result in price increases between 12 per cent and 200 per cent,<sup>18</sup> which is highly likely to have an impact on effective access to medicines in these countries. In their research on the subject, DFID refers to various studies confirming important price differences between patented and generic pharmaceutical products.<sup>19</sup>

A sufficient degree of generic competition will typically contribute to price decreases,<sup>20</sup> although there are some cases when generic prices are not lower than those charged for patented products.<sup>21</sup> Companies that produce generics operate according to the same market principles as brand name pharmaceutical producers and are sometimes unable to offer the lowest price available in small developing countries that do not possess sufficient purchasing power. It is for this reason that the present Guide seeks to promote a cooperative and, ideally, regional approach to intellectual property in relation to local pharmaceutical production issues by developing country governments, in the hope of fostering regional pharmaceutical markets and economies of scale and scope.<sup>22</sup>

This Guide is based on several underlying premises:

- a) This Guide takes the stance that, were the existing flexibilities available to WTO members for the implementation of international IP standards fully utilized, there would be beneficial effects for developing countries, both in terms of availability of medicines as well as local pharmaceutical R&D and innovation. However, this Guide does acknowledge that IPRs are only one factor among many that affect the availability and production of pharmaceutical substances in developing countries. Some believe that the impact of IPRs on access to medicines in developing countries should be minimal<sup>23</sup>, because pharmaceutical patents are concentrated in larger,

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<sup>16</sup> See Abbott/Reichman; K. Outterson, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries", *American Journal of Law and Medicine*, Vol. 32, 2006, pp. 159 ff [hereinafter Outterson] (available at <http://www.cptech.org/ip/health/prizefund/files/outterson-buyouts.pdf>). See also Ministry of Public Health and National Health Security Office, Thailand, "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand", February 2008 (available at: [http://www.moph.go.th/hot/Second\\_white\\_paper\\_on\\_the\\_Thai\\_CL\\_%5BEN%5D.pdf](http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf)). The CIPIH Report, pp. 111/112, states that "companies may find it best for their profitability to concentrate only on high income segments in developing countries, in particular because it is more difficult to apply a differential pricing policy within developing countries than it is between them." It should be noted, however, that some companies have undertaken remarkable efforts in setting up systems of tiered pricing in developing countries. See, for example, Gilead, available at: [http://www.gilead.com/enabling\\_access](http://www.gilead.com/enabling_access).

<sup>17</sup> Commission on Intellectual Property Rights, p. 36.

<sup>18</sup> Ibid, p. 37, referring to studies by C. Fink (2000) and J. Watal (2000).

<sup>19</sup> DFID, p. 20.

<sup>20</sup> See the CIPIH Report, p. 112, referring to the significant role that competition within the generics industry has played in bringing down prices of off-patent pharmaceutical products.

<sup>21</sup> See DFID, p. 21. See also Noehrenberg, pp. 174-175, who provides several examples of patented products undercutting the prices charged by generic competitors.

<sup>22</sup> For details, see below, Section 3.3.3.2.

<sup>23</sup> Ibid; Noehrenberg, p. 172; for further sources see Commission on Intellectual Property Rights, p. 35, with references.

developed market<sup>24</sup>. One piece of evidence used to support this view is the fact that the majority of drugs included on the World Health Organization's (WHO's) Essential Medicines List (EML) are not patented in sub-Saharan African countries and other LDCs. There are multiple reasons that this conclusion is inaccurate: First, the overall cost of treatment and cost-effectiveness are criteria for inclusion of a pharmaceutical product on the EML, so a number of on-patent essential medicines are likely omitted on these grounds.<sup>25</sup> Second, the low percentage of patented drugs on the EML is an overall figure, which does not necessarily apply to large developing countries with a high number of HIV/AIDS patients. Even in sub-Saharan Africa, pharmaceutical patent coverage is rather comprehensive in countries with large populations and/or relatively higher incomes and a considerable number of HIV/AIDS patients, such as Kenya, South Africa and Zimbabwe.<sup>26</sup> Third, patents granted in large developing countries can have a direct effect on the access to that same drug in smaller LDCs, even if it is not patented in the latter. Patients and local producers in the smaller country often depend on the importation of medicines or pharmaceutical substances from larger developing countries. High prices in the source country, as generated by patents, may considerably decrease access to these substances.<sup>27</sup> Fourth, the fact that drugs patenting is higher in large countries limits generic producers to the remaining small markets, which may complicate efforts to benefit from economies of scale.

- b) The appropriate and balanced implementation of multilateral rules on IP, particularly those regarding patents and pharmaceutical test data, plays an important role in a government's strategy to promote local pharmaceutical production. In this area, IP may provide incentives to local inventors and foreign investors.<sup>28</sup> This is particularly true in more advanced developing countries where local industries have acquired a certain level of technological capacity that enables them to engage in inventive activity. IPRs may also play a role in facilitating the licensing of technology necessary to this inventive activity, as well as purchases of related products that would not otherwise be available without such protection. However, supplier firms may also use

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<sup>24</sup> See A. Attaran. "How do patents and economic policies affect access to essential medicines in developing countries?" *Health Affairs*, Vol. 23, No. 3, 2004 (available at: <http://content.healthaffairs.org/cgi/content/full/23/3/155>), stating that only 1.4 per cent of the drugs included on the EML are patentable.

<sup>25</sup> See Commission on Intellectual Property Rights, p. 53, footnote 41.

<sup>26</sup> See UNCTAD-ICTSD, "Intellectual Property Rights: Implications for Development", Policy Discussion Paper, Geneva, 2003 p. 97, Box 6.2 [hereinafter UNCTAD-ICTSD Policy Discussion Paper] (available at <http://www.iprsonline.org/unctadictsd/policyDpaper.htm>), citing Oxfam, Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign and Health Gap, "Comment on the Attaran/Gillespie-White and PhRMA surveys of patents on Antiretroviral drugs in Africa", 2001 (available at: <http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html>). The above-mentioned NGOs in their comment state that "the 23 countries in Sub-Saharan Africa that have 4 or more ARV products on patent have 53 per cent of the HIV+ patients and 68 per cent of the Region GDP. The 20 Sub-Saharan countries that have patents on 6 or more ARV products have 46 per cent of the patients and 56 per cent of the region's GDP."

<sup>27</sup> Commission on Intellectual Property Rights, p. 35, referring to South Africa as one important pharmaceutical supplier for its small neighbouring countries, and the possibility of affecting drug supply in the latter by limiting drug patents to South Africa.

<sup>28</sup> See, for instance, A. Arora, A. Fosfuri and A. Gambardella, "Markets for Technology, Intellectual Property Rights and Development", in Maskus/Reichman, pp. 321 ff. (325-26: "Strong patent protection provides incentives to codify and organize new knowledge in ways that are meaningful and useful to others."); A.O. Sykes, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha 'Solution'", *Chicago Journal of International Law*, Vol. 3, No. 1, 2002, pp. 47 ff. (48: "The ultimate wisdom of measures that relax intellectual property protection for pharmaceuticals in developing countries turns on complex matters, including empirical issues about which one can only hazard an educated guess."). See also discussion, *infra*, on the limits of IPRs and the need for balance.



IPRs to restrict the availability of both technology and high-technology products by either refusing to deal with local entrepreneurs or extracting such high rents that local business owners become uncompetitive on world markets. For this reason, this Guide identifies areas of competition law and policy that are of particular relevance to the control of IP-related practices and that potentially have a restrictive effect on competition and the transfer and dissemination of technology.

- c) IPRs should be geared to the technological capacities of the country in question to the extent that the policy space under the TRIPS Agreement allows in order to maximize incentives to invent. In some advanced developing countries, these incentives must take into account the needs of an emerging research and development (R&D)-based pharmaceutical industry. Moreover, countries with some capacity in pharmaceutical R&D will also benefit from the availability of IPRs in OECD markets, irrespective of the level of IP protection at home.<sup>29</sup> For most developing countries and LDCs, however, inventive capacity in the pharmaceutical sector remains very low. The availability of affordable generic medicines from both local production and imports is best guaranteed by the establishment of a pro-competitive environment as created through the use of certain legal tools available under the TRIPS Agreement.<sup>30</sup>
- d) It is thus an underlying principle of this Guide that the effective promotion of a pro-competitive environment is one of the major driving forces behind product improvement and pharmaceutical innovation. In most developing countries, the notion of a “pro-competitive environment” is understood to be much broader than issues relating only to competition law; rather, it requires the design of IP law and policy that reflect a proper balance between the granting of exclusive rights and the promotion of follow-on innovation through competitors.
- e) The distribution of patented drugs in developing countries should, in principle, follow a high-volume, low-margin pricing strategy, rather than a low-volume, high-margin approach, in order to make products broadly available to more who need them. In relation to this premise, an increase in the local production capacity of developing countries’ pharmaceutical industries will also likely exert a considerable influence on prices, as well as expand local technological capacity.
- f) The establishment or growth of local pharmaceutical production facilities has spill-over effects of potentially great benefit to both developing countries and LDCs. In addition to the direct employment benefits that such facilities produce, local production results in the diffusion of know-how and may create networking effects between the producer and local universities and research institutes. Through such connections, developing countries may continue to increase their ability to

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<sup>29</sup> This is due to the principle of independence of patents obtained for the same invention in different countries, see Article 4*bis* of the Paris Convention for the Protection of Industrial Property [hereinafter Paris Convention] (available at [http://www.wipo.int/treaties/en/ip/paris/trtdocs\\_wo020.html](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html)). According to S. Chaudhuri, increased patenting by major Indian pharmaceutical companies since 1995 is due to the availability of broad patent protection in OECD countries, rather than the introduction of product patent protection in India. See S. Chaudhuri, “Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS”, Indian Institute of Management Calcutta, *Working Paper Series*, WPS No. 614, 2007 (available at <http://ictsd.org/i/ip/health/24097/>).

<sup>30</sup> See also the CIPIH Report, p. 112: “Governments should work to create a pro-competitive environment for the marketing of medicines, as competition is in the last instance the key tool to drive prices down and improve access to medicines.”

manufacture existing drugs, invent new medicinal technologies, and develop applications of traditional knowledge, which can lead to additional exports and marketing opportunities.

## **B. Limits of intellectual property rights and the need for balance**

There has been a tendency in recent years for courts to grant exclusive rights on derivatives of existing pharmaceutical compounds whose inventiveness is questionable.<sup>31</sup> In 2002, the United States Federal Trade Commission found that generic producers had a success rate of close to 75 per cent in challenging pharmaceutical patents in the United States.<sup>32</sup> Between 2000 and 2007, generic producers prevailed in 62 per cent of the final judgments rendered by European courts in patent litigation cases between originator and generic companies. The vast majority of these cases were initiated by originator companies.<sup>33</sup> Where not challenged, improperly granted exclusive rights may cause considerable obstacles for follow-on innovation, especially in countries where local industries lack inventive capacity. Broad exclusive rights (often held by foreign companies) may block access by local producers to informal means of technology transfer through reverse engineering, imitation or adaptation. Learning and follow-on innovation by domestic manufacturers in developing countries also depend on the public domain availability of data, information, materials and research tools, as well as know-how. Denying access to these latter inputs through overly broad exclusive rights may hinder or prevent the development of local expertise, thereby limiting the potential for effective collaboration between foreign investors and local industries. A 2003 OECD study on the impact of IPR protection on foreign direct investment (FDI) found that:

“[...] The results do not imply that stronger patent protection (or correlated IPRs) will always raise FDI and trade. There may come a point where these types of IPRs are too strong – in the sense that they grant producers of intellectual products excessive market power – in which case IPRs may negatively influence FDI and trade. Thus, the empirical finding [i.e. that there is a positive correlation between IPR protection and the promotion of FDI] is conditional on intellectual property systems not reaching excessive levels of strength.”<sup>34</sup>

In order to establish sustainable pharmaceutical production in developing countries, the present Guide underlines the importance of foreign investment, either through the R&D-based or the generic pharmaceutical industry. Depending on the investor's priorities, IPRs can play a positive role by encouraging the transfer of needed technology and know-how, leading to the production of existing pharmaceuticals and the innovation of new medicines.<sup>35</sup> However,

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<sup>31</sup> For details, see below, Section 2.4.2.2.

<sup>32</sup> See Federal Trade Commission, “Generic Drug Entry Prior to Patent Expiration: An FTC Study”, Washington, D.C., July 2002, p. 17 [hereinafter United States FTC Study] (available at: <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>).

<sup>33</sup> See Competition Directorate General of the European Commission, “Pharmaceutical Sector Inquiry”, Final Report, 8 July 2009, p. 12 (para. 3.2.2.) [hereinafter EU Pharmaceutical Sector Inquiry] (available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>).

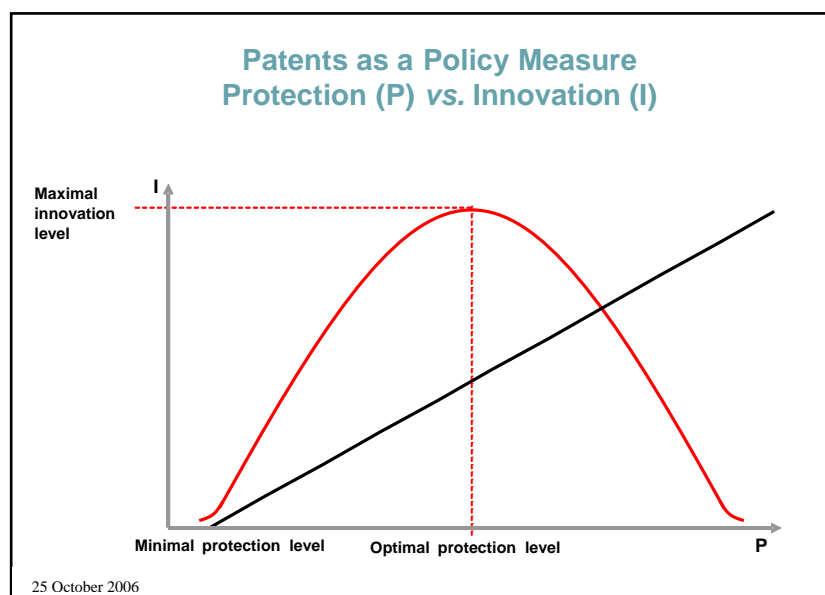
<sup>34</sup> OECD, Working Party of the Trade Committee, “The Impact of Trade-Related Intellectual Property Rights on Trade and Foreign Direct Investment in Developing Countries”, 2003 (available at: <http://www.oecd.org/dataoecd/59/46/2960051.pdf>), p. 4.

<sup>35</sup> At the informal consultations on an earlier draft of this Guide held on 11 October 2007 at the Palais des Nations [hereinafter peer review meeting], stakeholders disagreed regarding the effects that IPRs can play in

putting one-sided emphasis on exclusive rights and inappropriately limiting the public domain may not only prevent domestic learning, but risks deterring an important source of foreign investment, i.e. big generic companies in countries such as India or the European Union member States. Representatives of the generic industry have indicated their interest in investing in local production sites in developing countries, particularly in Africa, provided the latter implement, to the fullest extent, available TRIPS flexibilities and take advantage of regional collaboration to create bigger markets.<sup>36</sup>

The importance of an appropriate balance between the protection of exclusive rights and the promotion of follow-on innovation through an accessible public domain has also been highlighted by the Swiss Federal Institute of Intellectual Property. Based on a number of recent studies, the conclusion has emerged that stronger patent protection does not necessarily lead to more innovation. This conclusion is illustrated by the following graph (figure 1).

**Figure 1: Striking a balance between exclusive rights and the public domain**



Source: N. Thumm, Swiss Federal Institute of Intellectual Property.

promoting local innovation and expanding foreign investment. Some saw IPRs as a positive factor in these areas, whereas others expressed that their role should not be overstated. These conflicting views reiterate the fact that empirical evidence concerning the link between the strength of a country's IP protection scheme and the decisions of companies to invest in that country is inconclusive. The effect of strengthened IP protection in a given country is often dependent on other factors, such as the size of the domestic market, the structure of factor supply, productive infrastructure and the level of stability of the macroeconomic environment. Countries are more likely to benefit from additional technology transfer under TRIPS if they coordinate IPR strengthening with broader modernization programs, such as programs for technology development that include human resource and skills development. See, e.g., UNCTAD, "The TRIPS Agreement and Developing Countries", Geneva, 1996, p. 18; UNCTAD-ICTSD Policy Discussion Paper, p. 87, with references to further literature). The view that there is no positive causal relationship between IP protection on the one hand and foreign investment on the other is emphasized by S. Chaudhuri, "The WTO and India's Pharmaceuticals Industry", Oxford University Press, New Delhi, 2005, chapters 2 and 4. Patents held in India by foreign companies prior to 1970 were even used to prevent local companies from manufacturing generic products (ibid., pp. 128 ff.).

<sup>36</sup> Representative of the Indian Pharmaceutical Alliance, oral communication to UNCTAD staff (September 2007); see also Abbott/Reichman, p. 42, footnote 219, citing a statement by a spokesperson of the European Generic Medicines Association, hearing before the European Parliament International Trade Committee, June 5, 2007.

This graph appears in several of the Institute's publications.<sup>37</sup> While the straight line represents the traditional conception of the relationship between IPR strength and innovation (higher protection always results in more innovation), the curve shows that in reality there is an optimal level of protection, beyond which innovation will drop.

In the local production context, too much protection risks cutting local producers off from essential know-how, thereby leaving the market to only originator firms and limit or exclude competition. The lack of generic competition may in turn increase incentives for the originator firm to neglect product improvement and follow-on innovation, focusing on the marketing of existing products instead.

The optimal level of IP protection varies from country to country, depending on the respective level of development (see Section 1.4 for details). As explained below, the TRIPS Agreement provides governments with a large array of tools with which to create a relatively more pro-competitive environment in the pharmaceutical sector by appropriately balancing exclusive rights and the public domain.

### **C. Countervailing tendencies in post-TRIPS agreements**

Since the entry into force of the TRIPS Agreement in 1995, the European Union (EU),<sup>38</sup> the countries of the European Free Trade Association (EFTA), Japan and the United States have been active in the negotiation of regional and bilateral free trade agreements (FTAs).<sup>39</sup> In addition, there have been efforts at the World Intellectual Property Organization (WIPO) to negotiate a Substantive Patent Law Treaty (SPLT).<sup>40</sup>

Some of these agreements have been viewed as seriously limiting the options to tailor national IP policies to domestic public health needs and varying levels of technological development that exist under the TRIPS Agreement.<sup>41</sup> In October 2007, a report published by the United States Congress found that negotiated FTAs with developing countries:

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<sup>37</sup> Such as in N. Thumm, "Reasonable patent protection with a statutory research exemption", in *IPR Helpdesk Bulletin* No 29, September-October 2006.

<sup>38</sup> Note that when the Treaty of Lisbon entered into force on 1 December 2009, the EU acquired legal personality, thus replacing the "European Communities" (EC) as formerly defined under Article XI of the WTO Agreement. See [http://europa.eu/lisbon\\_treaty/glance/index\\_en.htm](http://europa.eu/lisbon_treaty/glance/index_en.htm); the list of WTO members has been updated accordingly, see [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm).

<sup>39</sup> See F. Abbott, "The Cycle of Action and Reaction. Developments and Trends in Intellectual Property and Health" [hereinafter Abbott, *The Cycle of Action and Reaction*], in *Negotiating Health. Intellectual Property and Access to Medicines*, editors P. Roffe, G. Tansey and D. Vivas-Eugui, Earthscan, London, 2006 [hereinafter *Negotiating Health*], p. 27.

<sup>40</sup> For an overview of the evolution of the SPLT discussions at WIPO see [www.wipo.int/patent-law](http://www.wipo.int/patent-law); on the Open Forum on the SPLT see [http://www.wipo.int/meetings/en/2006/scp\\_of\\_ge\\_06/](http://www.wipo.int/meetings/en/2006/scp_of_ge_06/).

<sup>41</sup> For an overview of recent developments in FTAs, see P. Roffe and C. Spennemann, "Preferential Trade Agreements and Intellectual Property Rights", in: *Intellectual Property Rights: Legal and Economic Challenges for Development*, editors J. Stiglitz, M. Cimoli, G. Dosi, K. Maskus, R. Okediji, and J.H. Reichman, forthcoming, 2011); see also, e.g., Abbott, *The Cycle of Action and Reaction*; C. Fink and P. Reichenmiller, "Tightening TRIPS: The Intellectual Property Provisions of Recent United States Free Trade Agreements", *Trade Note* 20, The World Bank Group, 7 February 2005 [hereinafter Fink/Reichenmiller]; P. Roffe and C. Spennemann, "The Impact of Free Trade Agreements on Public Health Policies and TRIPS Flexibilities", *International Journal of Intellectual Property Management*, Vol. 1, Issue 1/2, 2006. On the SPLT, see Reichman/Cooper Dreyfuss.

“[...] threaten the ability of our trade partners to take necessary public health measures. These provisions, found in CAFTA [Central American Free Trade Agreement] and other FTAs already in effect, could significantly delay the availability of lower-cost generic medicines.”<sup>42</sup>

This issue of “TRIPS-plus” provisions in FTAs will be discussed in more detail in Section 3.5, below, in the context of the protection of pharmaceutical test data, which is one of the areas where FTA provisions are likely to have the biggest impact on a developing country’s options to promote generic competition. For now, it suffices to highlight the following basic facts:

- Existing FTAs signed by the United States that include terms that have the potential to impact public health involve countries such as Bahrain; the Central American countries Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic; Chile; Lebanon; Morocco; Oman; Peru and Tunisia. In addition, FTAs between the United States and Colombia, Panama, and the Republic of Korea have been signed, but not yet entered into force.<sup>43</sup> In early 2010 the EU, Colombia and Peru concluded negotiations regarding the IP chapter in a new EU/Colombia/Peru draft FTA, which provides, for the first time in an EU FTA, rules on exclusive protection of pharmaceutical test data.<sup>44</sup> The EU has suggested comparable provisions for a draft FTA with India. In January 2010, the Chairman of the EU Parliament’s Working Group on Innovation, Access to Medicines and Poverty-Related Diseases expressed concern about the effects of these rules on the availability of affordable Indian generic drugs, particularly in poor developing countries.<sup>45</sup>
- At this point in time, LDCs have not been parties to FTAs such as those referenced above. However, the European Partnership Agreement (EPA) between the EU and the countries of the Caribbean Forum (CARIFORUM) does address an LDC (i.e. Haiti).<sup>46</sup> EPA terms include a number of public health-relevant proposals by the EU that, where adopted, could potentially have a chilling effect on generic production in the African, Caribbean, and Pacific Group of States (ACP).<sup>47</sup> In 2007, the European Parliament adopted a report on EPAs, asking the EU Commission to refrain from including IP

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<sup>42</sup> See Committee on Oversight and Government Reform, “New GAO Report Indicates United States Trade Policy Neglects Public Health Issues”, 30 October 2007. See also United States Government Accountability Office (GAO), “United States Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification”, Report to Congressional Requesters, Washington, D.C., 2007 [hereinafter GAO Report].

<sup>43</sup> For the texts of these agreements, see <http://www.ustr.gov>. It should be noted that the recent FTAs signed by the United States with Colombia, Panama and Peru, subsequent to a bipartisan agreement of May 2007, include some important revisions to the IP chapters related to health. See P. Roffe and D. Vivas-Eugui, “A Shift in Intellectual Property Policy in United States FTAs?” ICTSD-BRIDGES, Vol. 11, No. 5, August 2007 (available at: <http://ictsd.org/i/news/bridges/4128/>).

<sup>44</sup> See Intellectual Property Watch (IP Watch), “Strong IP Health Provisions in Europe’s Colombia/Peru Trade Deal”, Newsletter, March/April 2010, p. 13.

<sup>45</sup> See IP Watch “New Parliament Group Monitors EU Trade Pacts’ Impact On Poor’s Medicines Access”, 28 January 2010 (available at <http://www.ip-watch.org/weblog/2010/01/28/new-parliament-group-monitors-eu-trade-pacts-impact-on-poor-s-medicines-access/>).

<sup>46</sup> For an analysis of the IP and innovation chapters of the EU – CARIFORUM EPA, see M. Spence, “Negotiating Trade, Innovation and Intellectual Property: Lessons from the CARIFORUM EPA Experience from a Negotiator’s Perspective”, UNCTAD-ICTSD Policy Brief No. 4, September 2009 (available at [www.unctad.org/en/docs/iprs\\_pb20094\\_en.pdf](http://www.unctad.org/en/docs/iprs_pb20094_en.pdf)).

<sup>47</sup> For details, see M. Santa Cruz, “Intellectual Property Provisions in European Union Trade Agreements”, *ICTSD Issue Paper* No. 20, 2007; and Abbott/Reichman.

provisions that could adversely affect access to essential medicines in the ACP countries.<sup>48</sup>

- LDCs may also be affected by South-South regional IP agreements that elevate standards of protection beyond those provided under TRIPS. The Bangui Agreement of the African Intellectual Property Organization (Organisation Africaine de la Propriété Intellectuelle, OAPI), for instance, contains a number of such provisions.
- Despite the impact FTAs may have on national public health policies, some stakeholders in developing countries may welcome the conclusion of such agreements with OECD countries and consider them major political and economic achievements.<sup>49</sup> FTAs are not only IP-related, but can also address such policy and legal matters as commitments on market access, public procurement, FDI and services, which may look promising to the public in a developing country that is party to an FTA. At the same time, the public may widely ignore the complex issue of intellectual property and its impact on public health.
- It should also be noted that any commitment made to another country under an FTA to provide higher IP protection than required under the TRIPS Agreement is extended to all other WTO members, due to the most-favoured-nation treatment clause under Article 4, TRIPS Agreement.
- In addition to the above-mentioned FTAs, there are a vast number of bilateral investment treaties (BITs) that define intellectual property as a type of investment, thus subjecting IP to the general guarantees afforded to investors under the relevant BIT.<sup>50</sup>

While the above tendencies may have significant repercussions on the involved countries' abilities to make use of the TRIPS Agreement's tools outlined in this Guide, awareness of these tools should be an issue of major importance to developing country stakeholders.

The most serious FTA restrictions on local autonomy concern only a select number of developing countries. Those countries having FTAs that include IP obligations may find in Section 3.5 of this Guide some useful policy options for the implementation of data protection commitments, thus limiting the impact of data exclusivity regimes on local generic producers. In addition, not all of the flexibilities discussed in this Guide are necessarily restricted in any given FTA. Being aware of the flexibilities that exist under the TRIPS Agreement should enable policy makers to understand the extent to which these flexibilities are or are not limited under the FTAs relevant to their country.

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<sup>48</sup> See European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines, P6\_TA-PROV(2007)0353, para. 9; and European Parliament resolution of 23 May 2007 on Economic Partnership Agreements, P6\_TA-PROV(2007)0204, at para. 45 (available at: <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2007-0204&language=EN>). See also Abbott/Reichman.

<sup>49</sup> Chile, for instance, actively pursued the conclusion of bilateral agreements on market access and trade liberalization. This policy has reportedly contributed to the reduction of the poverty rate from 47 per cent in 1989 to 20 per cent in 2003. See P. Roffe, "Bilateral agreements and a TRIPS-plus world: the Chile - United States Free Trade Agreement", *QUNO TRIPS Issues Paper No. 4*, Geneva, 2004.

<sup>50</sup> See UNCTAD, "Intellectual Property Provisions in International Investment Arrangements", IIA Monitor No. 1 (2007), International Investment Agreements, UNCTAD document UNCTAD/WEB/ITE/IIA/2007/1 (available at [www.unctad.org/sections/dite\\_pcbb/docs/webiteia20071\\_en.pdf](http://www.unctad.org/sections/dite_pcbb/docs/webiteia20071_en.pdf)).

A primary purpose of this Guide is to highlight the importance of maintaining the options available under the TRIPS Agreement. Additionally, regarding LDCs are concerned, the Guide will explain to what extent existing domestic TRIPS-plus rules may be suspended, in order to take full advantage of the flexibilities provided under the TRIPS Agreement.

## **PART TWO**

# **POLICY OPTIONS FOR THE IMPLEMENTATION OF TRIPS FLEXIBILITIES**

### **A. Summary of key policy options under TRIPS**

The Guide addresses those TRIPS flexibilities that a government may use to shape the broad scope of exclusive rights (on medical substances and others) both **before** a patent is even issued (*pre-grant*) and **after** a patent has been granted (*post-grant*). *Pre-grant* flexibilities constitute a pro-active tool for a government to design generally applicable IP laws, whereas *post-grant* flexibilities are usually limited to particular cases where the government considers an existing monopoly right to be too broad. Governments interested in limiting exclusive rights on medical substances are advised to pay particular attention to the *pre-grant* flexibilities, as these may reduce the need to utilize *post-grant* tools. This is particularly important in light of the possible tensions surrounding *post-grant* tools such as compulsory licenses and parallel imports. Overall, national policy makers should be aware of and may wish to take full advantage of both *pre-* and *post-grant* flexibilities.

The *pre-grant* and *post-grant* flexibilities available to policy makers both in developing countries in general and the LDCs are introduced here in tables 1 and 2 (see next pages). These policy options are subsequently analyzed in detail (Section B, below).



**Table 1: TRIPS flexibilities for developing countries in the area of pharmaceuticals**

**A. Pre-grant Flexibilities**

<p><b>1. No transition period</b></p>
<p><b>2. Observation/Opposition Procedures</b></p> <ul style="list-style-type: none"> <li>✓ Provide for possibilities to challenge patent applications and patents at the patent office</li> </ul>
<p><b>3. Patentable Subject Matter</b></p> <ul style="list-style-type: none"> <li>✓ Exclude from patentability: <ul style="list-style-type: none"> <li>▪ Substances existing in nature to the extent that a natural substance has been extracted from its natural environment (in isolated form)</li> <li>▪ New methods of using known products for pharmaceutical purposes (Article 27(3)b, TRIPS, methods of medical treatment)</li> <li>▪ Product derivatives that, compared to the original substance, show no significant improvements in medical efficacy (thus failing to constitute patentable “new chemical/medical entities”; example Indian Patents Act)</li> </ul> </li> <li>✓ Consider <i>sui generis</i> regime to promote incremental innovation in new pharmaceutical uses (“compensatory liability”)</li> </ul>
<p><b>4. Patentability Criteria</b></p> <p><b>a. Novelty</b></p> <ul style="list-style-type: none"> <li>✓ Adopt strict standards of novelty: <ul style="list-style-type: none"> <li>▪ Worldwide novelty approach</li> <li>▪ Oral disclosure destroys novelty</li> <li>▪ Novelty-destroying prior art may be derived from several separate documents</li> <li>▪ Theoretical accessibility of general public to information</li> <li>▪ “Implicit teachings” – implied in expressly published information</li> <li>▪ Information in other patent applications filed before priority date</li> </ul> </li> </ul> <p><b>b. Inventive Step</b></p> <ul style="list-style-type: none"> <li>✓ Identify relevant prior art: what a routine engineer would have reason to consider pertinent in particular case</li> <li>✓ For developing countries with modest inventive capacity, apply high standard of non-obviousness – assessment criteria: <ul style="list-style-type: none"> <li>▪ High level of ordinary skill in the pertinent art - not limited to domestic expertise</li> </ul> </li> </ul>

- Predictability indicates obviousness of the invention
- Structural similarity as *prima facie* case of obviousness
- Reasonable expectations of success indicates obviousness
- Combination patents - obviousness based on multitude of prior art references; common sense to combine separate references sufficient to indicate obviousness

**c. Industrial application**

- ✓ Adopt strict standards of industrial application
- ✓ Research tools: only if specific, concrete uses may be identified

**Examples**

**(1) New uses of known pharmaceutical products**

First and subsequent medical indications	
Product patent	Process patent
State in express terms in patent law or patentability guidelines that first medical use of known products cannot justify novelty of a known product	Carefully examine patentability criteria: <i>Novelty</i>
	<i>Inventive step</i> Strict non-obviousness standard: predictability?
	<i>Industrial applicability</i> Process might not be capable of industrial application

Alternative to process patents: exclude through TRIPS Article 27.3(a); introduce compensatory liability regime to promote new uses of traditional knowledge

**(2) Variations in pharmaceutical composition or behaviour/ product derivatives**

- ✓ Deny product patents on product variations (lack of novelty/Indian approach, or obviousness/United States approach) unless there are clear and demonstrable grounds to show that the modified substance produces truly new and significant therapeutic impacts (new, improved or unexpected properties – United States approach; significantly enhances efficacy – Indian approach)
- ✓ Provide in domestic law that structural similarities are *prima facie* cases of lack of novelty or inventive step – put burden of proving novelty or non-obviousness onto applicant
- ✓ Alternative: introduce compensatory liability regime to promote local incremental innovation

**(3) Selection patents**

- ✓ Deny product patents for lack of novelty or inventive step
- ✓ Provide incentives to the development of small scale innovation through compensatory liability regime

**(4) Incremental innovation**

- ✓ Encourage incremental innovation outside the formal patent system by adopting utility model protection or a compensatory liability regime
- ✓ Provide for compulsory license procedure in case of so-called “blocking patents”

## 5. Patent claims construction

- ✓ Address claims construction in patent examination guidelines, as opposed to Patent Act. This provides enhanced flexibility for governments to adapt rules to changing technological needs
- ✓ Combine *structural and functional* claims where purpose is to limit patent to particular structure and particular function
- ✓ Use-bound structural claims may preserve subsequent uses in public domain, especially where new uses are protected through compensatory liability regime
- ✓ Unlimited structural claims comprise all methods of use, but may result in denial of novelty of subsequent uses
- ✓ *Product-by-process* claims may be limited in various ways, where considered necessary to maintain a broad public domain
  - Limitation to process patent under Art 28 TRIPS, and
  - Limitation to products as actually obtained by the process, combined with a particular function
- ✓ *Markush* claims refer to a common structure of chemical variants, without disclosing structure and properties of all claimed alternatives
  - Inappropriate where governments seek to preserve broad public domain
  - May be softened through additional requirement to refer to particular common purpose of the claimed compounds
- ✓ *Jepson* claims facilitate the distinction between prior art and inventive improvements. Appropriate for all governments seeking to avoid trivial patents
- ✓ *Skuballa* claims: recite a multitude of potential uses of a product without establishing appropriate dosage for each claimed use. Only appropriate where local scientists have capacity to infer appropriate dosage from the broad patent claim

## 6. Patent claims interpretation

- ✓ Countries at early stages of development: focus on literal infringement, only limited expansion of literal patent scope through doctrine of equivalents. Narrow doctrine of equivalents may help to prevent the expansion of the patent to trivial improvements
- ✓ The more a country is capable of genuine inventive activity, the more flexibly it should apply the doctrine of equivalents: broader equivalents to protect major technical or medical advances, narrow equivalents to prevent patenting of small scale innovation and related blocking effects

## 7. Disclosure of patented inventions

Improve the effective value of patent application documents:

- ✓ Disclosure must be clear to developing country routine engineer
- ✓ Introduce best mode requirement
- ✓ Introduce requirement to provide information on foreign patent applications and grants

## B. Post-grant Flexibilities

<p><b>1. Exceptions to patent rights</b></p> <ul style="list-style-type: none"> <li>✓ Include in patent law experimental use exception to use patented invention for             <ul style="list-style-type: none"> <li>▪ Research done “on” patent for commercial purposes to reveal new knowledge about patented invention</li> <li>▪ Regarding research “with” patent (using patent as research tool): right to claim a non-exclusive license (“use and pay” regime)</li> </ul> </li> <li>✓ Include in patent law an express regulatory review (Bolar) exception             <ul style="list-style-type: none"> <li>▪ for acts directly or indirectly related to approval request</li> <li>▪ that is expanded to activities undertaken for regulatory review in foreign countries</li> </ul> </li> <li>✓ Include medical practitioner exception</li> <li>✓ Include teaching exception</li> <li>✓ Include stockpiling exception for medical emergencies</li> <li>✓ Include exception for humanitarian uses</li> </ul>			
<p><b>2. Parallel imports</b></p> <ul style="list-style-type: none"> <li>✓ Adopt international and/ or regional exhaustion doctrine (regarding patents, trademarks and copyright)</li> <li>✓ Ensure quality of imported drugs</li> <li>✓ Promote imports of ingredients needed for production</li> </ul>			
<p><b>3. Compulsory licenses</b></p> <p><b>Note:</b> Compulsory licenses are only necessary where patent protection is already in place</p> <ul style="list-style-type: none"> <li>✓ Include in patent law an express compulsory license provision as one tool – among others (e.g. price regulation) – to improve access to medicines</li> <li>✓ Accompany compulsory license option with other public-health related patent flexibilities</li> <li>✓ Include review mechanism (independent and more senior body)</li> <li>✓ Engage in regional cooperation (regional harmonization)</li> </ul>			
<b>Requirements</b>	<b>Article 31 TRIPS</b>	<b>Article 31bis TRIPS</b>	
		<i>Not a</i> member of free trade agreement with at least 50% LDCs	Member of free trade agreement with at least 50% LDCs

<b>Define Grounds</b>	<i>Non- exhaustive:</i> (1) Violation of competition law (2) Government/ non-commercial use (3) Case of national emergency (4) Other cases of extreme urgency (5) Abuse of patent right (6) Public interest (7) Dependent patent (8) Local non-working of patent (only to address public health issue; controversial)	Exportation of pharmaceuticals	+ <sup>51</sup>
<b>Prior Negotiations with Patentee</b> Reasonable commercial terms and conditions Reasonable period of time	Not in cases 1 – 4, above	As Article 31	+
<b>Adequate Remuneration</b>	To be paid	Not as an importing country	+
<b>Other Requirements and Conditions</b>	As an exporting country		
	Export limited to 49 %	Export of 100 %	
		Compulsory License (CL) authorizes production of amount needed and to be exported	Not required for exports within LDC FTA
		Labelling	Not required for exports within LDC FTA
		Website indicating quantities to be exported	Not required for exports within LDC FTA
		Notification to TRIPS Council	Not required for exports within LDC FTA
	As an importing country		
	Re-exportation limited to 49 % (except where remedy to anti-competitive conduct)	No re-export at all (unless new notification to TRIPS Council)	Re-export allowed to other members of regional trade agreement, without need for (new) notification
		General notification to	+

<sup>51</sup> “+” indicates that the situation is identical to the situation in a non-Member of a free trade agreement.

		TRIPS Council of use of system (Even, if drug is off-patent)	
		Notify names & quantities; establish lack of local production capacity; confirm CL if product is patented	No notification of imports in terms of names/quantities, lack of manufacturing capacities and CL grant if import from within LDC RTA

#### 4. Control of patent abuse and anti-competitive licensing practices

- ✓ Develop detailed domestic rules and policies regarding the control of:
  - Abuse, i.e. using IP right beyond its purpose and scope
  - Abuse of dominant position, such as:
    - Excessive pricing
    - Predatory pricing (sale of goods below marginal costs, without justification)
    - Refusal to license: under EU law (“essential facilities doctrine”), refusal to license constitutes abuse, if:
      - Licensee intends to develop new products or services
      - No objective reason for refusal to license by right holder, and
      - Refusal excludes any competition on secondary market (i.e. upstream patent blocks development of a new downstream product.) Secondary market – new products in the same market (or even same product in a different geographical market not covered by parallel patent – approach taken by Italian Competition Authority)
  - Anti-competitive conduct in licensing agreements that restrains competition and, due to this restraint, impedes technology transfer and dissemination (e.g. under certain circumstances cross-licensing, and patent pooling)
- ✓ By:
  - Specifying, in national law, licensing practices and conditions that *per se* constitute abuse of intellectual property rights and have an anti-competitive effect (e.g. exclusive grant back; no-challenge clause; coercive package licensing)
  - Defining, in national law:
    - legal terms, such as “excessive pricing”, “predatory pricing”, “abuse”
    - forms of remedy, such as compulsory licenses and/ or non-enforcement of patents

#### 5. Protection of Clinical Test Data in National Laws or Bilateral/ Regional Free Trade Agreements

- ✓ Choose one of the two ways to grant marketing approval

- (1) Either by recognizing in national law the approval of an equivalent product of the same producer in a foreign country
- (2) Or by requiring substantive examination of the pharmaceutical substance at issue

- ✓ If substantive examination required, adopt a system to protect originator's test data
  - *Compensatory liability/ cost-sharing approach*: "reliance" permitted, in exchange of remuneration of the data originator
  - *Misappropriation approach*: "reliance" permitted or
  - *Data exclusivity approach* to be avoided; where mandatory (FTAs), mitigate by, for instance,
    - Restricting exclusivity right to new chemical entities and undisclosed information
    - Limiting term of exclusivity protection to the extent possible
    - Waiving data exclusivity in case of compulsory licensing and public health concerns
    - Avoiding linkage between marketing approval and patent rights

## **6. Opposition Procedure**

- ✓ Provide for possibility to challenge patents

**Table 2: TRIPS flexibilities for LDCs in the area of pharmaceuticals**

**A. Pre-grant Flexibilities**

<b>1. Use of Transition Periods for LDCs</b>	
<b>Patent protection in place</b>	<b>No patent protection in place</b>
<p><i>Pharmaceutical products before 1 January 2016:</i></p> <ul style="list-style-type: none"> <li>- Suspend patent protection or amend patent law accordingly or</li> <li>- provide shorter term of protection</li> <li>- extend effects to already granted patents</li> <li>- do not implement mailbox</li> </ul> <p><i>Other technologies:</i></p> <ul style="list-style-type: none"> <li>- do not cut back on existing protection;</li> <li>- make patent provisions fully TRIPS-compliant by 1 July 2013</li> </ul>	<p><i>Pharmaceutical products before 1 January 2016:</i></p> <ul style="list-style-type: none"> <li>- introduce patents on pharmaceutical products not before <b>1 January 2016</b></li> <li>- implement mailbox for pharmaceuticals but mitigate impact through prior user rights</li> </ul> <p><i>Other technologies:</i></p> <ul style="list-style-type: none"> <li>- only <b>after 1 July 2013</b> patent protection required in all fields of technology (except pharmaceuticals)</li> </ul>
<b>2. Observation/Opposition Procedures</b>	
✓ Provide for possibilities to challenge patent applications and patents at the patent office	
<b>3. Patentable Subject Matter</b>	
<ul style="list-style-type: none"> <li>✓ Exclude from patentability: <ul style="list-style-type: none"> <li>▪ Substances existing in nature to the extent that a natural substance has been extracted from its natural environment (in isolated form)</li> <li>▪ New methods of using known products for pharmaceutical purposes (Article 27(3)b, TRIPS, methods of medical treatment)</li> <li>▪ Product derivatives that, compared to the original substance, show no significant improvements in medical efficacy (thus failing to constitute patentable “new chemical/medical entities”; example Indian Patents Act)</li> </ul> </li> <li>✓ Consider <i>sui generis</i> regime to promote incremental innovation in new pharmaceutical uses (“compensatory liability”)</li> </ul>	



#### 4. Patentability Criteria

##### a. Novelty

- ✓ Adopt strict standards of novelty:
  - Worldwide novelty approach
  - Oral disclosure destroys novelty
  - Novelty-destroying prior art may be derived from several separate documents
  - Theoretical accessibility of general public to information
  - “Implicit teachings” – implied in expressly published information
  - Information in other patent applications filed before priority date

##### b. Inventive Step

- ✓ Identify relevant prior art: what a routine engineer would have reason to consider pertinent in particular case
- ✓ Apply high standard of non-obviousness – assessment criteria:
  - High level of ordinary skill in the pertinent art - not limited to domestic expertise
  - Predictability indicates obviousness of the invention
  - Structural similarity as *prima facie* case of obviousness
  - Reasonable expectations of success indicates obviousness
  - Combination patents - obviousness based on multitude of prior art references; common sense to combine separate references sufficient to indicate obviousness

##### c. Industrial application

- ✓ Adopt strict standard on industrial application
- ✓ Research tools: only if specific, concrete uses may be identified

#### Examples

##### (1) New uses of known pharmaceutical products

- ✓ Exclude both product (lack of novelty) and process (TRIPS Article 27.3(a)) patents in patent law or patentability guidelines; consider introducing compensatory liability regime to promote new uses of traditional knowledge

##### (2) Variations in pharmaceutical composition or behaviour/ product derivatives

- ✓ Deny product patents on product variations (lack of novelty/Indian approach, or obviousness/United States approach), unless there are clear and demonstrable grounds to show that the modified substance produces truly new and significant therapeutic impacts (new, improved or unexpected properties – United States approach; significantly enhances efficacy – Indian approach)
- ✓ Provide in domestic law that structural similarities are *prima facie* cases of lack of novelty or inventive step – put burden of proving novelty or non-obviousness onto applicant
- ✓ Alternative: introduce compensatory liability regime to promote local incremental innovation

##### (3) Selection patents

- ✓ Deny product patents for lack of novelty or inventive step
- ✓ Provide incentives to the development of small scale innovation through

compensatory liability regime

**(4) Incremental innovation**

- ✓ Encourage incremental innovation outside the formal patent system by adopting utility model protection or a compensatory liability regime
- ✓ Provide for compulsory license in case of so-called “blocking patents”

**5. Patent claims construction**

- ✓ Address claims construction in patent examination guidelines, as opposed to Patent Act. This provides enhanced flexibility for governments to adapt rules to changing technological needs
- ✓ Combine *structural and functional* claims where purpose is to limit patent to particular structure and particular function
- ✓ Use-bound structural claims may preserve subsequent uses in public domain, especially where new uses are protected through compensatory liability regime
- ✓ Unlimited structural claims comprise all methods of use, but may result in denial of novelty of subsequent uses
- ✓ *Product-by-process* claims may be limited in various ways, where considered necessary to maintain a broad public domain
  - Limitation to process patent under Art 28 TRIPS, and
  - Limitation to products as actually obtained by the process, combined with a particular function
- ✓ *Markush* claims refer to a common structure of chemical variants, without disclosing structure and properties of all claimed alternatives
  - Inappropriate where governments seek to preserve broad public domain.
  - May be softened through additional requirement to refer to particular common purpose of the claimed compounds
- ✓ *Jepson* claims facilitate the distinction between prior art and inventive improvements. Appropriate for all governments seeking to avoid trivial patents
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**6. Patent claims interpretation**

- ✓ Countries at early stages of development: focus on literal infringement, only limited expansion of literal patent scope through doctrine of equivalents. Narrow doctrine of equivalents may help to prevent the expansion of the patent to trivial improvements
- ✓ The more a country is capable of genuine inventive activity, the more flexibly it should apply the doctrine of equivalents: broader equivalents to protect major technical or medical advances, narrow equivalents to prevent patenting of small scale innovation and related blocking effects

**7. Disclosure of patented inventions**

Improve the effective value of patent application documents:

- ✓ Disclosure must be clear to LDC routine engineer
- ✓ Introduce best mode requirement
- ✓ Introduce requirement to provide information on foreign patent applications and grants

## **B. Post-grant Flexibilities**

### **1. Exceptions to Patent Rights**

- ✓ Adopt a scientific research/experimental use exception to use patented inventions for:
  - Research done “on” patent for commercial purposes to reveal new knowledge about patented invention
  - Regarding research “with” patent (using patent as research tool): right to claim a non-exclusive license (“use and pay” regime)  
Implement transition period (non-availability of patents will make exceptions redundant)
- ✓ Include in patent law an express regulatory review (Bolar) exception
  - for acts directly or indirectly related to approval request
  - that is expanded to activities undertaken for regulatory review in foreign countries
- ✓ Include medical practitioner exception
- ✓ Include teaching exception
- ✓ Include stockpiling exception for medical emergencies
- ✓ Include exception for humanitarian uses

### **2. Parallel imports**

- ✓ Adopt international and/or regional exhaustion doctrine (regarding patents, trademarks and copyright)
- ✓ Ensure quality of imported drugs
- ✓ Promote imports of ingredients needed for production

### **3. Compulsory licenses**

**Note:** Compulsory licenses are only necessary where patent protection is in place

- ✓ Include in patent law an express compulsory license provision as one tool – among others (e.g. price regulation; “buy out” of foreign rights) – to improve access to medicines
- ✓ Accompany compulsory license option with other public-health related patent flexibilities
- ✓ Include review mechanism (independent and more senior body)
- ✓ Engage in regional cooperation (regional harmonization)

Requirements	Article 31 TRIPS	Article 31bis TRIPS	
		Not a member of free trade agreement with at least 50% LDCs	Member of free trade agreement with at least 50% LDCs
<b>Define Grounds</b>	<i>Non- exhaustive:</i> (1) Violation of competition law (2) Government/ non-commercial use (3) Case of national emergency (4) Other cases of extreme urgency (5) Abuse of patent right (6) Public interest (7) Dependent patent (8) Local non-working of patent (only to address public health issue; controversial)	Exportation of pharmaceuticals	+ <sup>52</sup>
<b>Prior Negotiations with Patentee</b> Reasonable commercial terms and conditions Reasonable period of time	Not in cases 1 – 4, above	As Article 31	+
<b>Adequate Remuneration</b>	To be paid	Not as an importing country	+
<b>Other Requirements and Conditions</b>	As an exporting country		
	Export limited to 49 %	Export of 100 %	
		Indicate in CL amount to be exported	Not required for exports within LDC FTA
		Labeling	Not required for exports within LDC FTA
		Website	Not required for exports within LDC FTA
		Notification to TRIPS Council	Not required for exports within LDC FTA
	As an importing country		
	Re-exportation limited to 49 % (except where remedy to anti-competitive conduct)	No re-export at all (unless new notification to TRIPS Council)	Re-export allowed to other members of regional trade agreement (RTA), without need for new

<sup>52</sup> “+” indicates that the situation is identical to the situation in a non-Member of a free trade agreement.

			notification
		Presumption of lack of local production capacity – no need for general notification to use system as importer	+
		But need to notify names & quantities (even if drug is off-patent!); confirm grant of CL if product is patented	No notification of imports in terms of names/quantities and CL grant if import from within LDC RTA

#### 4. Control of patent abuse and anti-competitive licensing practices

- ✓ Develop detailed domestic rules and policies on the control of:
  - Abuse, i.e. using IP right beyond its purpose and scope
  - Abuse of dominant position, such as:
    - Excessive pricing
    - Predatory pricing (sale of goods below marginal costs, without justification)
    - Refusal to license: under EU law (“essential facilities doctrine”), refusal to license constitutes abuse, if:
      - Licensee intends to develop new products or services;
      - No objective reason for refusal to license by right holder, and
      - Refusal excludes any competition on secondary market (i.e. upstream patent blocks development of a new downstream product.) Secondary market – new products in the same market (or even same product in a different geographical market not covered by parallel patent - approach taken by Italian Competition Authority)
  - Anti-competitive conduct in licensing agreements that restrains competition and, due to this restraint, impedes technology transfer and dissemination (e.g. under certain circumstances cross-licensing, and patent pooling)
  
- ✓ By:
  - Specifying, in national law, licensing practices and conditions that *per se* constitute abuse of intellectual property rights and have an anti-competitive effect (e.g. exclusive grant back; no-challenge clause; coercive package licensing)
  - Defining, in national law:
    - legal terms, such as “excessive pricing”, “predatory pricing”, “abuse”
    - forms of remedy, such as compulsory licenses and/ or non-enforcement of patents

## 5. Protection of Clinical Test Data in National Laws or Bilateral/ Regional Free Trade Agreements

- ✓ Choose one of the two ways to grant marketing approval
  - (1) Either by recognizing in national law the approval of an equivalent product of the same producer in a foreign country
  - (2) Or by requiring substantive examination of the pharmaceutical substance at issue
- ✓ If substantive examination required, adopt a system to protect originator's test data
  - *Misappropriation approach*: "reliance" permitted;
  - *Compensatory liability/ cost-sharing approach*: "reliance" permitted, in exchange of remuneration of the data originator (if main policy objective is to attract foreign investors); or
  - *Data exclusivity approach* to be avoided; where mandatory (FTAs), mitigate by, for instance,
    - Restricting exclusivity right to new chemical entities and undisclosed information
    - Limiting term of exclusivity protection to the extent possible
    - Waiving data exclusivity in case of compulsory licensing and public health concerns
    - Avoiding linkage between marketing approval and patent rights

## 6. Opposition Procedure

- ✓ Provide for possibility to challenge patents



## **B. ANALYSIS OF TRIPS FLEXIBILITIES**

### **1. Introduction**

The WTO's TRIPS Agreement resulted from the Uruguay Round of Multilateral Trade Negotiations and entered into force on 1 January 1995. The TRIPS Agreement is one of the major treaties under the overarching WTO Agreement.<sup>53</sup> It establishes the minimum standards for intellectual property protection that WTO members must implement in their legal regimes and also provides governments with a number of tools to design domestic intellectual property laws which are conducive to the promotion of access to medicines through importation and local production of drugs. These tools, which were subsequently reiterated by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of 2001, are discussed in this Section B of Part II of the Guide. In order to facilitate a comprehensive understanding of the tools, this introductory section will explain some basics aspects of the TRIPS Agreement.

#### **1.1 Objectives of the TRIPS Agreement**

According to Article 7 of the TRIPS Agreement, “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” In addition, WTO members may, when implementing TRIPS rules, “adopt measures necessary to protect public health” and other public policy objectives, “provided that such measures are consistent” with the provisions of the TRIPS Agreement (Article 8.1, TRIPS). The preamble to the TRIPS Agreement recognizes “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.”<sup>54</sup> The importance of public health policies was reiterated in the 2001 Ministerial Declaration on the TRIPS Agreement and Public Health, where members agreed that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health”. While reasserting their commitment to the TRIPS Agreement, members recognized that “the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>55</sup> The TRIPS Agreement is based on the assumption that the implementation and enforcement of minimum levels of IPRs will encourage owners of IP to transfer technologies

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<sup>53</sup> See Agreement Establishing the World Trade Organization and its annexes (Annex 1A: Multilateral Agreements on Trade in Goods; Annex 1B: General Agreement on Trade in Services (GATS); Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); Annex 2: Dispute Settlement Understanding; Annex 3: Trade Policy Review Mechanism; Annex 4: Plurilateral Trade Agreements). All WTO agreements available at [http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm).

<sup>54</sup> See preamble of the TRIPS Agreement.

<sup>55</sup> See paragraph 4 of the Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN(01)/DEC/2 of 20 November 2001 [hereinafter Doha Declaration].



to others (e.g. through licensing agreements or foreign direct investment). However, research on whether or not this is the case is inconclusive.<sup>56</sup> Many experts have emphasized that in order to effectively promote technology transfer and innovation, IPRs need to be adapted to the respective country's level of development and technological capabilities.<sup>57</sup>

Thus, the protection and enforcement of IPRs under the TRIPS Agreement should not be an end in itself, but should, reward inventors for their efforts, thereby promoting innovation and dissemination of technology for the benefit of society as a whole. Governments need to strike a balance between the rights and interests of inventors on the one hand, and their competitors and the public on the other. In the pharmaceutical sector, this implies the design of national IP systems that will encourage inventors' genuine innovative activity while also ensuring that scientific knowledge is made widely available and that pharmaceutical products are not priced beyond the reach of those who need them. Where such balance is found, IPRs will work "to the mutual advantage of producers and users of technological knowledge", as mandated by the TRIPS Agreement (see above). To this end, the TRIPS Agreement provides policymakers with some important legal tools, the explanation of which is the endeavour of this guide.

## **1.2 Minimum standards of IP protection**

The TRIPS Agreement obligates members to provide for minimum standards of IP protection in their domestic legislation in a manner consistent with their existing legal systems, as required by Article 1.1. Members may, but are not required to, go beyond such minimum standards. For example, the TRIPS Agreement (Article 33) requires all members to provide for a term of patent protection of 20 years counted from the date of filing the patent application. Members are free to grant 21 or more years of patent protection in their national laws, but must not limit protection to anything less than 20 years. As another example, TRIPS (Article 31) obligates governments, when issuing compulsory licenses, to respect certain procedural requirements.<sup>58</sup> Beyond these *procedural* minimum standards of protection, there are no *substantive* restrictions on the discretion of governments to freely determine the *grounds* upon which a compulsory license may be granted to allow the patented invention to be used without authorization of the patent holder.

The TRIPS provisions on minimum standards of protection encompass the following IPR categories:

- Copyright and Related Rights;

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<sup>56</sup> For an overview of different studies, see UNCTAD-ICTSD Policy Discussion Paper, pp. 87-88.

<sup>57</sup> See, for example, L. Kim, "Technology Transfer and Intellectual Property Rights: Lessons from Korea's Experience", *UNCTAD-ICTSD Issue Paper No. 2*, Geneva, 2003 [hereinafter UNCTAD-ICTSD Issue Paper No. 2]; K. Maskus, "Encouraging International Technology Transfer", *UNCTAD-ICTSD Issue Paper No. 7*, Geneva, 2004 (both available at <http://www.iprsonline.org/unctadictsd/projectoutputs.htm#top>); Commission on Intellectual Property Rights, pp. 24 ff. Concerns about broad exclusive rights and their impact on competition and innovation have also been expressed in developed countries; see, e.g., United States Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy", Report, 2003 (executive summary available at <http://xml.coverpages.org/FTC-InnovationReportSumm.pdf>).

<sup>58</sup> For instance, issuance of compulsory licenses shall be considered on a case-by-case basis; shall in general be preceded by unsuccessful negotiations for a voluntary license; shall be non-exclusive; and shall be compensated to the right holder through adequate remuneration. For the complete list of mandatory procedural requirements, see Article 31, TRIPS Agreement.

- Trademarks;
- Geographical Indications;
- Industrial Designs;
- Patents;
- Layout-Designs (Topographies) of Integrated Circuits; and
- Protection of Undisclosed Information (in particular pharmaceutical test data).

In addition, the TRIPS Agreement states that members reserve the right to prevent IPR abuses in general and control anti-competitive practices in licensing agreements in particular.

### **1.3 Leeway in implementation**

WTO members are obligated to “give effect” to the TRIPS provisions on minimum standards (Article 1.1, first sentence, TRIPS Agreement), i.e. to incorporate them in their domestic legal systems and practice (“implementation”). Members “shall be free to determine the appropriate method” of implementation (Article 1.1, third sentence), and therefore they may choose to either recognize the text of the TRIPS Agreement as part of their domestic legal system (“monist” approach) or adopt specific statutes or administrative rules to implement the Agreement (“dualist” approach).<sup>59</sup>

Irrespective of a country’s approach to implementation, most TRIPS provisions on IPR minimum standards are drafted in very general terms and require further elaboration in order to become operational. For instance, patents may only be granted to inventions that are “new, involve an inventive step and are capable of industrial application” (Article 27.1, TRIPS Agreement). In implementing this provision, every member will have to reflect these minimum requirements in its domestic law and practice. However, the TRIPS Agreement does not contain any definition of novelty, inventive step or industrial applicability.<sup>60</sup> Members are free to define in their domestic laws when and how an invention meets these criteria. For example, each member may decide whether new uses of a known substance fulfil the novelty requirement or not (for details, see Section 2.4.2.1).

Another example of the leeway available to members for the implementation of the TRIPS minimum standards may be found in the provision on patent exceptions (Article 30, TRIPS Agreement). This provision contains a multitude of undefined legal terms (i.e. “limited exceptions” that do not “unreasonably” conflict with a “normal exploitation” of the patent and do not “unreasonably” conflict with the “legitimate” interests of the patent owner (for details, see Section 3.1). In order for this provision to become operational all of the terms will have to be defined.

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<sup>59</sup> For details, see UNCTAD-ICTSD, “Resource Book on TRIPS and Development”, Cambridge University Press, 2005 [hereinafter UNCTAD-ICTSD Resource Book] (available at <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>), Chapter 2 (especially pages 19-20 and 25-27).

<sup>60</sup> The notions of inventive step and industrial applicability have traditionally been used in European countries. In order to accommodate United States terminology, the TRIPS Agreement specifies that its terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful”, as traditionally used in the United States (see footnote 5 to Article 27, TRIPS Agreement).

A third example pertains to the use of compulsory licenses under TRIPS, which is not limited to cases of national emergencies or other circumstances of extreme urgency.<sup>61</sup> Governments are free to authorize a compulsory license on other grounds, e.g. for the promotion of the public interest in areas such as security, the environment, public health or economic development. On the other hand, governments are also free to forgo their rights and subject the availability of compulsory licenses to certain substantive requirements.<sup>62</sup>

#### **1.4 Striking a balance between exclusive rights and public access**

The above examples show that members have considerable leeway (generally referred to as “flexibilities”) when implementing TRIPS provisions, so long as they apply the minimum standards expressly stipulated in the TRIPS Agreement. In essence, implementation of undefined TRIPS language provides an opportunity for members to tailor their laws and policies to strike a desired balance between the exclusive right promoted by the respective IPR at issue, and the area remaining outside the scope of exclusivity (i.e. the “public domain”). Governments will have to decide where the dividing line between these areas should be drawn, for example, whether to promote broad exclusive rights and a limited public domain, or vice versa. Shifting the balance in favour of one of these will automatically reduce the scope of the other. Given that foreign IP right holders must be provided treatment that is no less favourable than national or other foreign right holders, (Articles 3 and 4 of the TRIPS Agreement), the challenging task for governments is determining which approach is most appropriate for their country’s efforts to promote technological innovation and technology transfer. At the same time, they must ensure the pursuit of other policy goals in such diverse areas as public health and access to scientific and educational data, information and materials.

As illustrated by existing UNCTAD research, there is no “one-size-fits-all” model for striking this balance.<sup>63</sup> Instead, one of the main determining factors is the level of technological development of affected local industries.<sup>64</sup> The need to take the level of technological development into account is exemplified by the fact that when many European countries, as well as the United States, were in the early stage of technological development, they had fairly low levels of IPR protection, which would not necessarily meet many of today’s TRIPS minimum standards.<sup>65</sup> These countries gradually raised the strength of their IPR protection as

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<sup>61</sup> In the case of national emergencies or other circumstances of extreme urgency, the usual requirement of prior unsuccessful negotiations for a voluntary license may be waived under domestic law.

<sup>62</sup> This is the case in some FTAs, which limit the substantive grounds for compulsory licenses, thus going beyond the TRIPS minimum standards of IP protection. See, for example, the United States-Jordan FTA (Article 4, paragraph 20). Other such FTAs are United States–Australia; United States–Singapore; and United States–Viet Nam. Later US FTAs no longer contain this limitation.

<sup>63</sup> See UNCTAD-ICTSD Policy Discussion Paper.

<sup>64</sup> See UNCTAD-ICTSD Issue Paper No. 2, in particular on p. 25.

<sup>65</sup> For instance, United States copyright law historically contained a “manufacturing clause”, which originally limited copyright protection to works printed in the United States. The purpose was to promote the local printing industry. Such measures would nowadays be inconsistent with the TRIPS national treatment obligation, which requires Members to treat foreign IP right holders no less favourably than domestic right holders (Article 3, TRIPS). As another example, Switzerland, today a dedicated supporter of effective IP protection, prohibited patents between 1802 and 1888, due to the fact that free access to new technologies was thought to be more beneficial to its gradually developing industry than exclusive rights. As far as pharmaceutical products are concerned, Switzerland did not introduce patent protection until 1977. See UNCTAD-ICTSD Policy Discussion Paper, pp. 34, 36, and footnote 37. Such a policy would nowadays constitute an infringement of the TRIPS

their local technological capacities evolved. Such a strategy may be explained by the fact that in the early stages of development, indigenous learning and technology transfer in a given industry depend to a large extent on processes such as reverse engineering<sup>66</sup> and the duplicative imitation and adaptation to local conditions of mature foreign products. Broad IPRs will make these informal channels of learning more difficult.<sup>67</sup>

Limiting exclusive rights to the minimum required under TRIPS would result in a wider public domain, one in which developing country researchers and industry would be able to draw on existing technological know-how for purposes of follow-on innovation. As the local industry's capacity gradually moves from duplicative and creative imitation to incremental and larger-scale innovation, local industry is likely to become more interested in protecting their intellectual assets and recouping rising expenses for R&D investment. This evolution was clearly experienced by India, where the local pharmaceutical producers have considerably increased their R&D as well as patenting activities in recent years.<sup>68</sup>

It follows that, in order to promote the development of indigenous capacities, governments may wish to vary their approach to TRIPS implementation, tailoring the strength of their IPR protection to the level of technological development that their local industries have attained. Where governments seek to promote domestic technological learning through adaptation and follow-on innovation, they may elect to limit exclusive rights to the required TRIPS minimum standards and preserve a relatively broader public domain; where a government considers some key domestic industries to have reached a level of technological sophistication requiring more protection, it can expand the scope and depth of IP protection, provided that foreigners receive treatment no less favourable than domestic entities. The TRIPS flexibilities provide important tools that allow a government to make such considerations. Sections 2 and 3, below, will discuss these tools in the context of public health and local pharmaceutical production.

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obligation to provide for patent rights for both products and processes in all fields of technology (see Article 27.1, TRIPS).

<sup>66</sup> Reverse engineering refers to the practice of taking a product apart to examine and understand its functioning and process of manufacture. It typically leads to improvements and lower costs of production. See, for example, P. Samuelson and S. Scotchmer, "The Law & Economics of Reverse Engineering", *Yale Law Journal*, May 2002, pp. 1575-1663.

<sup>67</sup> The TRIPS Agreement (Article 28) provides the patent owner with an exclusive right to exclude others from, *inter alia*, the act of making the patented product or process. This includes making of the patented product through reverse engineering. To the extent that such reverse engineering is done only for non-commercial purposes (e.g. for scientific research and experimental purposes), it is still consistent with the TRIPS Agreement. But the point here is that engaging in reverse engineering for the promotion of domestic industries will necessarily imply a commercial aspect. The wholesale imitation of the patented product for commercial purposes cannot even be authorized under the broadest experimental use exception, see *infra* Section 3.1.2.

<sup>68</sup> See B. Dhar and K.M. Gopakumar, "Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: The case of the generic pharmaceutical industry in India", *UNCTAD-ICTSD Regional Research Paper*, November 2006, pp. 33 ff.

(available at <http://www.iprsonline.org/resources/docs/Dhar%20Indian%20Pharma%20April%202007.pdf>). According to these authors, the major pharmaceutical firms in India have been increasing the shares of their sales turnover that are subsequently allocated to their R&D budgets. For example, Dr. Reddy's Laboratories Ltd., which is a leader in the market, spent 2 per cent of its sales turnover on R&D in 1995, but 12.3 per cent in 2004 (*ibid.*, Table 8). Consequently, Indian firms have also increased their international patent filings. The leading firm, Ranbaxy Laboratories, Ltd., filed only 14 international patents in 1999, but 259 in 2005 (*ibid.*, Table 13).

## 1.5 Overview of TRIPS obligations relevant in the context of local pharmaceutical production

The TRIPS Agreement introduced the obligation to make patents available “for any invention, whether products or processes, in all fields of technology” (Article 27.1) for the first time at the multilateral level. Unlike many industrialized and developing countries were able to do in the past,<sup>69</sup> WTO members today may no longer exclude pharmaceutical products from patent protection, and must provide instead the pharmaceutical industry with the possibility of obtaining patents not only on pharmaceutical processes but also on products.

A granted patent confers specified exclusive rights on its holder. The patent is a public authorization that excludes others from the acts of making, using, offering for sale, selling, or importing a protected product for at least 20 years.<sup>70</sup> Thus, a patented medicine may be produced, sold, and imported only by the patent holder or with his/her authorization. Third party producers or importers are obligated to seek a license from the patent holder. Due to the fact that the use of the patented substance is subject to the patentee’s consent, unauthorized third parties engaging in the manufacturing of similar products risk patent infringement suits. The granting of pharmaceutical patents may therefore entail considerable challenges for generic drugs producers. A patent granted on the pharmaceutical substance is therefore usually considered to be a more serious obstacle for generic producers than a patent granted for the process of making or using a drug. Box 1 provides a basic overview of the different scopes of product and process patent protection under the TRIPS Agreement.

### **Box 1: Product and process patents and the implications for generic pharmaceutical production**

The scope of a pharmaceutical patent largely depends on whether the patent as granted covers the product itself, the way of making it, the way of using it, or some combination of these elements. Patent law formally distinguishes between products (such as machines, manufactures, or composition of matter) and processes (also termed methods), which are comprised of techniques and behavioural engagements expressed as a series of steps. This distinction is reflected in Article 28.1 of the TRIPS Agreement (with paragraph (a) providing minimum standards of product patent protection, whereas paragraph (b) contains minimum standards of process patent protection). However, an inventor “can claim the invention as he wishes” and may “write claims towards the same invention so that they describe it in terms of (1) a product, (2) a method of using that product, (3) a method of making that product.”<sup>71</sup> What the inventor obtains in the end typically depends on which of those claims survive the tests of novelty and non-obviousness.<sup>72</sup>

The most important implications for generic producers arise when originator drugs are protected through patents that cover the drugs in themselves (i.e. product patents). Article

<sup>69</sup> For example, Germany excluded pharmaceutical products from patentability until 1968; India did the same until 2005.

<sup>70</sup> See Article 28.1, TRIPS Agreement. Rights of importation, distribution, use and sale of a protected product may only be relied upon until they are “exhausted” (for details, see *infra* Section 3.2). Comparable rights are conferred on the holder of a process patent, see Article 28.2, TRIPS Agreement.

<sup>71</sup> J.R. Thomas, “Pharmaceutical Patent Law”, BNA Books, Washington, D.C., 2005 [hereinafter Thomas], pp. 30-31.

<sup>72</sup> *Ibid.*

28.1(a) of the TRIPS Agreement requires members to provide patent holders with the right to exclude others from the acts of, *inter alia*, making and using the protected product. The terms of “making” and “using” are not further defined. There seems to be consensus, in the member States of the European Patent Convention (EPC), that a product patent encompasses **all possible methods of making that product**, even where not expressly mentioned in the product claim.<sup>73</sup> This wide protection may be based on the broad reference in Article 28.1(a) of the TRIPS Agreement to “making”, which must be distinguished from making the product through a particular process, as provided under Article 28.1(b), TRIPS Agreement (i.e. process patents, see below). By contrast, State practices vary with respect to the extent to which the **methods of using** a patented product are protected.<sup>74</sup> Members are free to limit protection to those uses of the product expressly referred to in the patent application (“use-bound” product claims).<sup>75</sup> In all cases, a product patent granted on a pharmaceutical substance will prevent generic producers from making that substance without the patent holder’s authorization. By contrast, the granting of a process patent (Article 28.1(b), TRIPS Agreement) for a drug would cover a particular way of **making and using** that drug,<sup>76</sup> leaving the generic producer free to reverse engineer the product in order to learn how to make it through a different process.<sup>77</sup> In addition, the generic producer would be allowed to use the

<sup>73</sup> See M. Scuffi, “The construction of product-by-process claims”, in *The construction of product-by-process claims*, 11th European Patent Judges’ Symposium, Copenhagen, *Official Journal of the European Patent Office* 2003, Special Edition, No. 2 [hereinafter Scuffi], pp. 60-74; see also UNCTAD-ICTSD Resource Book, p. 419; with respect to German law, see J. Ensthaler, “Gewerblicher Rechtsschutz und Urheberrecht”, second edition, Springer, Berlin, Heidelberg, 2003 [hereinafter Ensthaler], p. 120. For the United Kingdom, see the House of Lords Decision in *Generics (United Kingdom) Limited and others v H Lundbeck A/S*, [2009] UKHL 12, holding that a patent claim to a single product includes all methods of making that product, even if the description and specifications cover only one method and other methods emerge only at a later stage. See summary by L. Lodenquai of Deeth Williams Wall LLP, available at <http://www.dww.com/?p=1430>: “[...] The House of Lords (like the Court of Appeal) recognised there may be initial concerns over the ‘inherent breadth of a product claim’, but the statutory framework of the United Kingdom Patents Act and the European Patent Convention, as well as European Patent Office jurisprudence (such as *Exxon*) is clear. Where a product claim satisfies the requirements of patentability (i.e., it is novel and non-obvious), the *technical contribution to the art* is the product itself and not the process for making it, even if that process was the only *inventive step*. Provided that the specification sufficiently explains to the person skilled in the art how to make the product, it does not matter that there may be other methods of making it. [...]”

<sup>74</sup> For more details, see below, Section 2.5 on patent claims construction.

<sup>75</sup> According to Scuffi, p. 64, this is the current practice in Italy. The same approach has been adopted in the EU Biopatent Directive (98/44/EC), see in particular its Article 5 (3), which requires applicants for patents on gene sequences to disclose the industrial application of the gene sequence in the patent application, thereby limiting the scope of the patent to the expressly disclosed uses.

<sup>76</sup> This follows from the language in Article 28.1 (b) of the TRIPS Agreement on process patents:

“1. A patent shall confer on its owner the following exclusive rights:

(a) [...]

- where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.”

Here, “using the process” refers to the **making** of a product (method-of-making claims), while “using [...] the product obtained directly by that process” refers to the **use** of the product (method-of-use claims).

<sup>77</sup> In this context, Article 34 of the TRIPS Agreement establishes an important obligation for members regarding the allocation of the burden of proof. In proceedings related to an alleged infringement of a process patent, the claimant (i.e. the patent holder) must establish that the defendant has infringed his process patent by using the patented process to make a particular product. Taking account of the difficulty for the patent holder to prove elements that fall into the sphere of the defendant, the TRIPS Agreement establishes that any identical products, produced without authorization by the right holder, shall be deemed to have been obtained by the patented process, unless proved otherwise by the defendant. This assumption applies both if the product obtained by the patented process is new (the newer the product, the less likely it is for the defendant to have developed an alternative production process), or if the likelihood that the identical product was made through the protected

product in ways not covered by the process patent, for example to administer the drug differently from what is described in the process patent claims, provided the country uses a narrow doctrine of equivalents.<sup>78</sup>

Having outlined the potential impact of pharmaceutical patents on generic pharmaceutical production, a number of qualifications should be made. *First*, under TRIPS rules, LDCs enjoy transition periods for the implementation of TRIPS obligations. During these transition periods, LDC members are not obligated to make patent protection available for pharmaceutical products and related processes or to enforce them. This important qualification will be discussed in detail in Section 2.1 on LDC transition periods.

*Second*, for those LDCs not taking advantage of their transition periods, and for developing countries, the obligation to make patents available does not necessarily mean that a patent will actually be granted for each patent application. A country's national patent office will have to examine whether each specific invention (e.g. a specific pharmaceutical product) meets the three patentability criteria of novelty, inventive step and industrial applicability, as defined in domestic law, and may refuse the grant of a patent where this is not the case.

*Third*, patents remain territorial by nature, meaning that a pharmaceutical product that is protected in country A does not enjoy patent protection in country B unless a national patent has also been granted in country B. Moreover, country B's evaluation of patent standards is usually independent of that which is applied in country A (principle of independence of patents, see Paris Convention, Article 4*bis* (1), as incorporated into TRIPS by Article 2.1 of the TRIPS Agreement). Pharmaceutical companies do not always seek patent protection in every country, due to, *inter alia*, a perceived lack of market size. Therefore, it is possible that in some countries, despite the existence of a national patent law, certain pharmaceutical substances remain off-patent and may be freely used, made and imported in that country. Should the original inventor change his/her mind seek patent protection at a later point, the application would be rejected for lack of novelty if the substance at issue has been made available to the public prior to the filing of the patent application.

The TRIPS Agreement also obligates WTO members to provide some protection for clinical trial data submitted to governments or their regulatory agencies (see Article 39.3 of the TRIPS Agreement). This is particularly applicable to safety and efficacy test data submitted by manufacturers of pharmaceutical products for the purpose of receiving the approval by a drug regulatory authority to market the drug in question. It is important to note that such test data protection is not necessarily or inherently exclusive in nature (for details, see Section 3.5)

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process is substantial and the patent holder through reasonable efforts is incapable of determining that their process was actually used. For details, see UNCTAD-ICTSD Resource Book, pp. 496 ff.

<sup>78</sup> Note that a broad application of the doctrine of equivalents could limit competitors' possibilities of making and using the pharmaceutical substance: manufacturing processes and methods of using the drug that are considered equivalent to the initially patented processes would be barred from the unauthorized use by competitors. See South Centre, "A Guide to Pharmaceutical Patents", editor C. Correa, Vol. I, Geneva, 2008, p. 144 [hereinafter South Centre Guide]. For more details on the doctrine of equivalents, see below, Section 2.6 on patent claims interpretation. Even under a broad doctrine of equivalents, however, process patent claims would not encompass all possible ways of making and using a product (including unknown ones), as opposed to the scope of product patents.

## **2. Pre-grant flexibilities**

### **2.1 Full use of LDC transition periods**

#### **2.1.1 Background**

The first option for governments seeking to influence the scope of exclusive rights in medical products has generally been to refuse to grant patents on pharmaceutical products. This option is no longer available for developing country members.<sup>79</sup> For LDC members, the TRIPS Agreement originally provided for a transition period lasting until 1 January 2006 for the implementation of TRIPS obligations (Article 66.1). However, this period has been extended in two different ways, one affecting the implementation of the TRIPS provisions in general, and the other one relating to the protection of pharmaceutical products, in particular.

#### **General extension of TRIPS implementation**

LDC members have been granted an extended transition period until **1 July 2013** for the general application of the TRIPS provisions (with the exception of the obligation to respect national and most-favoured nation treatment).<sup>80</sup> This general extension is limited by the requirement that any changes in a country's "laws, regulations and practice" made during the transition period shall not result in a lesser degree of TRIPS consistency (hereinafter referred to as the "no-roll-back requirement"). Full consistency in this respect refers to the minimum standards of the TRIPS Agreement. A "lesser degree" of consistency thus means any reduction of existing IP protection below the minimum standards, either by lessening the strength of exclusive rights in legislation that was previously TRIPS-compliant, or by rolling back TRIPS-inconsistent legislation even further. Thus, any **amendments** to existing IP laws or regulations that would have this effect are precluded.

The Decision on the 2013 Extension, in paragraph 1, authorizes members to **suspend the application** of the provisions of the TRIPS Agreement, such as the provisions on patents. At the same time, however, the no-roll-back requirement also applies to existing, IP-related **practice** (paragraph 5). "Practice" in this sense refers to the application through courts and the administration (e.g. IP offices) of a country's IP laws and regulations. Read together, paragraphs 1 and 5 of the Decision on the 2013 Extension mean that LDCs are required to maintain their general IP laws, regulations and practice as they were before the start of the additional transition period (i.e. 1 January 2006). However, they are exempted from the obligation to make their laws, regulations and related practices fully TRIPS-compliant before

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<sup>79</sup> Most developing country WTO members had until 1 January 2000 to comply with the obligations under the TRIPS Agreement (Article 65.2, TRIPS Agreement). Those developing countries that on 1 January 2000 did not provide product patent protection to certain areas of technology (particularly including pharmaceutical products) were granted an additional period of 5 years (until 1 January 2005) to introduce such protection (Article 65.4, TRIPS Agreement).

<sup>80</sup> See Decision of the Council for TRIPS, "Extension of the Transition Period Under Article 66.1 For Least-Developed Country Members", 29 November 2005 [hereinafter Decision on the 2013 Extension] (available at: <http://docsonline.wto.org/imrd/directdoc.asp?DDFDdocuments/t/IP/C/40.doc>). The obligation to respect national and most-favoured nation treatment essentially means that LDC Members may not deny IP protection to the citizens of certain Members if they grant the same to their own citizens or to citizens of any other country. See Articles 3-5, TRIPS Agreement.



2013, to the extent that they have not already done so. Where an LDC's IP-related practice (e.g. through continuous jurisprudence) has in the past excluded certain areas of technology from patentability, or applied particularly large exceptions to a particular technology, this LDC may continue such practice, despite the obligations under TRIPS to make patent protection available in all fields of technology, without discrimination between different fields of technology. On the other hand, the same country may not disapply patent protection to areas of technology previously covered by its law.<sup>81</sup> While the no-roll-back requirement sets important limitations for LDCs' industrial policies, it should be emphasized that this limitation does not apply in the area of pharmaceutical products (see below).<sup>82</sup> Finally, the 2013 extension does not prevent LDC members from reducing existing domestic "TRIPS-plus" provisions (i.e. going beyond the TRIPS minimum standards) and moving toward TRIPS minimum standards.

### **Extension for pharmaceutical products and clinical trial data**

LDC members are granted an additional transition period until **1 January 2016** for the implementation of the TRIPS provisions on patents and undisclosed information (including clinical test data) in the area of pharmaceutical products.<sup>83</sup> This extension encompasses at the very least those pharmaceutical processes needed for the manufacture of the respective products. Otherwise, the 2016 extension would be of very limited value, as exclusive rights on the required manufacturing process would still block access to the pharmaceutical product directly obtained through the patented process.<sup>84</sup>

The 2016 extension for pharmaceutical products and processes exempts LDC members from the obligation to:

- implement the above-mentioned TRIPS provisions; or to
- apply them; or to
- enforce rights provided for under these TRIPS provisions.

By contrast to the 2013 extension, the 2016 extension is not subject to a no-roll-back requirement. Existing laws and regulations may thus be expressly amended, or their

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<sup>81</sup> See Decision on the 2013 Extension, para. 5. In the literature on this subject, this no-roll-back requirement has been described as illegal and therefore non-enforceable through the WTO dispute settlement system. See for example S. Musungu, "A Conceptual Framework for Priority Identification and Delivery of IP Technical Assistance for LDCs during the Extended Transition Period under the TRIPS Agreement", Quaker United Nations Office, Geneva, 2007 (available at <http://www.quno.org/geneva/pdf/economic/Issues/Priority-ID-English.pdf>). Musungu considers the no-roll-back requirement to be an additional substantive obligation for LDCs, one that the Council for TRIPS does not have a mandate to implement. The Council on TRIPS is thus acting *ultra vires* (p. 9) and upsetting the negotiated balance of rights and obligations (p. 10). Musungu compares the Decision on the 2013 Extension with another TRIPS Council Decision specifically related to the LDC transition period in the area of pharmaceutical products (i.e. Decision by the Council for TRIPS of 27 June 2002 on "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products", WTO document IP/C/25 [hereinafter Decision on the 2016 Extension]). The Decision on the 2016 Extension does not contain any no-roll-back requirement, and Musungu challenges the rationale for such distinction (p. 10).

<sup>82</sup> Technically, the 2013 extension and the no-roll-back requirement also apply to pharmaceutical products, however the 2016 extension takes precedence over the 2013 extension as regards the particular area of pharmaceutical products (see para 6 of the Decision on the 2013 Extension).

<sup>83</sup> See Decision on the 2016 Extension. This Decision was based on paragraph 7 of the Doha Declaration.

<sup>84</sup> See F. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO", *Journal of International Economic Law*, Vol. 5, 2002, pp. 469-505) [hereinafter Abbott, Dark Corner] (p. 504, footnote 102, referring to TRIPS Article 28.1(b) as covering process patents that are arguably related to the subject matter of "pharmaceutical products" within the meaning of paragraph 7 of the Doha Declaration).

application may simply be suspended. The authorization of LDC members not to “enforce” rights provided for under the TRIPS provisions on patents means that an LDC may choose not to grant product patents on pharmaceuticals until 2016. In addition, this also means that an LDC is authorized not to enforce pharmaceutical product patents that have already been granted.<sup>85</sup> Under this option, LDCs may choose to limit such non-enforcement to particular pharmaceutical products, while maintaining patent protection for other pharmaceutical products. For example, Rwanda in July 2007 notified the Council for TRIPS of its intent to no longer enforce TRIPS provisions on patents and undisclosed information with respect to a particular drug it intended to import in its generic form from a Canadian producer (for details, see box 8, Section 3.3, below).<sup>86</sup>

Upon termination of the transition period (i.e. 2016 or later, if LDCs decide to request another extension at the WTO Council for TRIPS), patents existing at the time when a specific LDC decided to invoke the transition period would again have to be enforced, unless their term of protection had expired in the meantime.<sup>87</sup>

The question arises as to what extent members taking advantage of the above-mentioned transition periods have to comply with the “mailbox” obligation under Article 70.8 of the TRIPS Agreement. This obligation normally requires that that members that do not make patent protection available for pharmaceutical products nevertheless are required to provide a system under which patent applications can be filed and kept (“mailbox”) during the transition period.<sup>88</sup> Upon termination of the transition period, all applications “in the mailbox” will then have to be examined.<sup>89</sup> For generic producers, this may have important implications, as products they have used during the transition period may become subject to a patent once the transition period expires in 2016. LDC members addressing this problem may face some legal uncertainty, the degree of which depends on the design of their current domestic patent legislation, and on regulatory measures they may take to alleviate the effects of patents that emerge from the mailbox (as discussed under the policy options below).

### **Non-availability of pharmaceutical patents under domestic law on 1 January 1995**

LDC members which, as of the date of entry into force of the WTO Agreement (i.e. 1 January 1995), did not make available patent protection for, *inter alia*, pharmaceutical products, were subject to the mailbox obligation up to the expiry of the original transition period on 1

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<sup>85</sup> See also F. Abbott and R. Van Puymbroeck, “Compulsory Licensing for Public Health. A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision”, *World Bank Working Paper* No. 61, World Bank, Washington, D.C., 2005 [hereinafter World Bank Guide], p. 21. This leaves open the question of remuneration for expropriation of the patent holder, which WTO Members may have to provide, according to their own constitutional law. See the next section on policy options, below.

<sup>86</sup> See “Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, WTO document IP/N/9/RWA/1 of 19 July 2007.

<sup>87</sup> Neither the TRIPS Agreement nor the Decision on the 2016 Extension specify whether the use of the transition period should have any effect on the term of protection of existing patents. Without any specific provision in this respect, it may be assumed that the patent term is not interrupted, but expires 20 years from the filing date, irrespective of the transition period.

<sup>88</sup> See Article 70.8, TRIPS Agreement. Unavailability of patent protection in this sense may take several forms, such as through express amendments to the legal infrastructure; the suspension of the application of patent provisions or the mere non-enforcement of granted rights.

<sup>89</sup> For details, see Article 70.8 (b), TRIPS Agreement, as well as the UNCTAD-ICTSD Resource Book, pp. 766-772.

January 2006, as expressly provided for under Article 70.8 of the TRIPS Agreement.<sup>90</sup> There is reason to believe that the 2016 extension decision for LDCs maintained the mailbox obligation intact.<sup>91</sup> The express language of the 2016 waiver extension only refers to the TRIPS obligations on patents and undisclosed information, and does not refer to the obligations under Article 70 of the TRIPS Agreement to provide for a mailbox system and to provide for exclusive marketing rights (EMRs).<sup>92</sup> The LDCs had asked for a waiver of both obligations, and it was understood at the time that an express waiver would be necessary for both obligations to be waived.<sup>93</sup> While the WTO General Council did grant, in a separate 2002 decision, an express waiver for the requirement for LDCs to provide for EMRs during the transition period,<sup>94</sup> it never granted a waiver on the mailbox. This differential approach to the mailbox on the one hand and EMRs on the other hand is likely to be read as indicative of the General Council's intent to maintain the mailbox obligation during the extended 2016 LDC transition period, despite the adoption of the 2001 Doha Declaration on the TRIPS Agreement and Public Health.<sup>95</sup> In addition, the 2016 Extension Decision expressly refers to the extension of the original LDC transition period under Article 66.1 of the TRIPS Agreement, which was subject to the mailbox obligation (Article 70.8 (a)). As a result, those LDCs that did not make patent protection for pharmaceutical products available on 1 January 1995 and that continue such practice until 2016 must at least provide, in their domestic law, for a mailbox, which gives patent applicants the opportunity to file patent applications at any time and to then process and validate them upon the expiry of the 2016 transition period.

This obligation arguably conflicts with the underlying policy objective of the transition period, which is to prevent the TRIPS patent rules from becoming an obstacle to LDC members' efforts to protect public health. Although the mailbox obligation does not affect the LDC members' right to refuse to issue or enforce patents on pharmaceutical products until 2016, it does require them to install and maintain administrative procedures that permit the receipt and retention of pending pharmaceutical patent applications for the purpose of later examination (i.e. from 2016 on). These procedures may entail considerable financial and administrative efforts that would burden poor LDCs' health budgets and thus further strain their capacity to address those non-IP-related infrastructural and health care bottlenecks that some stakeholders

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<sup>90</sup> See Article 70.8 (a), TRIPS Agreement, providing for the mailbox obligation "notwithstanding the provisions of Part VI" of the TRIPS Agreement, which contains the original LDC transition period under Article 66.1 (i.e. 1 January, 2006).

<sup>91</sup> The same observation applies to the Decision on the 2013 Extension. That Decision extended the transition period under TRIPS Article 66.1 in 2013. The Decision on the 2013 Extension expressly refers to the LDC transition period "under Article 66.1 of the Agreement", i.e. the transition period that had to respect the mailbox obligation under Article 70.8(a). This reference has to be understood as carrying over into 2013 the original mailbox obligation under the original transition period. While the 2013 decision only refers to TRIPS Articles 3-5 as remaining obligations for LDCs, it makes clear in its heading that what is being extended is the transition period as applicable to the mailbox obligation.

<sup>92</sup> See Abbott, *Dark Corner*, p. 502. See also UNCTAD-ICTSD Resource Book, p. 719-720.

<sup>93</sup> Communication to the authors from Professor Frederick M. Abbott, referring to a WTO website announcement from the relevant time which referred specifically to the continuing obligation to provide mailbox protection.

<sup>94</sup> See WTO General Council Decision, "Least-Developed Country Members - Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products", 8 July 2002, WTO Document WT/L/478, 12 July 2002 (available at: [http://www.wto.org/english/tratop\\_e/trips\\_e/art70\\_9\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm)). With respect to other product areas, the 2013 extension also waives the EMRs obligation.

<sup>95</sup> The Ugandan representative in the Council for TRIPS, speaking on behalf of the LDCs, stated that he would have preferred the waiver to cover also Article 70.8 of the TRIPS Agreement, but he had not, in the spirit of compromise and cooperation, insisted on this. See WTO document IP/C/M/36, paragraph 217. See paragraphs 193 - 217, *ibid.*, for the minutes of the discussion on the waiver of the obligations under Article 70.8 and 70.9 of the TRIPS Agreement.

have identified as major obstacles to access to medicines in developing countries.<sup>96</sup> Perhaps WIPO could be asked to set up and maintain administrative procedures for this purpose on behalf of LDCs that request such assistance. The costs of the mailboxes could then be borne by beneficiary OECD countries, perhaps as part of their technical assistance obligations under Article 66.2 of the TRIPS Agreement.

### **Availability and later suspension of pharmaceutical patents under domestic law**

While under the above scenario (i.e. pharmaceutical product patent protection not available on 1 January 1995), the mailbox obligation applies until 2016, this issue is less clear with respect to those LDCs that on 1 January 1995 did make pharmaceutical product patent protection available, but later chose to suspend such protection, as authorized under the Decision on the 2016 Extension. In this context, it should be mentioned that on 1 January 1995, a considerable number of LDCs did provide for pharmaceutical product patent protection, even though they were not obligated to do so.

Interpreted literally, the mailbox obligation does not apply in such a case, as Article 70.8 of the TRIPS Agreement is limited to situations where pharmaceutical product patent protection was **not** available on 1 January 1995. Previous decisions by the WTO Appellate Body suggest the importance of an interpretation that remains close to the express language of the TRIPS Agreement, in order to not add any new commitments to a carefully negotiated balance of rights and obligations.<sup>97</sup> Establishing a mailbox filing system requires financial and other resources that may adversely affect a very poor country's potential to address more urgent public health issues.

#### **2.1.2 Policy options**

The way in which to take full advantage of the extended transition period depends on the domestic legal situation in any given LDC member. The easiest case arises where an LDC has no patent protection in place at all, because that country may continue this policy until mid-2013 for all technologies, and until 2016 for pharmaceuticals (and perhaps longer, if further waivers for LDCs are granted by the Council for TRIPS). However, those LDCs would seem to be required to establish a mechanism for mailbox patent filings.

In reality, many LDCs in their existing patent legislation do not make any specific reference to the (non-) patentability of pharmaceutical products. Instead, these laws typically contain broad references to the general requirements for the patentability of any products, including pharmaceuticals.<sup>98</sup> Such laws do not make use of the 2013 and 2016 transition periods accorded to LDC members under WTO law.

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<sup>96</sup> See, for example, T. Jones in the CIPIH Report, p. 202.

<sup>97</sup> See World Trade Organization Appellate Body, "India - Patent Protection for Pharmaceutical and Agricultural Chemical Products", WTO Document WT/DS50/AB/R, 19 December 1997. See also UNCTAD-ICTSD Resource Book, pp. 776-778.

<sup>98</sup> See S. F. Musungu and C. Oh, "The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?", Study 4C for CIPIH, Geneva, August 2005 (available at: <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>).

There are basically two options available to these LDCs if they should now decide they want to exploit the extended transition periods.

### **Option 1**

If an LDC has already provided for patent protection in its domestic law, it may **suspend** both the granting of new patents on pharmaceutical products and processes as well as the enforcement of existing patents on these subject matters. However, it may not cut back on existing protection in other technological areas under the no-roll-back provision of the 2013 Extension.

Alternatively, such an LDC could accomplish the same end by **enacting an express amendment** to the existing legal infrastructure stating that until 1 January 2016, patents for pharmaceutical products shall not be made available or enforced. This approach could include additional provisions permitting the granting of some pharmaceutical patents under specified and justifiable national interest exceptions (provided that care was taken to avoid potential discrimination against foreign applicants).

### **Option 2**

If an LDC has already provided for patent protection in its domestic law but declines to suspend the granting or enforcement of pharmaceutical product or process patents for political or policy reasons of its own, it may nonetheless consider shortening the term of protection for such patents, at least until 2016.

The TRIPS Agreement requires members to provide for a minimum term of 20 years, counted from the date of filing the application (Article 33). However, because of the 2016 extension, nothing prevents LDC governments from providing shorter terms for pharmaceutical products and processes, such as, for instance, 5 years from the date of filing the application.<sup>99</sup> Regarding other fields of technology, however, LDCs remain bound by the no-roll-back requirement (see above), and any reduction of existing terms of patent protection for non-pharmaceutical products might violate that requirement.

### **Dealing with the Mailbox Provision**

As noted, Article 70.8 of the TRIPS Agreement and the 2016 Extension Decision imply that those LDCs which on 1 January 1995 did not provide for pharmaceutical patent protection are subject to the mailbox obligation. However, it is less clear that the mailbox obligation under Article 70.8 of the TRIPS Agreement would also apply to those LDCs that, on 1 January 1995, did provide for pharmaceutical patent protection but later chose to suspend it.

As analysed above, a literal interpretation of the language of Article 70.8 of the TRIPS Agreement supports the position that the mailbox obligation does not apply to these LDCs.

In those cases where the mailbox obligation does apply, governments struggling with dire economic and political circumstances may consider applying to the TRIPS Council for a country-specific waiver on grounds of hardship under Article IX.3 of the WTO Agreement in conjunction with Article 8.1 of the TRIPS Agreement.<sup>100</sup>

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<sup>99</sup> This was the practice in the United Republic of Tanzania; see Section 38 (1) of the Tanzanian Patents Act, 1987.

<sup>100</sup> This provision states: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance

Governments that are willing to implement the mailbox obligation in all cases may seek to mitigate its impact on local producers in various ways.

- One option in this regard is for LDCs to combine the implementation of the mailbox obligation with a right of prior use available to producers who were using the later protected substance in good faith before the mailbox patent application was filed. The prior user right is an exception to the rights conferred by a patent that is widely recognized in OECD country legislation,<sup>101</sup> and it may be deemed consistent with the requirements of the TRIPS provision on patent exceptions under Article 30 (see Section 3.1, below).<sup>102</sup> In domestic laws, prior use exceptions are usually provided without any right to remuneration for the patent holder. However, the prior use exception is limited to cases where the use of the respective substance occurred prior to the filing of the (mailbox) patent application.
- Another strategy that could be used to mitigate the impact of the mailbox obligation on local producers is to follow the example of the Indian Patents Act. It provides that patents granted on the basis of a mailbox application shall entitle the patent holder “only [...] to receive [a] reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.”<sup>103</sup> Unlike the typical prior use exception, the Indian law allows the use (against remuneration) of the patented substance even in instances where a third party had started using the substance only after the mailbox application was filed, but before the entry into force of the obligation for India to make available pharmaceutical product patent protection. Good faith on the part of the third party is not required, but s/he must show significant investment and prior continued use on the date of the patent grant.
- While the consistency of the Indian approach with the TRIPS Agreement has not been tested, the case for its compatibility rests on the grounds that it represents a “*sui generis* prior users’ right” under Article 30 of the TRIPS Agreement as reinforced by the Doha Declaration on TRIPS and Public Health.<sup>104</sup> However, it is not certain that the WTO Appellate Body would be persuaded that India’s interest in promoting access to affordable medicines justified converting the mailbox rights to a compensatory solution, nor is it clear that a WTO decision favouring India, if the issue were litigated, would automatically authorize its use by other countries in other circumstances. This said, one should note that the United States Supreme Court held in 2006 that injunctions in patent cases may be denied on grounds either of public interest or a showing that monetary damages are adequate.<sup>105</sup> One may therefore predict with some

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to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”

<sup>101</sup> See, for instance, § 12 (1) of the German Patent Act; and Section 64 of the United Kingdom Patents Act.

<sup>102</sup> C. Garrison, “Exceptions to Patent Rights in Developing Countries”, *UNCTAD-ICTSD Issue Paper No. 17*, Geneva, 2006, pp. 2, 5, and 6 [hereinafter Garrison].

<sup>103</sup> See Section 11-A (7) of the Indian Patents Act (Amendment Act, 2005).

<sup>104</sup> Professor F.M. Abbott, email communication to the authors, December 2007.

<sup>105</sup> See *eBay Inc v. MercExchange*, L.L.C., U.S. 126 S. Ct. 1837 (2006).

confidence that LDCs would be given the benefit of the doubt on in this matter, in the unlikely event their use of this approach were to be challenged at WTO.

### **Other considerations**

- In technology areas other than pharmaceuticals, the no-roll-back requirement applies (see above). Thus, where there is an existing practice of refusing to grant patents on certain non-pharmaceutical technologies, such practice may be continued, but TRIPS rules would not authorize extending such a practice to areas of non-pharmaceutical technology for which patents used to be available.
- Depending on national constitutional law and rule of law principles, the suspension of the existing patent law could require the government (e.g. the responsible minister) to issue a decree or to receive parliamentary approval.
- Suspensions and amendments would have to refer to a specific date after which patents would no longer be granted. Moreover, while the Decision on the 2016 Extension clearly allows members to suspend the application and enforcement of patents already granted, there may be domestic laws regarding constitutional rights to property, and principles governing expropriation that may have to be taken into account. Such laws might entitle the patent holder to adequate remuneration under some theories.<sup>106</sup> In any event, existing patents would again have to be enforced after 1 January 2016, unless the transition period is further extended by the TRIPS Council.

## **2.2 Administrative observation and opposition procedures**

### **2.2.1 Background**

There is a risk even in developed countries that patent offices may inadvertently grant patents for inventions that do not meet the basic patentability requirements of novelty, inventive step and industrial applicability as courts of commentators would interpret them.<sup>107</sup> These questionable or so-called “weak” patents constitute an even more serious problem in developing countries and especially LDCs, where patent examiners often lack expertise in the evaluation of complex technical patent applications. There is a tendency in some developing country patent offices to grant patents without thorough examination, particularly when a parallel patent on the same substance has been granted by a developed country patent office.<sup>108</sup>

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<sup>106</sup> For example, in Chile and Germany, existing intellectual property rights are part of the constitutional right to private property, the suspension of which will normally require the Government to adequately remunerate the patent holder (see, for instance, Article 14.3 of the German Constitution).

<sup>107</sup> See, e.g., Reichman/Cooper Dreyfus, section II. See also the results of the United States FTC Study and the EU Pharmaceutical Sector Inquiry.

<sup>108</sup> For example, the patent law of Uganda provided for the automatic registration in Uganda of patents granted in the United Kingdom. See Uganda Law Reform Commission, “A Study Report on Industrial Property Law (Patents, Industrial Designs, Technovations and Utility Models),” Law Com Pub. No. 12 of 2004, Kampala, 2004. Each WTO member may require patent applicants to provide information on the applicant’s corresponding foreign applications and grants, Article 29.2, TRIPS Agreement. For details, see Section 2.7.2 below.

Wrongly granted patents provide exclusive rights on materials that should be freely available to all competitors from the public domain. In the public health context, this means that generic producers will be prevented from using the wrongly patented substances for their own production, and generic competition will thus be less effective in bringing down drugs prices. It may also have an adverse impact on innovation. Challenges to weak patents typically occur in domestic courts. However, this process is both time consuming and very costly, which risks deterring generic producers and other stakeholders from such action.

It is thus appropriate to provide a system under which patents can be challenged before the patent office itself (pre-grant and post-grant opposition) in addition to providing a system for post-grant court procedures. Administrative procedures are in general less time-consuming and less expensive than litigation, and may provide significant opportunities for third parties to draw the patent examiners' attention to elements that would justify the non-granting or reduction in scope of a patent.

### **2.2.2 Policy options**

The TRIPS Agreement leaves members considerable discretion concerning the establishment of administrative procedures for patent opposition. National law may make such procedures available before or after the actual grant of the patent, or both.

**Option 1 (pre-grant observation or opposition procedure)** is to provide third parties with the possibility to file an observation or opposition with the patent office on a pending patent application. The objective is to provide third parties with the opportunity to submit evidence to the patent office that could help to prevent the granting of a poor quality patent. For this purpose, the patent office may be obliged, under national law, to hear the arguments advanced by the opposing party and to take them into account in its decision regarding pending applications. Alternatively, the patent office may hear third party arguments but are not required to consider the information in their ultimate decision. Procedures that have a binding effect are referred to as “opposition”, whereas procedures that do not obligate the patent office to respond to third party comments are termed as “observations”. Pre-grant opposition and observations may be raised on the grounds that the patentability requirements are not met or for other reasons, such as insufficiency of disclosure.<sup>109</sup> The refusal or revocation of a patent grant on the basis of insufficient disclosure of origin of genetic resources and traditional knowledge used in a claimed invention is an important issue under discussion, in both the WTO Council for TRIPS<sup>110</sup> and WIPO.

Legislation establishing a pre-grant observation/opposition procedure will have to set some time span during which observations/opposition are admissible before the patent office. The

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<sup>109</sup> See UNCTAD-ICTSD-WHO Working Paper, C. Correa, “Guidelines for the examination of pharmaceutical patents: Developing a public health perspective”, *UNCTAD-ICTSD Regional Research Agenda*, Geneva, 2007, Section 3 (p. 24) [hereinafter UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*] (available at [http://www.iprsonline.org/unctadictsd/docs/Correa\\_Pharmaceutical-Patents-Guidelines.pdf](http://www.iprsonline.org/unctadictsd/docs/Correa_Pharmaceutical-Patents-Guidelines.pdf)). See also C. Correa, “Integrating Public Health Concerns into Patent Legislation in Developing Countries”, The South Centre, 2000, pp. 83-85 [hereinafter South Centre, 2000].

<sup>110</sup> For an overview of these discussions, see WTO secretariat, “The Relationship between the TRIPS Agreement and the Convention on Biological Diversity” Summary of Issues Raised and Points Made. Note by the Secretariat. Document no. IP/C/W/368/Rev.1 of 8 February 2006. See also UNCTAD-ICTSD Resource Book, pp. 397-399; 457-459.



determining date in this scenario is the date of publication of the patent application. Governments may provide that, for a certain amount of time counted from the date of publication, observations and oppositions may be filed by interested third parties. National administrative law may define the requirements to qualify as an “interested” third party. In general, this may be any natural or juridical person whose rights or economic interests may potentially be affected by the patent. In addition, national legislation should provide for the possibility to appeal the decisions made by the patent office with regard to third party observations and oppositions. The TRIPS Agreement imposes no limitations in this respect.

**Option 2 (post-grant opposition procedure)** may be used in addition to – or as an alternative to – option 1. Under this option, a third party may file an opposition with the patent office *after* a patent has been granted. The grounds for post-grant opposition may be the same as in the case of a pre-grant observation/opposition procedure. In addition, the patent may be challenged where its subject matter as granted goes beyond what has been applied for in the patent application.<sup>111</sup> Such opposition may be filed within a pre-determined period after the publication of the patent grant.<sup>112</sup> Also, national legislation should implement a process through which to appeal decisions that are passed down subsequent to an opposition. Finally, domestic law may provide that, in the context of patent infringement proceedings before a court, the patent office may be requested any time during the life of the patent to re-examine the grant in light of prior art newly called to the patent office’s attention.<sup>113</sup>

## **2.3 Patentable subject matter**

Before addressing the patentability criteria (or “patent eligibility criteria”) of novelty, inventive step and industrial application (see Section 2.4), a patent examiner must examine whether the claimed product or process actually qualifies as an invention, and whether there are other characteristics that prevent its patentability. If such examination does not confirm the existence of “patentable subject matter”, the patent application will be rejected and there is no need to consider the eligibility criteria. The substance at issue will consequently remain in the public domain and should be freely available to the public, including generic producers of pharmaceuticals and researchers.

Regarding patentable subject matter, the TRIPS Agreement authorizes members to exclude certain types of subject matter from patentability. Only “inventions” are patentable (Article 27.1 of the TRIPS Agreement), but the TRIPS Agreement does not define what is an “invention”. Members are therefore free to define what constitutes an invention. Depending on national legislation, natural substances, which often provide important inputs to pharmaceutical products may or may not qualify as “inventions” (see below).

In addition to the exclusion from patentability of non-inventions, Article 27.3(a) of the TRIPS Agreement authorizes members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals (for details, see Section 2.3.2). Methods of treatment are considered to be inventions under TRIPS, but may nevertheless be excluded from patentability. Substances that are not considered an invention in the first place

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<sup>111</sup> See Article 100 (c) of the European Patent Convention (EPC).

<sup>112</sup> For instance, under the EPC, an opposition may be filed within nine months after the publication of the grant (Article 99, EPC).

<sup>113</sup> South Centre, 2000, p. 84, referring to United States law.

(such as natural substances under some national laws) do not need such exclusion; they are non-patentable subject matter in all circumstances.

The following three sections (2.3.1-2.3.3) will discuss the issues of natural substances, new uses of known substances and product derivatives, and examine to what extent these may constitute patentable subject matter. The important issues of new uses and of product derivatives will arise again under Section 2.4 on patentability criteria.

### **2.3.1 Substances existing in nature**

#### **2.3.1.1 Background**

The extent to which naturally existing substances may be patented has some important implications for generic pharmaceutical production. Medicaments may consist entirely or partially of biological substances, including extractions from plants, algae, human proteins, and the results of genetic engineering.<sup>114</sup>

Article 27.1, TRIPS Agreement, obligates members to make available patent protection for “inventions”. The Agreement does not define this notion. However, national legislation in developed WTO members has traditionally excluded, *inter alia*, discoveries and scientific theories.<sup>115</sup> The reason for the exclusion of discoveries stems from the basic rationale of patent protection: to reward human ingenuity and creativity as a contribution to the advancement of humankind. The inventor, in exchange for his/her efforts and readiness to make his/her invention available to the benefit of society is granted a reward, i.e. a monopoly to exploit the invention over a limited period of time. Mere discoveries, including, arguably, substances found in nature, need not be treated under patent law as deserving of such a reward.<sup>116</sup> They do not result from anyone’s ingenuity or creativity.

Abstract scientific theories, principles and ideas, on the other hand, are expressions of human ingenuity and creativity. However, because technological progress depends on the availability of theories and ideas as inputs for follow-on innovation, patent law (and copyright law) has traditionally been construed so as to exclude these building blocks of knowledge from IP protection.

For these reasons, national patent laws have traditionally defined an invention as resulting from a **technical** contribution to the art, or as being of a **technical character, representing the solution to technical problems**, or having a **technical effect**, as opposed to ideas, abstract scientific principles and, arguably, substances found in nature.<sup>117</sup> Even so, the

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<sup>114</sup> See South Centre, 2000, pp. 15-16.

<sup>115</sup> See, for instance, Article 52 (2) (a) of the European Patent Convention. According to United States Supreme Court case law, laws of nature, physical phenomena and abstract ideas are not patentable subject matter. See, for example, the recent decision in *Bilski et al v. Kappos, Under Secretary of Commerce for Intellectual Property and Director, Patent and Trademark Office*, Decision of 28 June 2010, Syllabus, p. 2 [hereinafter *Bilski v. Kappos*] (available at <http://www.supremecourt.gov/opinions/09pdf/08-964.pdf>).

<sup>116</sup> Note that domestic patent laws differ on this issue.

<sup>117</sup> These references to technical character/technical contribution or effect are oftentimes not made in express terms. Article 52 (2) (a) of the European Patent Convention, for instance, by excluding “discoveries”, implies a technical character of an invention. One reason for this is that there is no internationally agreed definition of technical character/effect/contribution. These notions derive from German patent law, see UNCTAD-ICTSD

distinction, under domestic law, between a technical invention on the one hand and abstract principles and natural substances on the other hand may be made depending on whether the definition standards are strict or lax. The TRIPS Agreement does not contain any express restrictions on national discretion in this respect.

### **2.3.1.2 Policy options**

Based on the background above, a case can be made that substances occurring in nature need not be considered inventions. However, this argument weakens in regards to natural substances that have been extracted from their natural environment and, due to such extraction, or subsequent refinement, behave differently from their original form. Some jurisdictions consider such isolated or purified matter as potentially patentable, as long as it satisfies the other eligibility requirements, even if the (isolated) substance as such remains unchanged. For those extracted substances, what triggers the patentability is the act of isolating or purifying, which is regarded as a technical contribution to the art in its right.<sup>118</sup>

Governments seeking to ensure broad access by local producers and researchers to natural substances relevant for pharmaceutical production may wish to consider adopting a definition of “invention” that would exclude naturally occurring substances in isolated form. For example, Article 7 (b) of Argentina’s Patents Act excludes from patentability, *inter alia*,

“all biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including

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Resource Book, p. 361. The current German Patents Act contains no express reference to the technical character of an invention (see § 1 of the 1980 Patents Act, as amended on 21 June 2006), as this requirement is generally accepted as a principle of common law. In the United States, two recent decisions have discussed the issue of technical effect versus abstract idea in the context of process patent claims. In more concrete terms, these decisions addressed the applicable criteria to determine whether a process is patentable or constitutes an abstract (and non-patentable) idea. In a 2008 decision, the Court of Appeals for the Federal Circuit (CAFC) stated that in order for a process to constitute eligible patent subject matter, rather than an abstract idea, it (1) needs to be tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing (see *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008)). The CAFC in this decision reversed its older case law, which stated that a process is patentable so long as it creates a “useful, concrete and tangible result” (see *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F. 3d 1368 (Fed. Cir. 1998)). This decision has been interpreted by members of the legal profession as elevating the requirements for processes to qualify as patentable subject matter (see D. Vogel, “Grünes Licht für Software-Patente”, in *Neue Zürcher Zeitung* of 24 September 2010 [hereinafter Vogel], arguing that the creation of a useful, concrete and tangible result appears easier to do than the transformation of an existing article into something else. That author refers, *inter alia*, to software used in the context of medical diagnostics, which creates a result in the above sense, but does not necessarily transform an article into a different state or thing.). The United States Supreme Court in the same case (*Bilski v. Kappos*) confirmed the usefulness of the “machine-or-transformation test”, but stressed that this test could not be considered the only criterion in the distinction of patentable subject matter and abstract ideas. Thus, the test would have to be complemented through a case-by-case analysis, according to expert commentators of the decision. See IP Watch, “Bilski Decision Tough But Vague On Business Method Patents”, *Monthly Edition*, July 2010, pp. 4/5. Vogel has interpreted the Supreme Court decision as softening the stricter “machine-or-transformation test” established by the CAFC, thus facilitating the patentability of processes.

<sup>118</sup> See Article 3.2 of the EU Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions: “Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature”. The same approach is taken under § 1 (2) of the German Patents Act. But see discussion on industrial application, Section 2.4.1.3, for limitations of the scope of granted gene patents under both European Union and Member States law.

genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature.”<sup>119</sup>

Brazil’s patent law establishes that

“all or part of natural living beings and biological materials found in nature, even if isolated there from, including the genome or germplasm of any natural living being, and the natural biological processes” are “not considered to be inventions or utility models.”<sup>120</sup>

Similarly, the Decision of the Andean Community on the Common Regime of Industrial Property states that

“any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing” shall not be considered inventions.”<sup>121</sup>

Moreover, some commentators contend that domestic law could stipulate that in order to be an invention, the biological material *itself* needs to have undergone a structural change, for example by means of genetic engineering.<sup>122</sup> In any event, the *process* used for isolating biological substances remains patentable subject matter, but a process patent places fewer restrictions on other potential users than a product patent.<sup>123</sup>

It must be remembered that the TRIPS Agreement forbids discrimination against foreign nationals. Therefore, a member that opts to implement this standard must also exclude local innovators from patents on matter existing in nature. Local inventors would still have the ability to patent such substances abroad, however, under the independence of patents doctrine.

## **2.3.2 New uses of known products**

### ***2.3.2.1 Background***

In pharmaceutical patent law, an important question is whether or not new uses of known products should be patentable. This issue arises because additional therapeutic uses of a product are often only discovered after the product has been available to the public for quite some time. One scenario in which this is important is the discovery of the first medical use of

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<sup>119</sup> Law 24.481, as amended by Law 24.572, consolidated text approved by Decree 260/96, of March 20/96.

<sup>120</sup> See N. De Carvalho “The Problem Of Gene Patents”, *Washington University Global Studies Law Review*, Vol. 3, No. 3, 2004, pp. 701 ff.

<sup>121</sup> *Ibid.*

<sup>122</sup> See South Centre, 2000, p. 20. In that case, the technical contribution required for patentability would not be the isolation of the biological substance from its natural environment, but the modification of the biological substance in itself.

<sup>123</sup> As opposed to process patents, product patents render illegal any unauthorized production through reverse engineering of a product for commercial purposes. Under a process patent, the product may still be used by third parties if the latter use a different process for manufacturing the product, assuming they rebut the burden of proof under Article 34 of the TRIPS Agreement. See above, box 1.

a product (“first medical use”<sup>124</sup>; for instance, where a substance used for food consumption is later discovered to help prevent cancer), or the second use (“second medical use”;<sup>125</sup> for example, the AZT drug (Retrovir), previously used to combat cancer, was later found to also be effective against HIV/AIDS). Finding a new, more efficient or less invasive way of administering a known drug is also a case of new use. It is important to emphasize that a new use by definition results from the same chemical entity, i.e., a known pre-existing substance. The new drug prescribed for the new use thus makes no change to the chemical structure of the existing product (as would be the case of derivatives, which are discussed later in this Guide).

Because the same chemical entity is at issue, new therapeutic uses may come to light during late-stage clinical trials, or afterward, when physicians themselves start to use the drug for a new therapeutic effect that was unknown to the patentee. In some instances, the patentee himself may invest in additional R&D that leads to new uses of an existing pharmaceutical product.<sup>126</sup>

Because new uses of known substances entail no change of chemical structure, they conceivably fall within the R&D capabilities of industries in many developing countries and even some LDCs. This is particularly true in countries where knowledge of traditional medicines exists, and new indications might be found through targeted research. While companies in developing countries may possess unique opportunities in this area, the costs of establishing the safety and efficacy of new uses are high, as are the costs of establishing production facilities for this purpose. Hence, thought must be given to the legal incentives that local producers might need to invest in this type of production.

At the same time, governments should consider the potential of obtaining medicines based on new uses of known substances at prices their citizens and their public health systems can afford. Precisely because new chemical entities are not involved, there are no large R&D expenditures that need to be recovered through patents, and therefore a case can be made for adopting a more pro-competitive regime that allows all would-be producers to enter the market without intellectual property rights. This regime can be consistent with the TRIPS Agreement, as will be explained below. It should also be noted that a totally free market policy towards new uses risks significantly lessening the incentive to explore such uses, even for potential local producers. For this and other reasons, we shall also discuss other means of protection that offer an alternative to patents that developing countries might find particularly well-suited to promoting investment in the discovery of new uses of known pharmaceutical substances.

With these policy issues in mind, it is important to realize that international patent law allows developing countries a broad legal space in which to determine whether or not to allow patents on new uses at all, and to adjust the scope of those patents that are allowed. As will be further described below, the manner in which governments implement the options available under the TRIPS Agreement will determine both the extent to which the originator patentee will have control over new uses and the space available for follow-on innovators, including local companies, to produce the product in question for such uses. The task for governmental policymakers is to understand the different legal options available under the TRIPS

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<sup>124</sup> Also referred to as first medical indication.

<sup>125</sup> Also referred to as second medical indication.

<sup>126</sup> See South Centre Guide, p. 121.

Agreement and to adopt a strategy consistent with the financial and technical capabilities of their own pharmaceutical sectors.

#### 2.3.2.1.1 Legal requirements under TRIPS

Two basic questions must be addressed in order to promote informed IP policy making on the regulation of new uses of known pharmaceutical products. The first concerns the extent to which TRIPS obliges countries to protect new uses of known substances at all, as a technical legal matter. If the TRIPS Agreement does not include such a requirement, the second question concerns the benefits and detriments of choosing whether or not to protect new uses of known substances.

There is an inherent tension in the TRIPS Agreement between Article 27.1, which broadly defines patentable subject matter as encompassing “all fields of technology,” and Article 27.3(a), which codifies a very old and established subject matter exception for “diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.” Narrowly construed, everyone understands that Article 27.3(a) is meant to prevent medical doctors from being limited by patents when administering treatments in their everyday practice, for example, prescribing the dosage of patented medicines for specified patients. The question arises as to whether this general exclusion of “therapeutic methods of treatment”, read together with other TRIPS provisions (i.e. the patentability criteria of novelty, inventive step and industrial application), can be construed as justifying the exclusion of “new uses of known pharmaceutical compositions” as a legitimate subject matter for a process patent.

The answer to this question will partly depend on how the member where protection is sought interprets Article 27.3(a) of the TRIPS Agreement, in the absence of any authoritative interpretation of that provision by either the WTO Ministers or Tribunals. At one extreme, members’ legislation may expressly deny recognition of even process patents on new uses of known substances under a broad interpretation of the terms “diagnostic, therapeutic and surgical methods” under Article 27.3(a). Under this approach, “there is no real difference between patent claims relating to the use of a substance and those relating to a therapeutic method: in both cases a new medical activity is claimed, i.e. *a new way of using* one or more known products.”<sup>127</sup> Under this refine, the patenting of new therapeutic effects of a known pharmaceutical substance would be illegal.<sup>128</sup> While there are few supporting state examples of this practice, the European Patent Office’s (EPO) own practice under the 1973 EPC indirectly supports this interpretation, see box 2, below.

At the opposite extreme, members may narrowly interpret Article 27.3 (a) so as to exclude only medical practitioners’ every day work from patentability. Under this approach, new medical uses of known substances could be considered to be patentable subject matter, if the member so desires. In these cases, producers meeting the novelty and non-obviousness requirements could obtain process patents on the relevant uses. State practice in the United States indirectly supports this option. In effect, the relevant United States legislation altogether ignores Article 27.3(a), perhaps because Congress did not want to entangle the protection of new medical uses of known substances in these questions of interpretation. Rather, United States legislation recognizes a narrow medical practitioners’ exception that would fall under Article 30 of the TRIPS Agreement, and thus sidesteps the subject matter

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<sup>127</sup> UNCTAD-ICTSD Resource Book, 387 (italics supplied) (citing Domeij at footnote 641).

<sup>128</sup> Ibid.

issue altogether. By the same token, United States patent law denies product patents on any known product for which a new use – medical or otherwise - is discovered.<sup>129</sup> This practice appears to be based on the interpretation that such products could not be “new” in the patent sense. Nevertheless, United States law clearly allows process patents on both the first medical use of a known substance and second or later medical uses of such a substance, provided that the claimed new use otherwise meets the eligibility requirements.<sup>130</sup> Such process patents would also be available under United States law for new uses of products found in nature.

It follows from this overview of State practice that Article 27.3 (a) of TRIPS is not viewed as imposing specific obligations on members regarding the patentability of new uses, at least in the absence of an authoritative interpretation by the Ministers or a judgement under the WTO dispute resolution process. Members seeking to bestow process patents on new medical uses of known substances will accordingly find little resistance in Article 27.3 (a), and may indeed go so far as to grant product patents for first and subsequent medical uses of such substances, as exemplified by EPO practice. Even where only process patents are granted, as in the United States, Article 28.1 (b) will further ensure that the relevant patents cover “at least the product obtained directly by that process”.

Members unwilling to grant even process patents on new medical uses of known products (or of substances found in nature) may seek shelter behind Article 27.3(a) of the TRIPS Agreement. Their recourse to the broad construction of this provision is indirectly supported by the EPO’s own perceived need to sidestep similar language in the EPC through the legal fiction of “Swiss claims”, although the terms have changed under the 2007 version of the EPC (see box 2, below). Even so, the TRIPS consistency of such a broad construction of Article 27.3(a) of the TRIPS Agreement cannot be guaranteed until the WTO formally pronounces upon this question.

Having discussed the implications of Article 27.3(a), TRIPS Agreement, regarding its implications for the granting of **process** patents on new medical uses of known pharmaceutical substances, it is appropriate to consider a second, closely related problem. This pertains to the eligibility of the inventor of a new use for a known substance to obtain a **product** patent on that substance that would cover the new use that has been found. Logically, this practice gives rise to a contradiction, in that the substance remains the same in all cases and only a “new method of use” has been added to the prior art. On this reasoning, United States law allows only a process patent on the new use,<sup>131</sup> besides any previous product patent that may or may not exist on the substance. It is this type of process patent that developing countries may freely exclude under Article 27.3 (a) of the TRIPS Agreement.

In European practice, however, and despite the logical contradiction it entails, the inventor of a new use for a known pharmaceutical substance may obtain either a product or a process patent for the new use in question (see box 2). A product patent is generally much more valuable to pharmaceutical companies than a process patent. If the originator company followed the product patent route, it could possess two patents on the same substance: depending on local law, the first pharmaceutical patent would cover uses known or disclosed at the time the first patent was filed, and the second pharmaceutical patent would cover the

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<sup>129</sup> Ibid, at 356.

<sup>130</sup> See Thomas, at p. 37-38.

<sup>131</sup> Ibid.

new specific use discovered later, which would protect the same substance for another twenty years, at least with respect to that new use.<sup>132</sup>

## Box 2: New use pharmaceutical patents under the European Patent Convention

Since the revised version of the European Patent Convention (EPC) entered into force in December 2007, pharmaceutical product patents are available not only for first, but equally for second and subsequent medical uses. Article 54(4) of the EPC applies to first pharmaceutical uses of substances that were known previously, but which medical properties were only discovered later.<sup>133</sup> For such medical uses of known products, the EPC, through a legal fiction, establishes broad product patent claims encompassing all possible pharmaceutical uses.<sup>134</sup> The fact that the product in question had been used for some other non-medical purpose, say, as a food product, would thus not prevent it from being considered as novel in the medical field in the EPC member States.

By employing a legal fiction comparable to Article 54(4), Article 54(5) of the revised EPC clarifies that second, third and subsequent pharmaceutical uses of known pharmaceutical substances qualify for use-bound product claims.<sup>135</sup> This rule potentially enlarges the scope of pharmaceutical product patents as compared to process patents. The existence of a product patent for a first pharmaceutical use, which in fact covers all possible medical uses, does not prevent the patenting of the same substance for specific medical uses discovered after the first use patent was granted. The broad first use patent may then be considered as retroactively limited by the grant of a subsequent product patent on a specific, later discovered medical use.<sup>136</sup>

Prior to the revised version of the EPC entering into force, product patents were only available for first pharmaceutical uses of known products.<sup>137</sup> With regard to second, third and subsequent new medical uses of known medical substances, the lack of an EPC provision comparable to new EPC Article 54(5) forced the EPO to deny product patents, because the product as such had already been used *as a medical product* before and would therefore no longer be considered new in the patent sense. In theory, the language in old Article 52.4

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<sup>132</sup> See EPC Article 54(4) (for first pharmaceutical uses) and (5) (for subsequent pharmaceutical uses) as revised and entered into force in December 2007.

<sup>133</sup> Article 54(4), EPC reads as follows: “(4) Paragraphs 2 and 3 [i.e. on novelty] shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53 (c) [i.e. exclusion from patentability of methods for the treatment of humans and animals], provided that its use for any such method is not comprised in the state of the art.” The terms “use for any such method” refer to the general methods for human or animal treatment listed under Article 53(c), i.e. surgery or therapy and diagnostic methods. The use of the known product must be novel for any of these methods. This may be the case with first medical uses, as the substance at issue is for the first time used for the purpose of surgery or therapy and diagnostic methods.

<sup>134</sup> See case T128/82, OJ EPO 1984 (available at: [http://archive.epo.org/epo/pubs/oj1985/p059\\_094.pdf](http://archive.epo.org/epo/pubs/oj1985/p059_094.pdf)), p. 164, as cited by South Centre Guide, p. 140.

<sup>135</sup> Article 54(5), EPC reads as follows: “(5) Paragraphs 2 and 3 [i.e. on novelty] shall also not exclude the patentability of any **substance** or composition referred to in paragraph 4 for any **specific** use in a method referred to in Article 53(c) [i.e. exclusion from patentability of methods for the treatment of humans and animals], provided that such use is not comprised in the state of the art.” (emphasis added)

<sup>136</sup> See South Centre Guide, p. 139, in respect of the relationship between an original, non-pharmaceutical product patent and a subsequent product patent on a first medical use. The same legal fiction may be applied to the relationship between a broad first-use pharmaceutical product claim and product claims for subsequent pharmaceutical uses.

<sup>137</sup> Article 54(5) of the former EPC (1973), which is identical to Article 54(4) of the new EPC (2007).



EPC,<sup>138</sup> which mirrors the exemption in Article 27(3)(a) of the TRIPS Agreement, could even have obliged the EPO to deny process patents for subsequent medical uses on subject matter grounds.<sup>139</sup> Instead, the EPO used to have recourse to another legal fiction, known as the “Swiss formula” or “Swiss claims”, to enable process patents to issue for second and subsequent medical uses of a known substance. The EPO construed the relevant process claims as referring to how the drug was *made* (in order to achieve a certain purpose) rather than as process claims describing a *use* for a certain purpose, which would have raised questions of compatibility with old EPC Article 52.4. In effect, a method-of-use claim was thus treated as if it constituted a method-of-production claim, which was not barred by the former EPC Article 52.4 or Article 27.3 (a) of the TRIPS Agreement. Indeed, the EPO contended that such Swiss claims also fell outside the scope of old Article 52.4 EPC, which it saw as limited to method-of-use claims.<sup>140</sup>

Developing country governments may be disinclined to allow originator pharmaceutical companies to extend the duration of patent protection for a given substance by allowing for product patents on new medical uses. More generally, they may not wish to allow originator companies to control new uses of known substances at all. To pursue this objective, however, a broad application of Article 27.3 (a), TRIPS Agreement alone will not suffice. Rather, the local patent law must explicitly exclude product patents for new uses of known substances on the logical grounds that the inventor would have contributed no new product to the prior art at all, consonant with United States law and practice.<sup>141</sup> This result can be achieved by issuing a specific regulation governing novelty in such cases.<sup>142</sup> Alternatively, some commentators argue that a developing country could justify this exclusion of product patents for new uses on the grounds that the new use in such cases was merely an unpatentable “discovery” rather than a patentable “invention.”<sup>143</sup> However, this approach seems weaker and riskier than the United States model just discussed because it would raise questions about the proper breadth of exclusions for discoveries that only the WTO Appellate Body could settle.

In any event, a developing country could altogether exclude both process patents (on subject matter grounds, through a broad application of Article 27.3(a)) and product patents (through the novelty requirement) for new uses of a known pharmaceutical substance. In that case, it could freely allow qualified local producers to market generic versions of the product for that

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<sup>138</sup> I.e. new Article 53(c), EPC.

<sup>139</sup> Former Article 52.4 of the EPC states that: “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1 [i.e. the eligibility requirements of novelty, inventive step and industrial applicability]. [...]” As discussed in the context of the similar provision under Article 27.3 (a) of the TRIPS Agreement, when interpreted broadly, this provision may be understood as excluding from process patent protection new medical uses of known products.

<sup>140</sup> See, for example, Decision G 1/83 of the Enlarged Board of Appeal, in its headnotes (available at <http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ar52.html>):

“I. A European Patent with claims directed to the use may not be granted for the use of a substance or composition *for the treatment of the human or animal body by therapy*.

II. A European patent may be granted with claims directed to the use of a substance or composition *for the manufacture* of a medicament for a specified new and inventive therapeutic application.” (emphasis added).

<sup>141</sup> See UNCTAD-ICTSD Resource Book, p. 356.

<sup>142</sup> The regulation would thus invoke the novelty standard of eligibility for this purpose, as is done for product patent applications in the United States, without however necessarily allowing for process patents on new uses, as is done in the United States. For a discussion of the novelty standard, see below.

<sup>143</sup> South Centre Guide, pp. 124, 130.

specific use in the most pro-competitive manner, ensuring innovation through an alternative incentive system, which will be discussed below.

Of course, a government may also decide that it wishes to allow process patents on new uses of pharmaceutical products, but no additional product patents, in the United States fashion. In that case, the patentee can prevent third parties from “the act of using the process, and from the acts of: using, offering for sale, selling or importing for these purposes at least the product obtained directly by that process.”<sup>144</sup> In theory, a second comer could nonetheless reverse-engineer the product in order to devise a different process that would not infringe the originator’s process patent. In practice, the second comer’s effective ability to reverse-engineer the underlying substance and to exploit a resulting process patent in such a case could depend on whether there was a blocking patent on the underlying substance;<sup>145</sup> on the scope of the research exemption under local law; on the availability of a compulsory license for dependent improvement patents; or on some combination of the above.

Under yet another approach, a developing country government could decide to allow process and product patents for new pharmaceutical uses, in the same manner as the member States of the EPC. If a developing country took this latter route, it would be ignoring the advice of some governmental and intergovernmental organizations.<sup>146</sup> One reason for such decision could be that policymakers had prioritized the incentive effects of patents over the freedom of action allowed for competitors if no patents were made available in this area. In so doing, however, policy makers could still choose among two strategic options to accommodate local producers.

1. Under the first option, a country’s legislation that makes product patents available for new medical uses could limit the scope of such patents to the uses expressly claimed and disclosed in the patent applications. Under that scenario, the authorities could decide to allow second comers – whether foreign or domestic – to obtain product patents pertaining to the new uses that were subsequently discovered. In that case, however, the originator pharmaceutical company could be in the best position to capture the new product and extend its legal monopoly on the underlying substance for another period of 20 years.<sup>147</sup> If a generic competitor did succeed in discovering the new use, which he could presumably do under this option (and a proper research exemption), his resulting patent could still be treated as a dependent patent under the laws of some countries. In this case, the generic producer would need either to negotiate a license to manufacture the original patented substance<sup>148</sup> or obtain a compulsory license for dependent patents under Article 31(l) of the TRIPS Agreement. Alternatively, the generic producer could also try to argue that the second patent was not dependent on the first, because the first patentee never acquired the right to exclude others from making the product for a new use he had never applied for nor disclosed. Whether this approach succeeds or not would depend on local law. At least in the member States of the EPC, the first patentee would acquire the right to exclude

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<sup>144</sup> Article 28.1(b), TRIPS Agreement.

<sup>145</sup> Even if the patent on the underlying substance were limited to the uses referred to in the patent claims (“use-bound claims”), product patents cover all possible ways of making the protected substance, see Box 1, above. See below, section 2.5 (patent claims construction).

<sup>146</sup> See, e.g., South Centre Guide, p. 153.

<sup>147</sup> See South Centre Guide, p. 133. The twenty-year period would be reduced by the time needed to seek marketing approval for the new use.

<sup>148</sup> *Ibid.*, p. 133.

others from all possible ways of making a product, even if the product claims were limited to certain uses only.

2. Under the second strategic option a developing country's patent law could structure the allowance of product patents on first medical uses so as to cover all uses of the initial patented pharmaceutical product. This approach would automatically exclude third parties from exploiting new uses of the same substance during the life of the original patent only.<sup>149</sup> It would permit the originator patentee to control both the initial pharmaceutical product patent for such new use and any new pharmaceutical uses discovered later without extending the life of the original patent at all.<sup>150</sup> This approach maintains some – albeit limited<sup>151</sup> – incentives to the originator patent company to make and market products for new uses, while precluding the local manufacture of generic products having the same uses during the life of the initial pharmaceutical patent only. Alternatively, a country could strengthen the generic competitors' incentive by invoking the EPO fiction, under EPC Article 54(5), which recognizes additional specific uses beyond a claim for all uses in the initial patentee's application. This situation is comparable to the first option discussed above, with the difference that, in case no subsequent medical uses are claimed, the initial product patent on a first medical use will comprise all possible subsequent uses, rather than being use-bound. As under the first option, therefore, the originator pharmaceutical company is in practice often the likeliest to discover subsequent new uses and benefit from this legal fiction.<sup>152</sup>

#### 2.3.2.1.2 Policy considerations: the promotion of incremental innovation in developing countries

In general, neither the discovery of new medical uses of known products nor the other relevant practices discussed below in this Guide (i.e. producing trivial product derivatives and/or devising “selection patents”) constitute groundbreaking innovation. Such modest contributions to the existing state of the art are referred to as “incremental innovation”. Such innovation often lies within the range local firms, particularly those that could not realistically aspire to developing truly new or non-obvious inventions that may require more technical research capabilities than are available.

It could be argued that high standards for the definitions of novelty and non-obviousness, which render more difficult the patenting of trivial variations that do not represent significant gains in efficacy, may discourage local producers capable of incremental innovation at the expense of foreign research-based pharmaceutical companies. This approach arguably frames the problem incorrectly. The elimination of product patents on new uses and trivial modifications frees up key active ingredients – provided that these ingredients are not themselves covered by a separate patent – for generic production at prices that poor people

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<sup>149</sup> This assumes the member has decided not to follow EPO practice of admitting separate product patents on specific second, third and subsequent uses despite the broad coverage under the initial first use patent of all possible pharmaceutical uses (Article 54(5), EPC).

<sup>150</sup> See South Centre Guide, pp. 132-33.

<sup>151</sup> South Centre Guide, p. 133, noting that due to his monopoly position, the patentee's inclination to engage in costly R&D for new use discoveries will be very limited.

<sup>152</sup> Ibid., p. 133.

can afford. Sacrificing those pro-competitive benefits in order to stimulate investment in incremental innovation seems a steep price to pay, especially when alternative modes of protecting and stimulating incremental innovation that would not trigger such high social costs exist. These alternatives to patents are discussed further below in the present section.

The need to consider incremental and sequential innovation in formulating national intellectual property policy can lead to internal tensions between groups seeking maximum freedom to compete, who may oppose patents altogether, and groups that have reached a high level of technical capability, who want to lower the eligibility standards. A third group of companies that can only attain incremental innovation may fall between these other two interest groups. To address this problem, one must first clarify that the status of patentability in any given developing country has no effect whatsoever on the ability of a local inventor to patent his/her invention abroad in, say, the United States and EU countries. Under the doctrine of independence of patents incorporated into TRIPS from Paris Convention Article 4*bis*, each country must apply its own law to foreign inventors without regard to the state of patent protection in that inventor's home country. Thus, one who produces an incremental innovation even in an LDC without any patent protection at all can nonetheless patent the same invention in all foreign countries that normally protect incremental innovation in their patent laws.

As discussed in the previous section, the legal requirements of the TRIPS Agreement leave developing countries and LDCs plenty of legal space in which to design beneficial IP regimes regarding the treatment of new medical uses of known substances. Here one may usefully subdivide the question into "defensive" and "offensive" considerations. These terms are meant to emphasize the need for poor countries to balance their concerns about the impact of foreign patents on public health at home and the need to have the freedom to obtain affordable medicines from any available source (defensive considerations) against the policy objective of providing local entrepreneurs with incentives to invest in the production of medicines for both domestic and foreign markets (offensive considerations).

From a defensive perspective, by negating the availability of both process and product patents for new medical uses of known products on subject matter and other grounds, a member will reduce the high costs of examining relevant patent applications and of testing novelty, inventive step and industrial applicability on a case-by-case basis.<sup>153</sup> To the extent that the bulk of such new use patents emanates from foreign pharmaceutical suppliers, this strategy would maximize the space available for qualified local producers to enter the market for the relevant processes and products on a purely competitive basis, without *de jure* discrimination against foreign patentees. At the same time, it would also broaden the space available for obtaining generic substitutes, when available from foreign suppliers.

It follows, however, that the foreign patentee may not want to bring the relevant product or process (including the product directly made from it) to the local market. This is always a possibility when foreign patents are rejected in a member for any reason. The resulting need can be met either by generic producers with a capacity to reverse engineer the non-patentable invention or by resorting to the worldwide pharmaceutical products market, either under the exhaustion doctrine, where the imported product has been sold abroad first at an affordable price, even under patent protection, or by virtue of the new compulsory licensing machinery

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<sup>153</sup> This assumes that the novelty issue has been addressed by a suitable regulation, providing that a known product, for which a new medical use has been discovered, may not be considered as new in the sense of domestic patent law.

established by the draft Article 31*bis*, TRIPS Agreement, for the purpose of acquiring medicines that cannot be locally produced.<sup>154</sup>

From an offensive perspective, however, the strategy of totally barring product and process patents on new medical uses of known products on subject matter and other grounds will yield palpable social costs that must be carefully evaluated in light of local conditions. To begin with, the absence of patent protection here could limit the incentives for local entrepreneurs with sufficient capacity to invest in finding new uses of medical products initially developed abroad. This effect could be offset by giving local producers the ability to generate sufficient income to cover R&D costs under purely competitive local conditions, without the need for strong exclusive property rights, as was the case in India until the introduction of pharmaceutical product patents in 2005. Moreover, the lack of patentability in domestic law will not prevent the local entrepreneur from patenting abroad any use he discovers under the independence of patents doctrine of Article 4*bis*, Paris Convention, as long as the invention meets the foreign members' own subject matter and eligibility requirements. How these considerations play out in practice largely depends on the local producers' growing capability to reverse-engineer or innovate over time.

A more serious objection to the denial strategy set out above is that it will prevent local producers from patenting new uses of traditional medicines that have evolved from relevant traditional knowledge. In many countries where there is a rich heritage of traditional treatments, a case can be made for conferring intellectual property rights on those who invest in applications of traditional knowledge, with particular reference to medicines, as long as local access and benefit sharing regimes and relevant provisions of the Convention on Biological Diversity (CBD) are respected.<sup>155</sup> Here again, the true social cost of denying any protection for new medicinal uses will depend on the ability of local investors and innovators to flourish under purely competitive conditions. Moreover, the effect on the local producer of denying patent protection in cases of new uses of traditional medicine could also be attenuated to an unknown extent by the undiminished ability of the local innovator to obtain the relevant patents abroad and by the obligations on foreigners who make use of traditional knowledge and local genetic resources to satisfy requirements of access and benefit sharing under the CBD. An important element in this context is the actual market potential of traditional knowledge-based medicinal applications, not all of which are likely to generate consumer demand in those high income countries where they may be patentable.

Between these two extremes – a strategy of admitting patents on new uses of known substances and a policy of excluding the same – there lies an intermediate strategy. Members could consider adopting a “second-tier” intellectual property regime – or to extend an existing regime – to cover some or all of the innovation excluded from patent protection on subject matter or other grounds. For example, members could confer *sui generis* protection on new medical uses of known substances. Such a law might draw upon principles applicable to utility models, or, alternatively, build upon proposals for so-called “compensatory liability regimes” (i.e. “use and pay” regimes).

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<sup>154</sup> See Abbott/Reichman. The exhaustion doctrine would apply to the extent that the original patent is still valid in the country where patents on new uses of that product have been refused.

<sup>155</sup> See T. Cottier, M. Panizzon, “Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection”, in Maskus/Reichman, pp. 565-594; G. Dutfield, “Legal and Economic Aspects of Traditional Knowledge”, in Maskus/Reichman, pp. 495-520; A. Taubman, “Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge”, in Maskus/Reichman, pp. 521-564. In this context, relevant multilateral provisions are in particular Articles 8(j), 15, and 16 of the CBD.

Each of these alternative protection modalities offers advantages that may compare favourably with patent protection as such. In addition, room for domestic flexibilities under the TRIPS Agreement is much broader in these cases than with patents. While we cannot explore these options in detail here, we urge developing country policymakers to explore them more fully before taking final positions on patent law and policy.

Before entering into a discussion of utility models and compensatory liability regimes, the following needs to be emphasized. Regardless of the options chosen, every developing country that may have any capability to engage in improvements of existing inventions and incremental innovation must be aware of the need to address so-called blocking patents, i.e. patents (which are typically foreign) that stand in the way of locally developed improvements. For this scenario, the TRIPS Agreement itself provides a solution in Article 31(l), which allows a compulsory license that enables the second comer to practice a patent on an improvement that might often infringe the dominant patent. Developing countries are free to adopt legislation enabling the issuance of compulsory licenses for dependent patents consistent with Article 31(l) of the TRIPS Agreement.

The first alternative to patents in the area of incremental innovation is protection through utility models. This approach has been widely tested in practice. For example, Germany and Japan, which introduced pharmaceutical product patents in 1968 and 1976, respectively, successfully used their utility model laws to protect small-scale innovation for decades.<sup>156</sup> The Japanese utility model law, which once witnessed close to some 200,000 applications a year,<sup>157</sup> allowed Japanese inventors to protect small-scale improvements of foreign inventions. Indeed, these local innovators often “surrounded” the foreign invention to the point where negotiated cross-licensing became necessary. Utility models (“petty patents”), for which the TRIPS Agreement does not provide any binding minimum standards, are usually granted for small-scale inventions that do not meet the eligibility standards under patent law, especially the inventive step requirement. Most of those jurisdictions that allow for utility model protection either require a lower standard of inventive step or waive that requirement altogether.<sup>158</sup> The advantages of utility models, as compared to patents, are their rapid registration<sup>159</sup> and low registration fees, which can accommodate small businesses.

In the area of new uses of known products, however, a problem could arise in respect to the novelty requirement under utility model law: as observed under the previous section, the fact that a known product is used for a new purpose does not alter the fact that the product itself is not novel in the patent sense. In some jurisdictions, the novelty standard under utility model

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<sup>156</sup> See U. Suthersanen, “Utility Models and Innovation in Developing Countries”, UNCTAD-ICTSD Issue Paper No. 13, Geneva, 2006 [hereinafter Suthersanen].

<sup>157</sup> See Suthersanen, p. 17.

<sup>158</sup> See [http://www.wipo.int/sme/en/ip\\_business/utility\\_models/utility\\_models.htm](http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm). In Australia, for example, utility models (“innovation patents”) are required to include an “innovative” step, as a lower threshold than inventive step. Going even further, the new IP Law of Rwanda includes no requirement of inventiveness at all. The novelty and industrial application standards are comparable to those under Rwandan patent law. See Republic of Rwanda, Ministry of Trade and Industry, “Rwanda Intellectual Property Policy”, (Kigali, November 2009), p. 17 (on file with the authors; hereinafter Rwanda’s IP Policy). By contrast, the inventive step standard for utility models in Germany appears to be very close to the one required under German patent law, at least in practice. See A. v. Uexküll/N. Hölder, “A clever move. Utility models for second medical use inventions in Germany”, Patent World # 183, June 2006, pp. 22 ff. [hereinafter v. Uexküll/Hölder] (available at <http://www.vossiusandpartner.com/pdf/Clevermove1.pdf>).

<sup>159</sup> Unlike patents, there is usually no substantive examination of the utility model eligibility requirements, unless through a court in case of infringement litigation.

law may differ from the novelty standard under patent law.<sup>160</sup> However, other WTO members currently apply the same standard of novelty to patent and utility model law.<sup>161</sup> In addition, even for those members that have adopted different novelty standards, it would appear difficult to affirm the novelty of a known product for a new use utility model claim, where the product is covered by an existing domestic or foreign patent. These cases would require some creative interpretation of the novelty standard, such as the language that is used in the new (2007) version of the EPC in respect of new use patents (see above, box 2). In the area of utility models, the German Federal Court of Justice (Bundesgerichtshof/BGH, i.e. the highest instance court for, *inter alia*, patent-related disputes) has paved the way for such an interpretation of novelty: in 2005 the Court considered that a claim of a new medical use (i.e. a *process*) of a known product would include elements of a *product* claim, because it concerns the suitability of a (known) product for the indicated use. In the view of the BGH, the use of a known product for a new purpose results in the novelty of the product for that particular use. This is a much more permissive standard of novelty than the one suggested in this Guide for the area of patent law.

The BGH thus ruled that new medical uses of known pharmaceutical products may be protected as product claims through utility models.<sup>162</sup> Developing countries that are interested in promoting incremental innovation, but are concerned about the long term of exclusivity of a patent and its implications on generic competition, could follow this approach.<sup>163</sup> In that case, a member that rejects product patent claims for new medical uses on the basis of the novelty requirement would, in order to provide for utility model protection, have to devise a novelty standard under its utility model law that is much more permissive than the one under its patent law.

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<sup>160</sup> See v. Uexküll/Hölder, p. 24: in German utility model law, oral publication abroad does not destroy novelty, as opposed to patent law.

<sup>161</sup> See, for example, Rwanda's IP Policy.

<sup>162</sup> See v. Uexküll/Hölder, p. 23.

<sup>163</sup> At the UNCTAD peer review meeting, some participants argued that utility model regimes would not provide for appropriate incentives for incremental pharmaceutical innovation. Accordingly, utility models would protect the shape or structure of a device and therefore most pharmaceutical inventions would have to be regarded as being out of the scope of protection. It is true that former German legislation limited the scope of utility models to the external configurations of the devices in question (see Suthersanen, p. 15, referring to the German "Gebrauchsmustergesetz" of 1891). However, there are no internationally binding obligations on the design of domestic utility model laws, and the limitation to external configurations is by no means required and has not been maintained under German law (the German utility model law as last modified in 2006 no longer provides for a scope of protection limited to external configurations but protects any invention of technical character that are new, based on an inventive step and are capable of industrial application. See § 1 of the Gebrauchsmustergesetz of 28 August 1986). A second argument raised in the context of the UNCTAD peer review meeting against the appropriateness of utility model protection in the pharmaceutical context has been the short and limited protection available under utility models, which would not adequately reflect the need to recoup important investment costs incurred even when developing incremental inventions. Irrespective of the actual costs involved in incremental inventions, the question arises whether IPRs should be understood as a general means to recoup investment costs. According to the TRIPS Agreement (Article 7), the protection of IPRs should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology". Furthermore, compared to other IP disciplines, the Agreement does not set minimum standards on the protection of utility models. Thus, the rationale for granting exclusive rights is the promotion of innovation. Costs invested in R&D may be recouped through the use of exclusive rights to the extent such investment has actually contributed to innovative products. Whether or not an invention merits a patent does not depend on the amount of investment made, but on the extent to which the invention meets the patentability criteria. If this is not the case, as may be argued with respect to a number of incremental inventions, the product is not sufficiently new or inventive to deserve patent protection. The lower degree of inventiveness may only be rewarded by a weaker degree of exclusivity, as promoted through utility models.

The term of protection for a utility model is normally much shorter than for a patent.<sup>164</sup> From a public policy standpoint, it seems much more appropriate to protect sub-patentable inventions outside the patent system, rather than to alter the patentability criteria to encompass small-scale inventions. The result of the latter would be to block access by competitors to substances needed for product improvement over a considerable period of time. This being said, it is clear that the same concern arises with utility models, which confer exclusive rights similar to a patent, albeit for a much shorter period. It appears legitimate to question, from a policy standpoint, the rationale for providing exclusive rights for inventions that do not contain any inventive step.

This concern is addressed by the proponents of compensatory liability (use and pay) regimes, which constitute another alternative means of encouraging incremental innovation outside the patent system. In the literature, a regime of compensatory liability has been suggested as a way to stimulate incremental innovation in general,<sup>165</sup> as well as in new applications of traditional knowledge in various contexts.<sup>166</sup> A compensatory liability regime, as suggested in the literature basically confers three separate rights on the incremental innovator:<sup>167</sup>

- The first right is the right to prevent second comers, for a certain period of time, from wholesale imitations of the right owner's product. In the case of traditional knowledge products, the term of protection could be longer than for other small scale innovation, taking account of the slow accretion of traditional knowledge over time. A term of protection of 20 years has been recommended for these materials.<sup>168</sup> In areas of more systematic and commercially driven technological innovation, the term of protection could be shorter, also taking account of divergent lengths of product life cycles. There would be no need to protect short lived innovations from wholesale copying for a period of more than a few years.
- Under the second right conferred, the incremental innovator may claim reasonable compensation from any party that uses the protected innovation for value-adding improvements for a specified period of time. This right, which could last for up to 20 years, could be preceded by a much briefer period of market exclusivity for the inventor (e.g. one or two years), in order to give him the opportunity to establish his brand. Under the subsequent, longer period of compensation, the original innovator would be prevented from blocking the access of competitors to his innovation, unless wholesale duplication is sought. Competitors would be authorized not only to use the innovation for research activities to develop a superior product, but also to make and sell that product. This differs from a utility model or patent regime, under which an experimental use or research exception may enable competitors to use the protected substance for improvement-oriented research, but not for the sale or other commercialization of the results of their research before the expiry of the underlying product patent, unless a license (voluntary or compulsory) is granted (see below, Section 3.1.2, experimental use exception).

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<sup>164</sup> For example, the term of protection for utility models in Uganda is 10 years from the grant (see Section 69(3) of the 2009 Industrial Property Bill), as compared to the TRIPS minimum term of protection of 20 years from filing for patents (Article 33 of the TRIPS Agreement).

<sup>165</sup> See J.H. Reichman, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation", *Vanderbilt Law Review*, Vol. 53, 2000, pp. 1753 ff. [hereinafter Reichman, Green Tulips].

<sup>166</sup> See J.H. Reichman, T. Lewis, "Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge" [hereinafter Reichman/Lewis], in Maskus/Reichman, pp. 337-366.

<sup>167</sup> See Reichman/Lewis, 349-351.

<sup>168</sup> *Ibid.*



- As to the amount of compensation payable to the incremental innovator, Reichman has suggested royalty rates between 3 and 9 per cent of the sales revenue of the improved product.<sup>169</sup> The amount of payable royalties would, *inter alia*, depend on the amount of resources needed by the second comer to develop the improved technology or application. Disputes over the amount of royalties to be paid to the incremental innovator should be settled through mediation or arbitration. Importantly, the mediation or arbitration procedures would not entitle the right holder to ask for an injunction; his technology could be used at all times for follow-on improvements, with royalties being payable after the final mediation or arbitration award is rendered.
- Finally, the third right conferred under a use and pay regime would entitle the original inventor, for a certain period of time, to make use of a second comer's technical improvements, in exchange for the payment of reasonable compensation to the latter. This right could be the same length of time as the second right (i.e. to claim reasonable compensation for improvement uses of the original technology), although that detail would be left to policymakers to decide.

In practice, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) establishes a use and pay regime for plant breeders who breed new varieties off of exemplars deposited in a repository managed by the Consultative Group on International Agricultural Research (CGIAR).<sup>170</sup> Additionally, the United States Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) establishes a use and pay system in the area of agricultural chemical test data, which is, however, preceded by a ten-year term of exclusivity in these data.

Compensatory liability regimes of this kind would endow local innovators with incentives to discover new medical uses of existing products, and could stimulate investment in applications of traditional knowledge for this purpose.<sup>171</sup> At the same time, it would attenuate or eliminate the blocking effects of patents. To be sure, foreign patentees who are denied protection on subject matter or on other grounds must have the right to obtain similar protection under a member's second-tier or alternative regime, by dint of the equal national treatment requirement of the Paris Convention that has become an operative component of TRIPS.<sup>172</sup> In such a case, however, the foreign right holder would at most be entitled to equitable compensation for improvement uses, and he could not prevent generic competitors willing to pay such compensation from entering the market after a brief period of exclusivity. Finally, local innovators who obtained only *sui generis* protection at home could nonetheless file patent applications for the same uses abroad, in countries granting such patents, under the independence of patents doctrine incorporated into TRIPS.

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<sup>169</sup> Reichman, *Green Tulips*, p. 1784.

<sup>170</sup> See Articles 12.3(a) and 13 of the ITPGRFA. For more details, see M. Halewood, K. Nnadozie, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture", in *The Future Control of Food*, *A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (editors Tansey G and Rajotte T.), Earthscan, London, 2008, pp. 115 ff.

<sup>171</sup> For an elaborated model see Reichman/Lewis.

<sup>172</sup> See Articles 2(1) of the Paris Convention and 2.1 of the TRIPS Agreement. For detailed analyses of the national treatment clause (Article 3) under the TRIPS Agreement, see WTO Appellate Body, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, 2 January 2002 ("United States – Havana Club"); and *European Communities - Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R of 15 March 2005 (United States complaint) and WT/DS290/R of 15 March 2005 (Australian complaint). Both complaints were essentially based on the same claims, *inter alia* a national treatment violation.

### 2.3.2.2 Policy options

#### Option 1

A member may exclude product and process patents on new medical uses of previously known products altogether, drawing on the broad interpretation of Article 27.3(a), TRIPS Agreement, and a strict novelty standard as needed. While the TRIPS consistency of this option cannot be guaranteed, there is reason to believe that the EPC precedents support it. LDCs without any innovative pharmaceutical capacity might logically implement this option, with the understanding that they may need ancillary legislation enabling them to obtain the excluded medicines from other sources under the doctrine of international or regional exhaustion (Article 6 of the TRIPS Agreement) or by imports under draft Article 31*bis*, if they cannot reverse engineer or otherwise manufacture the needed substances themselves.

#### Option 2

The member may allow *process* patent protection for new medical uses of known substances while restricting the scope of Article 27.3 (a) to treatments and methods affecting the medical practitioners' every day work. In the context of examining novelty (discussed below), the member must also decide whether or not to allow *product* patents on first medical uses of a known substance, as occurs at the EPO, or deny such protection, as occurs in the United States. Generally speaking, these options are only of interest to countries with a relatively advanced pharmaceutical sector and R&D capacity, and even under those circumstances these options should be used with due care to the consequences of different drafting options.

#### Option 3

A member that excludes new medical uses of known substances from patent protection under Option 1 may nonetheless wish to protect such uses through exclusive rights outside the patent system, i.e. through utility models. These provide for shorter periods of exclusivity than patents and may be granted for inventions that do not meet the stricter eligibility requirements under patent law (in particular the novelty and the inventive step criteria). From a policy perspective, this approach appears more appropriate than to lower the patentability standards to embrace incremental innovations. On the other hand, it is questionable why exclusive rights should be awarded at all to those inventions that lack inventive character. Option 4 provides a noteworthy alternative in this regard.

#### Option 4

A member that excludes new medical uses of known substances from patent protection under Option 1 may nonetheless wish to protect such uses through a tailor-made *sui generis* regime that, for example, requires equitable compensation in exchange for the right to freely use the protected innovation (except for purposes of wholesale imitation), after a brief period of market exclusivity for the innovator. This option would provide incentives to local innovators to find such uses, both with respect to the adaptation of foreign substances to local conditions and also with respect to stimulating investment in new uses of substances rooted in traditional knowledge. As opposed to option 3 (utility models), a system of compensatory liability would not provide the right holder with the right to deny access of competitors to the protected subject matter for purposes of product improvement.

### **2.3.3 Variations in pharmaceutical composition or behaviour/product derivatives**

#### **2.3.3.1 Background**

The above sections have outlined two possibilities through which a country may exclude pharmaceutical products or their uses from qualifying as patentable subject matter (i.e. as discoveries of naturally existing products and as new uses of known products). This section considers briefly a third possible exclusion from patentable subject matter, i.e. pharmaceutical derivatives of existing medical products.

As opposed to the new use issue, the question of patentability of pharmaceutical product derivatives does not concern different uses of the same product, but different forms of a single product. While the new use issue relates to several uses of identical products, the present section discusses products that are similar to the original product but nevertheless not identical, because of their slightly different chemical structures.<sup>173</sup> These slight variations in structure may or may not have some important effects on the medical efficacy of the respective drug. Pharmaceutical companies likely want the derivatives of their own products to be protectable by patent. For policy makers, it is important to decide whether product derivatives merit patent protection. An example is a case where the derivative significantly increases the efficacy of the medical product, thus contributing important benefits to society.

In this context, the question arises as to at which point in the patent examination process the patent office should take the criterion of medical efficacy into account. This may be done at two different stages:

- At the point of examination of patentable subject matter;
- At a later stage, i.e. when examining the patentability requirements of novelty, inventive step and industrial applicability.

This Guide will refer to the issue of derivatives and enhanced medical efficacy at both of these stages.

#### **2.3.3.2 Policy options**

One option for addressing patent applications based on minor structural modifications of existing medical products is to take account of the question of efficacy of medical product derivatives in the context of the examination of patentable subject matter. This is the approach taken under the new Indian patent law. Article 3(d) of the new Indian Patent Act has pushed subject matter exclusions in the area of medicines further than most other known patent laws. It is understood to exclude any pharmaceutical product that does not rise to the level of “new chemical entities” or a “new medical entity”. New chemical/ medical entities in this sense are

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<sup>173</sup> “Similar” in a legal sense means: “Nearly corresponding; [...] Word ‘similar’ is generally interpreted to mean that one thing has a resemblance in many respects, nearly corresponds, is somewhat like [...] **but is not identical in form and substance**, although in some cases ‘similar’ may mean identical or exactly alike. It is a word with different meanings depending on context in which it is used” (Black’s Law Dictionary, Sixth Edition, St. Paul, 1990, p. 1383; emphasis added). For some examples of these slight differences in chemical structures, see Thomas, pp. 184-197.

only those substances that, when compared to the known substance, show significant improvements in medical efficacy.<sup>174</sup>

The particularity of the Indian approach is that the efficacy of a pharmaceutical product, which is normally dealt with under the novelty and non-obviousness standards, will be tested in the context of the subject matter examination, i.e. as a condition for qualifying as an invention in the first place. While this Guide takes the position that the pertinent Indian provision can be defended against allegations of TRIPS-inconsistency,<sup>175</sup> another option would be to address the issue of patents based on minor structural changes of existing pharmaceutical products that produce trivial differences in therapeutic effects under the novelty and non-obviousness standards. In this Guide, the bulk of the discussion on pharmaceutical product derivatives will therefore be provided in the context of analysing the patent eligibility requirements. This being said, if the eligibility requirements are used to repress the granting of patents for trivially modified products, there is a risk that patent examiners and courts, over time, issue inconsistent decisions in particular cases. This case-by-case approach tends inevitably to favour a downward pressure on eligibility standards, which may occur before any given country is in a position to profit locally from such standards. To avoid such a result, examiners and courts should be able to resort to a high level expert body, staffed by people (not necessarily all nationals, but experts in which the government has confidence) who have both the expertise to evaluate these issues in specific cases and a common understanding of and dedication to the local patent policies and strategies.

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<sup>174</sup> This provision has been challenged by foreign pharmaceutical producers as inconsistent with TRIPS. By contrast, distinguished academic authorities have expressed the view that the Indian provision can be defended. See F. Abbott, “The Definition of Pharmaceutical Substance and Exclusion of Micro-Organisms under the WTO TRIPS Agreement”, prepared for the Indian Pharmaceutical Alliance, 2005 (on file with the authors). [Hereinafter Abbott, The Definition of Pharmaceutical Substance]. See also Box 4, below. In August 2007, the Madras High Court rejected the Novartis challenge to Section 3 (d) of the Indian Patents Act. The High Court confirmed the constitutionality of the Indian provision. On TRIPS, it said it had no jurisdiction to adjudicate the matter and referred to the WTO Dispute Settlement Understanding. This decision, however, did not deal with the rejection by the Indian Patent Office of the actual Novartis patent application for an anti-cancer drug, “Glivec”. The High Court only upheld the legality of the domestic provision on which the rejection was based. The question whether this provision was applied correctly in the particular case was addressed by another court in India, the IP Appellate Board (IPAB). In its decision of 26 June 2009, the latter confirmed the patent office’s rejection of a patent for Glivec, denying “significantly enhanced efficacy” of Glivec under Article 3(d) over a previously known molecule (see the IPAB decision in *Novartis AG v Union of India et al.* at [www.spicyip.com/docs/NovartisvsUnionofIndia.pdf](http://www.spicyip.com/docs/NovartisvsUnionofIndia.pdf); see also P.B. Jayakumar, “Novartis loses battle for cancer drug patent”, *Business Standard* of 5 July 2009). In addition, the IPAB ruled that because of the price charged for Glivec, poor cancer patients in India would not be able to afford the drug, which in turn would threaten many people’s lives and thus create public disorder in the country (p. 191 of the decision). The IPAB thus invoked Section 3(b) of the Indian Patents Act, which implements Article 27.2 of the TRIPS Agreement (exclusion from patentability for reasons of public order). Following the IPAB decision, Novartis has appealed to India’s Supreme Court, see IP Watch “Novartis Persists in Challenge To Indian Patent Law; India Rejects More AIDS Drugs Patents”, online publication, 2 September 2009 (available at [www.ip-watch.org/weblog/2009/09/02/novartis-persists-in-challenge-to-indian-patent-law-india-rejects-more-aids-drugs-patents/](http://www.ip-watch.org/weblog/2009/09/02/novartis-persists-in-challenge-to-indian-patent-law-india-rejects-more-aids-drugs-patents/)). For further discussion of Article 3 (d) see Section 2.4.2.2. In another case (an interim proceeding), the Delhi High Court in 2008 refused to grant an injunction to the patentee (Roche) on the basis of public interest – the Court considered the public interest to be affected if patients no longer had access to cheaper generic copies of the patented drug (*F. Hoffmann-La Roche Ltd. & Anr. V Cipla Ltd.*).

<sup>175</sup> See Section 2.4.2.2.

## **2.4 Patentability criteria**

### **2.4.1 Background**

In order to be protected with a patent, inventions covering patentable subject matter still need to meet three basic criteria, as required under the TRIPS Agreement (Article 27.1): they need to

- Be new;
- Involve an inventive step; and
- Be capable of industrial application.

These terms will be explained in the following sections.

#### **2.4.1.1 Novelty**

The TRIPS Agreement does not define novelty. According to traditional patent law that prevails in many developed country jurisdictions, this requirement generally means that information describing the invention must not have been available to the public prior to the original application date (the priority date).<sup>176</sup> If such information was available to the public before that date, it is considered to be part of the “prior art”. The quality and nature of the information qualifying as prior art varies from one jurisdiction to another. Members are free to adopt strict standards of novelty, which would treat more inventions as prior art in the public domain and thus make it more difficult to obtain exclusive rights in any given product or process. As one scholar put it: “while the term ‘new’ indicates that an invention should be

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<sup>176</sup> The priority date refers to the date on which a patent applicant files her/his first patent application for a given invention in any WTO member. If the inventor files an application for the same or an equivalent invention in any other member within 12 months from the filing of the first application, the later application will be regarded as if it had been filed on the same day as the original application. Thus, the later application enjoys a priority status with respect to all applications relating to the same invention filed after the date of the first application. Likewise, a public use or publication of the invention between the date of the first and a subsequent application will not destroy the novelty or inventive step of the subsequent application, even though it was filed after such public use of the invention (see WIPO, “Intellectual Property Reading Material”, Geneva, March 1998, p. 235-237; see also Article 4 A. (1), and C. (1) of the Paris Convention for the Protection of Industrial Property, which is binding for WTO members, Article 2.1, TRIPS Agreement). The later application concerns an equivalent invention (thus benefiting from the priority right) where it is implied in the priority application, according to an average expert skilled in the relevant art. Competing applications on the same or equivalent invention will thus be considered as lacking novelty, as the first application has already disclosed the invention to the public. Countries that are Parties to the Patent Cooperation Treaty (PCT) have to extend the 12-month time limit under the Paris Convention (national filing) to a 30-month (20 months in some countries) period for international filings, during which the application will be granted priority as under a national filing (see Article 4A(2) of the Paris Convention in conjunction with Articles 8(2), 11(3), (4), 22(1) of the PCT). The applicant of an international patent application has 30 (20) months from the priority date to provide the designated national patent offices with a copy of the international application, a translation thereof (as prescribed), and to pay the national fee (if any). This extended priority period may cause generic producers to delay a decision to enter a market in a given country until the expiry of the 30-month period. Inventions claimed by the original applicant in subsequent patent applications within that period would preserve their novelty and could potentially block generic production in that territory. See WHO, “Workbook and Diagnostic Tool on Trade and Health: Medicines, Diagnostics and Devices, Vaccines and Intellectual Property Rights” (Section 3m of the Workbook), by F. Abbott, in *Building a National Strategy on Trade and Health: A Diagnostic Tool for Policy Makers*, forthcoming, 2011.

distinguished from subject matter that preceded it, there is scope for deciding how far ‘prior art’ should disqualify later claims. The criterion of “new-ness” or novelty may be construed [...] such that only a later claim exactly the same as the prior art is considered to lack novelty. Alternatively, the criterion of novelty may be construed [...] so that subject matter implicit or inherent in the prior art is considered to defeat novelty.”<sup>177</sup>

In particular, a strict novelty standard could provide that:

- Both oral and written prior disclosures of the invention to the public anywhere in the world results in a rejection of the novelty of a patent application (worldwide novelty, as opposed to domestic novelty);
- Even if the invention is not publicly available in a single document, but can be derived from a combination of publications, it is considered to be part of prior art and therefore is not new;<sup>178</sup>
- Even the theoretical possibility for the general public of having access to information renders it, by definition, available to the public.<sup>179</sup> However, information which may be accessed only by a limited group of people is not part of the prior art. Thus, a document distributed to a closed meeting under confidentiality rules does not constitute prior art; on the other hand, where such document may be further distributed by the participants to third parties, it could be considered as falling within the prior art;<sup>180</sup>
- Information that has not been published in express terms, but that may be implied in expressly published information may also be regarded as prior art (“implicit teachings”, “functional identity”).<sup>181</sup> In particular, such prior art may be derived from training activities, judgment, intuition, as well as tacit knowledge obtained through field experience.

Many jurisdictions consider as part of the prior art information contained in other patent applications, which were filed before the date of filing of the application under examination, but are only published on or after the date of that filing.<sup>182</sup>

### **2.4.1.2 Inventive step**

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<sup>177</sup> See Abbott, The Definition of Pharmaceutical Substance.

<sup>178</sup> By contrast, the United States requires complete disclosure in a *single* publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications. See UNCTAD-ICTSD Resource Book, p. 359.

<sup>179</sup> This strict approach has been developed under European Patent Office case law (case T 444/88). See UNCTAD-ICTSD Resource Book, p. 359.

<sup>180</sup> See Thomas, p. 116.

<sup>181</sup> See Correa, 2000, p. 41, referring to European Patent Office practice. The greater the extent to which implicit teachings in existing information are admitted, the more often will novelty of new applications be rejected. The view was expressed at the UNCTAD peer review meeting that the practice of rejecting novelty on the basis of implicit teachings would be rather ambiguous, creating legal uncertainty, which in turn would deter patenting and innovation would suffer from lack of protection. On the other hand, even if implicit teachings are considered not to destroy **novelty**, they may be taken into account when examining the **obviousness** of the invention: the average expert skilled in the art may be deemed to derive existing prior art from multiple sources, and express references are not necessarily required to destroy non-obviousness. See below, Section 2.4.1.2.

<sup>182</sup> Under the EPC, this concept is restricted to European patent applications (Article 54.3). The TRIPS Agreement does not obligate members to limit such prior art to patent applications filed within their own jurisdiction. Thus, members may provide that yet unpublished patent applications filed anywhere in the world may destroy novelty. This will increase the likelihood that an application is rejected due to lack of novelty.

The TRIPS Agreement also does not define inventive step. According to the classical definition available in many developed country jurisdictions, an invention shall be considered as involving an inventive step if, taking into account the prior art, it would not have been obvious to a person skilled in the art (sometimes called the “routine engineer”) on the date of filing or priority. While for the novelty test (see above), a quantitative difference between the invention at issue and prior art is sufficient, the inventive step test requires the new invention to qualitatively exceed what the routine engineer with knowledge of the prior art could produce.<sup>183</sup> As will be shown in this Section, the inventive step analysis can be applied more or less strictly. The higher the prior art hurdle that the inventor must exceed to qualify for the protection of a given substance, the more likely it is that this substance will remain in the public domain freely available for generic production. Conceptually, the inventive step test consists of two basic elements:

- Identification of the relevant prior art;
- Assessment of the extent to which the invention embodied in the claims was obvious to a person skilled in the art, who had knowledge of the relevant prior art. This assessment is usually made up of subjective and objective considerations/factors.

### **Identification of relevant prior art**

In the context of the inventive step test, the identification of prior art serves a different purpose than it does under the novelty test, as it is used as a basis for the qualitative assessment of non-obviousness. While under the novelty test, any publicly available information is taken into account as prior art (thus potentially destroying novelty), prior art under the inventive step test is often limited to the publicly available knowledge that an average expert skilled in the art would reasonably consider pertinent in the particular case. Thus, where an average expert has no good reason to use certain publicly available information in the pursuit of a technical solution, such information would usually not be taken into account as a basis for assessing non-obviousness.<sup>184</sup> The less prior art taken into account, the greater is the likelihood that the invention will be assessed as non-obvious.

In jurisdictions such as the EPO, the amount of prior art relevant for the assessment of non-obviousness is further limited by the rule that prior patent applications shall not be taken into account (Article 56, second sentence, of the EPC).<sup>185</sup> This reduces the quantity of available prior art from which a person skilled in the art may infer a new invention. Without pertinent information contained in other patent applications, it is more likely that the new invention will be characterized as non-obvious to a person skilled in the art. The rationale behind this rule is that the non-obviousness of an invention is assessed against the expertise of a routine engineer; the engineer would have no reason to consider information contained in another patent application that was not yet published during the time the inventor was devising his invention as pertinent. Including such information in the relevant prior art would base the inventive step assessment not on the subjective position of the routine engineer, but on that of an omniscient person, which would contradict the basic understanding of the inventive step test.

### **Assessment of non-obviousness**

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<sup>183</sup> See also M. Franzosi, “Novelty and Non-Obviousness. The Relevant Prior Art”, *The Journal of World Intellectual Property*, Vol. 3, September 2000, No. 5, p. 683-695 [hereinafter Franzosi], p. 683.

<sup>184</sup> See Franzosi, p. 693, referring to EPO case law. According to that author, regard has to be given (in the context of determining the decisive prior art) to what a skilled person *would* have done, as opposed to what he *could* have done, thus emphasizing a subjective prior art assessment rather than an objective one.

<sup>185</sup> On the other hand, prior patent applications may be relevant when determining what is prior art under the **novelty** test, see below Section 2.4.1.1.

On the basis of the relevant prior art, as described above, the patent examiner will assess whether the claimed invention would have been obvious to a person of ordinary skill in the art. Where the patent examiner deems that this is the case, there is a lack of inventive step and the invention deserves no patent protection. In order to examine non-obviousness, patent examiners in developed countries typically rely on considerations related to the person of the inventor (“subjective” considerations/factors), and in addition to factors related to the invention itself (“objective” or “secondary” considerations/factors).<sup>186</sup>

### Subjective factors

Considerations relating to the inventor address the following two issues:

- **The level of ordinary skill in the pertinent art:** it is advisable to determine what a hypothetical, ordinarily skilled artisan would have been able to infer from the prior art at the time the patent was filed.<sup>187</sup> WTO members are free to provide for specific factors to be taken into account in this context. For example, the United States Court of Appeals for the Federal Circuit (CAFC) looks at
  - The educational levels of both the inventor and active workers in the field;
  - The type of problems encountered in the art;
  - The prior art solutions to those problems;
  - The sophistication of the technology at issue; and
  - The rapidity with which the invention was made.<sup>188</sup>

In addition, it is important to note that, in the determination of the level of ordinary skills, a country is not bound to refer to the expertise available in its own territory. Developing countries, by taking foreign expertise into account, may considerably elevate the level of ordinary skill in the relevant prior art, thereby increasing the likelihood of a negative finding on the inventive step/non-obviousness requirement.

- **The differences between the prior art and the invention at issue:** the core question is whether, based on the prior art, a person having ordinary skills in the pertinent art would be likely to develop the invention at issue. Members are free to set up certain criteria for determining cases of (non-)obviousness in specific product areas. In the pharmaceutical context, for example, it is often assessed in terms of the *predictability* of the claimed invention, based on prior art teachings. Moreover, under United States Federal Circuit case law, *structural similarities* between a prior art chemical compound and a claimed substance may under certain circumstances establish a *prima facie* case of obviousness of the claimed invention.<sup>189</sup> Also, the presence of a *reasonable expectation of success* to come up with the new product may be considered an indication of obviousness, especially when multiple prior art references must be combined.

Oftentimes, prior art does not exist in a single document but is spread across a multitude of sources (“prior art references”). The question arises as to what extent prior art references, in order to render a claimed invention obvious, must contain precise guidance (technically

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<sup>186</sup> Note that the reference to “secondary” (especially in United States law) does not indicate the reduced importance of these factors but the fact that considerations related to the invention itself often occur only some time after the patent has been granted. Thus, they cannot be taken into account during the granting procedure before the patent office, but only for infringement proceedings before the courts. For this reason, the subjective considerations will be presented first.

<sup>187</sup> See Thomas, pp. 156/157.

<sup>188</sup> Ibid, p. 157.

<sup>189</sup> See Thomas, p. 159. For more details, see Section 2.4.2.2.



termed “teachings”, “suggestions” or “motivations”) for the patent applicant to combine multiple prior art references to arrive at the desired solution.

In its *KSR* decision handed down on 30 April 2007,<sup>190</sup> the United States Supreme Court found that a claimed invention may be obvious despite the absence of clear teachings, suggestions or motivations to combine various prior art references. The Supreme Court emphasized that examiners and courts, “need not seek out precise teachings directed to the challenged claim’s specific matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ”.<sup>191</sup> This approach stresses the subjective perspective of the person having ordinary skill in the art,<sup>192</sup> who, under a rigid requirement of precise prior art teachings would be treated as a technical dumbbell with little initiative of his own.

The Supreme Court thereby elevated the non-obviousness standard to conform to its own earlier case law. In the *Graham* case of 1966, the Supreme Court had rejected the requirement that prior art references, in order to destroy non-obviousness, were required to address the precise problem that the patentee was trying to solve.<sup>193</sup> The Court in *KSR* reiterated its earlier instructions in *Graham* concerning the need for caution in granting a patent based on the combination of elements found in the prior art: warning that combination patents require a cautious and common sense approach, the Court observed that the diversity of modern technology “counsels against confining the obviousness analysis by a formalistic conception of the words’ teaching, suggestion, and motivation, or by overemphasizing the importance of published articles and the explicit content of issued patents. In many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility.”<sup>194</sup>

The Supreme Court added that, with regard to combination patents, “any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed.”<sup>195</sup> Moreover, in the opinion of the Supreme Court, it was an error on the part of the previous instance to focus only on those prior art elements designed to solve the same problem, because “[i]t is common sense that familiar terms may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.”<sup>196</sup>

Indeed, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”<sup>197</sup>

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<sup>190</sup> See Supreme Court of the United States, *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. (2007), Syllabus [hereinafter *KSR Syllabus*].

<sup>191</sup> *KSR Syllabus*, p. 4.

<sup>192</sup> See Amicus Brief on *KSR International Co. v. Teleflex Inc. et al.*, pp. 5/6, arguing that the Federal Circuit’s emphasis of prior art references blurs the distinction between the novelty and inventive step requirements.

<sup>193</sup> See Supreme Court of the United States, *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, especially pp. 17-18.

<sup>194</sup> *KSR Syllabus*, p. 5.

<sup>195</sup> *Ibid.*

<sup>196</sup> *Ibid.*

<sup>197</sup> *Ibid.*, p. 6.

It is unclear, at the time of writing, to what extent United States courts, and in particular the CAFC will follow the Supreme Court's approach to examining non-obviousness in *KSR*. While subsequent case law in the area of gene patents seems to have abandoned the teaching, suggestion, and motivation test,<sup>198</sup> the CAFC has continued applying that test in the context of small molecule patents.<sup>199</sup> Whatever the final outcome in the United States, developing country authorities concerned with the granting of new patents for trivial improvements to existing inventions, such as combining one drug with another, should consider building upon the United States Supreme Court's *KSR* decision in the context of their own laws, regulations and examining procedures. The new approach may reduce the number of trivial or dubious patents, especially in the information technology and pharmaceutical industries.

For example, obviousness may be inferred not only from express single or various prior art references, but equally and in particular from the nature of the problem to be solved, the prior art as a whole (including implicit teachings) and the typical levels of creativity and insight of those skilled in the art at the time the application was filed.<sup>200</sup> Thus, an invention could still be considered obvious in cases where, despite the lack of any explicit and specific prior art reference leading to the desired solution, the typical level of creativity and insight of a person skilled in the art would suggest the capability and motivation of such person to come up with the solution at issue or to combine multiple prior art references to that end.

Properly applied, the non-obviousness standard – as reiterated by the Supreme Court – could in and of itself enable developing country authorities to regulate and contain most of the problems raised by the patenting of minor innovations in any field, and decrease the need to invoke other defensive doctrinal techniques elsewhere discussed in this Guide. It should be remembered, however, that many OECD countries have developed *sui generis* regimes, such as utility model laws, specifically to provide some protection to sub-patentable or incremental innovation, and that other promising proposals for using alternatives to patents for this purpose have been put forward, such as compensatory liability regimes (see above, Section 2.3.2). Policymakers interested in special protection outside of the patent system for small-scale innovations within the reach of local entrepreneurs may wish to consider these alternatives.

### Objective factors

So far, we have discussed widely recognized subjective factors (i.e. related to the inventor) bearing on the evaluation of non-obviousness. In practice, courts and administrators in developed countries often supplement these factors by so-called “additional” or “secondary”, objective factors (i.e. related to the invention) bearing on non-obviousness. Most of these objective factors should be used with care, as they tend to lower the bar applied in the context of the inventive step test.

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<sup>198</sup> *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

<sup>199</sup> For an overall discussion of related case law, see P. Rao and G. Best, “Will *KSR*'s Effect On Small Molecule Patents Be Limited?”, IP Watch online publication of 14 September 2009, available at <http://www.ip-watch.org/weblog/2009/09/14/will-ksrs-effect-on-small-molecule-patents-be-limited/>. See also A. Mc Tague, “Secondary Pharmaceutical Patents Post-*KSR* : Do They Have A Future ? ”, *Pharmaceutical Law & Industry Report*, Vol. 6, No. 3, 18 January 2008 ; J.M. Mueller, “Chemicals, Combinations, and ‘Common Sense’: How the Supreme Court's *KSR* Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases”, *Northern Kentucky Law Review*, Vol. 35, No. 4, 2008.

<sup>200</sup> The importance of this point has been emphasized by the United States Federal Trade Commission (FTC), see “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy”, Executive Summary, pp. 11-12 [hereinafter FTC Report] (available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>).

Under United States and German patent law, for example, the following additional considerations have been used to reinforce a finding of non-obviousness of a claimed invention (all these cases indicate that there is a difference between the prior art on the one hand and the claimed invention on the other):<sup>201</sup>

- Technical progress over prior art: this consideration may be used under German patent law, but is not mandatory. The 2005 Indian Patents Act seems to have gone a step further by expressly requiring a technical advance over prior art;<sup>202</sup>
- Commercial success of the invention, on the condition that the success is specifically due to the claimed features of the invention. Members may provide that this condition has to be proved by the inventor in case the patent is challenged.<sup>203</sup> Again, the Indian Patents Act expressly requires “economic significance” for the invention to be non-obvious, alternatively or additionally to the technical advance requirement (see above);<sup>204</sup>
- Copying of the invention, on the condition that the motivation to copy is based on the assumption that independent development of the invention on the basis of prior art is too difficult;
- Long-felt need/prior failures of others to find a solution to a technical problem: The fact that a given technical problem has remained unresolved for a long time indicates the non-obviousness of the solution eventually found, on the condition that the solution directly addresses the need;
- Scepticism of skilled persons that the claimed invention could be achieved;
- Unexpected results: The TRIPS Agreement does not require an invention to generate unexpected results to be patentable. It is widely recognized that lengthy, trial and error-based research may lead to inventive results deserving a patent. Nevertheless, results that are unexpected for the average expert in the field normally indicate non-obviousness of the claimed invention.

In conclusion, the inventive step standard defines the line between free competition and exclusive protection that can spur innovation. An indirect function of the patent system is to mandate that non-patentable products and processes remain subject to free competition. How and where a country draws the line between free competition and exclusive rights depends on many factors, including its industrial policy, its innovative capabilities and the desire of its industries to maintain the freedom to reverse engineer. A country may change its standards over time, and this has occurred in the United States, for example, where even though heavy investment in basic research has led to pressures for broader protection of research results and their application, the United States Supreme Court has once again adopted a more pro-competitive approach (*KSR*). In principle, developing countries with a weaker technological base will generate more access to reverse engineering and more benefits from free competition by applying a relatively high standard of non-obviousness. However, the trade-offs of such a policy might be that local inventors would find it more difficult to obtain patents<sup>205</sup> and foreign investors may be more reluctant to license their technologies or allow imports of their high-tech products.

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<sup>201</sup> See Ensthaler, p. 117; Thomas, pp. 167 ff.

<sup>202</sup> See Indian Patents Act 2005, § 2 (1) (ia).

<sup>203</sup> The FTC has proposed this arrangement of the burden of proof in the context of the United States patent system, see FTC Report, p. 11.

<sup>204</sup> Indian Patents Act 2005, §2(1).

<sup>205</sup> At home, but not abroad.

### 2.4.1.3 Industrial application

This is the third and last requirement that an invention needs to meet in order to be protected by a patent. The objective of patent law is the promotion of technical and practical solutions, rather than the monopolization of theoretical knowledge, and therefore an invention has to be capable of industrial application. Again, the TRIPS Agreement provides no definition of this term. According to the traditional concept used in European countries, an invention is capable of industrial application if it may be manufactured or used in any commercial activity, including agriculture.<sup>206</sup> In other words, developments not leading to an industrial product or lacking technical effect cannot be patented. This definition seems stricter than the concept of “utility” followed under United States law. Until 2001, an invention under United States patent law only needed to be operable and useful in the most general sense, i.e. capable of providing some benefit to humanity.<sup>207</sup> However, the 2001 United States Patent and Trademark Office (USPTO) Utility Examination Guidelines toughened this standard by requiring credible, specific and substantial utility, particularly with respect to biotechnological inventions. For the pharmaceutical context, this means that purely experimental inventions do not seem to be patentable under either EPO or USPTO standards (for lack of an industrial product under the EPO concept of industrial applicability;<sup>208</sup> for lack of “substantial” utility in a real world context under the USPTO concept of utility).<sup>209</sup> This has important implications regarding to what extent research tools used by the pharmaceutical industry in the development of new medicines may be patented.<sup>210</sup> Only those research tools for which specific uses may be identified would seem to pass the industrial applicability/utility test, as they would result in an industrial product having substantial utility in a real world context. On the other hand, research tools that may be used for a variety of different uses, such as expressed sequence tags (ESTs)<sup>211</sup> and single nucleotide polymorphisms (SNPs)<sup>212</sup> cannot be

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<sup>206</sup> See § 5 (1) of the German Patents Act.

<sup>207</sup> UNCTAD-ICTSD Resource Book, p. 361.

<sup>208</sup> See, for example, EPO Boards of Appeal, Decision of 11 May 2005, case no. T 0870/04 - 3.3.8, p. 20, paragraph 21: “In the board’s judgment, although the present application describes a product (a polypeptide), means and methods for making it, and its prospective use thereof for basic science activities, it identifies no practical way of exploiting it in at least one field of industrial activity. In this respect, it is considered that a vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for fulfillment of the requirement of industrial applicability. The purpose of granting a patent is not to reserve an unexplored field of research for an applicant.”

<sup>209</sup> For United States law, see Thomas, pp. 68-69. This being said, some differences do remain between EPO and USPTO standards, but are not directly relevant in the pharmaceutical context. For instance, business plans, while providing a “real world context” and thus satisfying substantial utility under the USPTO standards, do not constitute an industrial product generating a technical effect under EPO standards. This being said, business methods under United States law could be denied the qualification as patentable subject matter, to the extent they do not meet the CAFC’s “machine-or-transformation test”, see above, Section 2.3.1.1. But see also the United States Supreme Court in *Bilski v. Kappos*, stressing the need of a case-by-case analysis beyond the “machine-or-transformation test”.

<sup>210</sup> The United States National Institutes of Health (NIH) Working Group on Research Tools defines the term “research tools” in its broadest sense, i.e. “to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as ‘end products.’ For our purposes, the term may thus include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools [...], methods, laboratory equipment and machines, databases and computer software.” (Available at: [www.nih.gov/news/researchtools/](http://www.nih.gov/news/researchtools/)).

<sup>211</sup> An EST is a tiny portion of an entire gene that can be used to help identify unknown genes and to map their positions within a genome, in a quick and inexpensive fashion. See National Center for Biotechnology Information, “ESTs, Gene Discovery Made Easier” (available at: [www.ncbi.nlm.nih.gov/About/primer/est.html](http://www.ncbi.nlm.nih.gov/About/primer/est.html)).

considered “industrially applicable” as such. According to United States Federal Circuit jurisprudence, patent applicants may not easily avoid this restriction by merely referring to some trivial use.<sup>213</sup> The patent applicant would have to disclose the particular function for which use of the EST or SNP is intended, and the scope of the patent would be limited to this specific use. This is the approach taken under the French and German patent laws in respect of human gene patents.<sup>214</sup>

## **2.4.2 Patentability criteria in the pharmaceutical context**

As shown above, under the TRIPS Agreement governments are free to interpret the patentability criteria narrowly or widely. In the public health context there are several cases under which the choice of a broad or a narrow approach will have important implications on the availability of pharmaceutical substances for generic production. These cases will be presented in the following sections. In general, they all concern scenarios under which the holder of a pharmaceutical patent seeks to extend the scope of the patent beyond the original claims in order to obtain another period of exclusivity on the patented substance or some of its elements (the “ever-greening” of patents). As a general rule, it may be stated that the TRIPS Agreement leaves members the freedom to either promote or prevent patent “ever-greening”.

### **2.4.2.1 New uses of known products**

#### **Background**

The issue of new uses of known products has already been dealt with under Section 2.3 on patentable subject matter. Granting another patent on a known product for a newly discovered use adds an additional layer of exclusive rights on the same chemical entity. This constitutes a classical case of “ever-greening” and considerably extends the period during which generic producers may not legally manufacture the protected substance. As discussed, new uses may be denied **product** patent protection to the extent that the (known) product in question fails the novelty test, either on the basis of a specific regulation governing novelty in such cases, or on the basis of case-by-case examination. In addition, **process** patent protection may be denied where domestic laws implement a broad exemption from patentability for methods of medical treatment, in accordance with Article 27.3 (a) of the TRIPS Agreement.

However, where members elect not to exclude new use patents *à priori* by regulation (on subject matter or novelty grounds), they will have to examine new uses on a case-by-case basis in light of the patent eligibility criteria of novelty, inventive step and industrial

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<sup>212</sup> SNPs are variations of a DNA sequence. Variations in the DNA sequences of humans can affect how humans develop diseases, respond to pathogens, chemicals, drugs, etc. As a consequence SNPs are of great value to biomedical research and in developing pharmacy products.

See [http://www.ornl.gov/sci/techresources/Human\\_Genome/faq/snps.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml).

<sup>213</sup> See *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005), where the United States Federal Circuit rejected the patentability of ESTs if disclosure of their use is not more specific than broadly referring to the isolation of protein-encoded genes for the purpose of performing further research. This being said, the decision whether a disclosed use shows a satisfactory degree of substantial and specific utility remains a delicate one.

<sup>214</sup> See Article L. 613-2-1 (France) and § 1a (4) of the Patents Act (Germany); both provisions are supposed to implement the EU Biopatent Directive (98/44/EC), in particular Article 5 (3) on the limitation of the scope of patents on gene sequences.

applicability. The application of these criteria to new uses of known products may follow a literal interpretation of the patent eligibility requirements, along the lines of United States patent law in this context,<sup>215</sup> and without resorting to complex legal fictions as the EPC does. Under a literal, straightforward application of the eligibility criteria, members could address the patentability of first, second, and subsequent “new” medical uses of known products as follows.

- **First medical uses of known products** could be considered as not qualifying for *product* patent protection, due to the product’s lack of novelty: the mere discovery of a medical use of an existing product does not alter the fact that the product as such has been available to the public before.<sup>216</sup> As for *process* patent protection, the first medical use would likely meet the novelty criterion. Whether or not the new use involves an inventive step may be made contingent on the predictability of the development of the new medical use, based on the analysis of the known substance by a person skilled in the art. New pharmaceutical uses (first or subsequent) are often predictable for pharmaceutical experts in developed countries. Developing countries are free to determine the criteria for obviousness of an invention based on the average scientific skills prevailing in developed countries, potentially helping to reduce the number of non-obvious inventions. Finally, the new use is industrially applicable to the extent that the pharmaceutical industry is capable of applying the new use to the human body to produce certain effects thereon. Thus, the **inventive step requirement** appears to be the decisive criterion to affirm or reject the patentability of first medical uses under process claims. As stated above, the patentability of a first medical use under a product claim may be excluded through a strict application of the **novelty requirement**.
- Regarding **second and subsequent medical uses**, the drug itself would arguably not be patentable for lack of novelty, as the product as such has been available to the public as a medical product for a different use. The protection of the second or subsequent medical use through a process patent (including new ways of administering known pharmaceutical products) would depend on multiple considerations. As opposed to the first use, it cannot be argued that the medical use as such is novel. However, as process claims may relate to the particular use of a product, the use of a drug previously known, e.g. to cure cancer in the context of an HIV/AIDS treatment could be considered novel. For the inventive step test, the question is whether the purpose of the second use (e.g. employing an anti-cancer drug to combat HIV/AIDS) is non-obvious to a person skilled in the art (i.e. a pharmacologist or pharmacist). This will depend to a great extent on the circumstances of the particular case. As stated in the context of first medical uses, the non-obviousness standard may be construed rather strictly to limit patent grants to genuinely unpredictable developments, and the United States Supreme Court in *KSR* has made clear that such developments are not precluded by the lack of precise

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<sup>215</sup> As explained in the overall discussion of the new use issue, United States patent law denies product patent protection on any new medical uses, allowing only process claims. These have to refer to a method of use. Even if intended for a new purpose, the method of use is only considered as new and involving an inventive step (“non-obviousness” under United States law) where the particular method at issue could not have been anticipated by other (existing) methods. See UNCTAD-ICTSD Resource Book, p. 356. See also Thomas, pp. 38; 46-49; 235-237.

<sup>216</sup> Note the opposite approach taken under Article 54(4) and (5) of the EPC, as well as by the German Federal Court of Justice, based on legal fictions (see Section 2.3.2, above).

prior art leads. For the industrial application test, the same arguments that are made regarding first uses apply. Again, the **inventive step requirement** is the decisive tool that governments may use in order to influence the extent to which process patents are granted on second uses. Regarding product patents, a strict application of the novelty requirement justifies their rejection also for second and subsequent medical uses.

### **Policy options**

Under a literal application of the patent eligibility criteria, developing countries could choose among the following main options.<sup>217</sup>

- **Option 1:** Exclude new use patents *à priori* by regulation:
  - Process claims on subject matter grounds (Article 27.3(a), TRIPS Agreement);
  - Product claims on novelty grounds.
- **Option 2:** Exclude only product patents by regulation, and continue to allow process patents that include new uses on a case-by-case basis, as explained above. As observed in the overall discussion of new uses in the context of patentable subject matter, granting process patents for new uses may only be of interest to countries with a relatively advanced pharmaceutical sector and R&D capacity, and even under those circumstances, process patents should be used with due care, above all through a rigorous application of the inventive step requirement.
- **Option 3:** Exclude new medical uses of known substances from patent protection but continue to protect such uses through exclusive rights outside the patent system, i.e. through utility models. Such alternative protections provide for shorter periods of exclusivity than patents and may be granted for inventions that do not meet the stricter eligibility requirements under patent law (in particular the novelty and the inventive step criteria). From a policy perspective, this approach appears more appropriate than one which lowers the patentability standards to embrace incremental innovations. On the other hand, it is questionable why any exclusive rights should be awarded at all to those inventions that lack inventive character. Option 4 provides a noteworthy alternative that takes this question into account.
- **Option 4:** Exclude new medical uses of known substances from patent protection through a rigorous application of the patentability criteria but also offer legal protection for such uses through a tailor-made *sui generis* regime that, for example, requires equitable compensation in exchange for the right to use the protected innovation (unless wholesale imitation is sought), after a brief period of market exclusivity for the innovator. This option, as explained in the context of patentable subject matter above, would provide incentives to local innovators to find such uses, both with respect to the adaptation of foreign substances to local conditions and the stimulation of investment in new uses of substances rooted in traditional knowledge. Unlike option 3 (utility models), a system of compensatory liability would not provide the right holder with the right to deny access by competitors to the protected subject matter for purposes of product improvement.

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<sup>217</sup> See above, policy options on new uses in the context of patentable subject matter.

Regarding the codification of domestic legislation on the patentability of new uses, governments have two broad options:

1. **Case-by-case approach:** Avoid any reference to the issue in the Patents Act. Instead, regulations for the examination of patent applications should provide guidance with respect to the application of the patentability criteria to pharmaceutical product and process claims, particularly the tests of novelty and inventive step/non-obviousness and the level of expertise of persons skilled in the art. Patentability of new uses would thus not be *à priori* precluded but would depend on the circumstances of the particular case and the concrete application of the patentability criteria.
2. **Express denial of novelty for newly used products and exclusion of new uses from patentable subject matter:** The above option presupposes a certain degree of technical expertise on the part of patent examiners. Such expertise might not be available in some countries. Those countries might need more direct guidance regarding the treatment of new uses. A strict concept of novelty will normally result in the rejection of *product* patents for new uses. This may be stated in express terms in a country's patent law or in regulations, resulting in an *à priori* rejection of the novelty test for product claims of new uses of known products. As regards the protection under a *process* patent, however, the situation is more complex. Whether or not a new use is obvious is case-specific and cannot generally be anticipated in a domestic patent law, but has to be left to a case-by-case examination. *A priori* exclusions of pharmaceutical process patents for new uses are possible, however, on subject matter grounds (Article 27.3(a), TRIPS Agreement).

#### 2.4.2.2 Variations in pharmaceutical composition or behaviour/product derivatives

##### Background

Another way that some pharmaceutical companies have found to “evergreen” existing patents is to claim new patents on minor structural modifications of pre-existing compounds. This issue has already been briefly referred to in the context of the discussion of patentable subject matter. This Guide, however, considers the question of patentability of product derivatives to constitute, above all, a problem of non-obviousness/inventive step.

Minor structural modifications of pre-existing compounds may consist of variations in the formulation of active ingredients as combined with each other or with other elements. Generally speaking, modifications of potential significance may pertain, *inter alia*, to drug substances; formulations; chemical intermediates; metabolites and pro-drugs; crystals and polymorphs; isomers; salts; and combination therapies.<sup>218</sup>

Sometimes small modifications of these kinds may actually result in significant gains in therapeutic effects, in which case the added efficacy must be carefully evaluated under the applicable non-obviousness standard. More often however, these variations produce “me-too” drugs, whose therapeutic benefits vary only in insignificant degrees from other existing formulations, and yet, under the very low eligibility standards in some countries, these small

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<sup>218</sup> See Thomas, pp. 38-44. It is not the purpose of this guide to discuss the chemical properties of medical substances, but rather to show the implications for the scope of pharmaceutical patents.



changes allow patentees to claim new patent protection.<sup>219</sup> If this occurs, generic producers of the original product, who are otherwise entitled to enter the market when the first patent expires, may effectively be blocked or hindered by lawsuits, some of them spurious, that allege infringement, based on patents covering modified versions of the same product. The United States Federal Trade Commission has criticized the patent authorities for insufficient attention to these problems and for lax granting procedures that may confound judges later and produce anti-competitive effects.<sup>220</sup> As previously noted, the United States Supreme Court acknowledged these complaints in 2007 and responded by elevating the non-obviousness standard for combination patents.

It should be reiterated at this point that, contrary to the new use issue, the question of patentability of pharmaceutical product derivatives does not concern different uses of the same substance, but different forms of that substance. While the new use issue relates to several uses of identical chemical entities, the present section discusses products that are of a slightly different chemical structure than the originally patented product (i.e. products that are similar to the original product but nevertheless not identical). Such modified chemical entities may be regarded as new in the patent sense (especially in countries applying a permissive novelty standard).

By applying strict novelty standards, members may sometimes be able to exclude product derivatives without reaching the inventive step issue. The Indian patent law, for example, provides that variations of known substances are considered to be the same substance (i.e. not new), unless they differ considerably in their efficacy, based on different chemical properties.<sup>221</sup> Such a regulation creates a scheme in which a given variation may be rejected for lack of novelty because it was previously claimed or disclosed. The deeper problem, however, typically arises when the modified product is tested under the inventive step requirement, given the bundle of prior art already associated with the original product.

### **The legal aspects**

It is important to note at the outset that, in theory, patents may be granted *separately* on the original active pharmaceutical ingredient and each of its variations as enumerated above, so far as these variations satisfy the eligibility criteria.<sup>222</sup> For example, when a patent is specifically granted on a *composition* of a prior art active ingredient and other elements, such as fillers or binders, it may only encompass *this composition*, but not the active ingredient standing *alone*.<sup>223</sup> This means that, in principle, a patent on a variation of an active ingredient

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<sup>219</sup> See Médecins Sans Frontières, “Q&A on patents in India and the Novartis case”.

<sup>220</sup> See FTC Report. At a 19 April 2007 Geneva seminar held by the France–Switzerland Chamber of Commerce, Mr. Roland Grossenbacher, Director of the Swiss Federal Institute for Intellectual Property *inter alia* stressed the importance of the inventive step requirement to ensure quality patents, warning that too much or too little protection could harm innovation. See IP Watch, “Top IP Official Cites Swiss Patent Litigation System, Global Over-Patenting”, online publication, 23 April 2007 (<http://www.ip-watch.org/weblog/2007/04/23/top-swiss-ip-official-cites-national-patent-litigation-system-global-over-patenting/>).

<sup>221</sup> See Section 3 (d) of the 2005 Amendment to the Indian Patents Act. From a technical point of view, this provision does not clearly distinguish between the different issues of patentable subject matter on the one hand and novelty on the other hand. While the overall heading of the Article refers to the subsequent subparagraphs as “not inventions within the meaning of this Act” (thus denying patentability on **subject matter grounds**), the explanation to subparagraph (d) states that certain derivatives of known products “shall be considered to be the same substance [...]” (thus denying patentability due to a lack of **novelty**).

<sup>222</sup> UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, p. 6.

<sup>223</sup> *Ibid.* The extent to which countries admit the patentability of known substances in new compositions varies, *ibid.* The above-mentioned scenario of a known active ingredient claimed in a new composition has to be distinguished from the case where the active ingredient as such is new. In that case, the patent is not solely

does not necessarily extend to the original active ingredient as such. In the above example, the grant of a 20-year term of protection on the composition of a prior art active ingredient and a binder would not prevent third parties from using the active ingredient alone, or in a different composition, provided that the active ingredient was no longer protected by a separate patent.<sup>224</sup> Theoretically speaking, the patenting of derivatives should therefore by no means extend the life of the existing patent on the original substance, as opposed to the new use issue, where another patent is claimed on the original substance (one example of “ever-greening”).

In practice, however, the patenting of derivatives may have the same “ever-greening” effect as in the case of new uses, i.e. prevent generic competitors from manufacturing the substance protected by the original patent. In the context of derivatives, judges, lawyers and other pharmaceutical lay persons may encounter serious difficulties in trying to distinguish between the particular chemical entities covered by a prior patent and those covered by the patent on a derivative product. In infringement actions pertaining to pharmaceutical patents, the judge will have to decide on the exact scope of the patent claims in each case, which may be an extremely challenging task considering the need to distinguish, for example, between the active ingredient and one of its salts or ethers.

These complexities may encourage patent holders to involve potential generic competitors in “strategic” infringement litigation by alleging the latter’s use of the protected substance and requesting provisional injunctions blocking commercialization of the generic product until a final judgment is rendered. These actions may delay the generic producer’s entry into the market or result in negotiated settlements, or even a payment to the potential competitor for leaving the market, which should attract the attention of anti-trust authorities. In this context, an interesting example for patent ever-greening is provided in the 2006 Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) Report, as briefly outlined in box 3, below.

### **Box 3: How invalid patent claims are used to prevent generic competition**

A pharmaceutical company, after its original patent on the substance *paroxetine* had expired, filed a patent application for *paroxetine hydrochloride hemihydrate*, a modified form of the originally patented substance *paroxetine*. After several years of litigation between the originator company and a generic competitor, the new claim to *paroxetine hydrochloride hemihydrate* was held invalid by the competent appeal court. By alleging that the generic competitor’s product (*paroxetine hydrochloride anhydrate*) fell within the scope of its (invalid) claim to *paroxetine hydrochloride hemihydrate*, the originator company succeeded in delaying considerably the market entry of the generic drug (which took place only five-and-a-half years after the generic producer’s application for marketing approval). During the court proceedings, the originator company pursued four additional infringement suits, alleging the generic product fell within the scope of several different forms and new uses of *paroxetine hydrochloride*. The infringement proceedings resulted in five overlapping 30-month stays,

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granted on the composition, but may cover the active ingredient as such, plus possibly the composition (depending on the drafting of the patent claims).

<sup>224</sup> Ibid. In case the active ingredient is new and patented in addition to the composition, third parties would not be in a position to legally use the active ingredient without authorization from the patent holder, or through a compulsory license. These considerations do not apply to the treatment of new uses of known products (see above): as opposed to the case of derivatives, new uses concern the *identical* substance. A product patent on a new use may therefore directly extend the life of the existing patent, unless the claims for the original and the new patent refer to specific and separate uses (“use-bound claims”, see below, Section 2.5).

which prevented the United States Food and Drug Authority (FDA) from authorizing the marketing of the generic product for over 65 months. During one year of artificially extended market exclusivity (based on an invalid patent), the originator company gained more than \$1 billion in net sales of the respective pharmaceutical product.

Source: Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) Report, box 4.7 (“Evergreening in the United States”, p. 133).

The granting of patents on variations of known substances increases the number of patents of which the scope is unclear and thereby increases the risk of frivolous or harassing patent infringement actions. Governments may seek to reduce the risk of such lawsuits by limiting patents on product variations unless there are clear and demonstrable grounds to show that the modified substance produces truly new and significant therapeutic impacts.

The question arises whether a structurally similar compound merits patent protection if it does show properties that are unexpected or superior to those of the prior art (for example, if the variant shows anti-inflammatory properties while the prior art compound was inactive).<sup>225</sup> In other words, should the new product be considered non-obvious, despite its structural similarity to prior art, due to its particular properties?

### United States and Indian approaches

Under United States patent law, the patent applicant may seek to invoke new or unexpected superior properties to rebut a *prima facie* case of obviousness resulting from structural similarities between pharmaceutical products.<sup>226</sup> Regarding the unexpected character of similar chemical structures, the May 2007 United States Supreme Court decision on this matter (*KSR*) suggests that combining the relevant elements may be a logical, common sense step that the person skilled in the art would have taken in due course, based on his/her technical know-how and despite the lack of any published single prior art reference directly on-point. While it is unclear, at the time of writing, whether this stricter standard will actually be followed by the lower courts in the United States,<sup>227</sup> authorities in developing countries may consider the *KSR* decision an important authority for the tightening of the inventive step requirement under domestic patent law.

In contrast to United States patent law, the new Indian patent law deals with derivatives (and new uses) by adopting a specific clause in Section 3(d) of the 2005 Patents Act, which purports to exclude derivatives from patentability on the following grounds:

“The following are not inventions within the meaning of this Act:

“The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

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<sup>225</sup> Example taken from Thomas, p. 179.

<sup>226</sup> See Thomas, pp. 177-181. According to Federal Circuit case law (*In re Dillon*, 1990), structural similarity between the claimed and prior art compound establishes a *prima facie* case of obviousness if in addition, there is a suggestion or motivation for the inventor to make the new compound with a reasonable expectation of success, and if the method of making the claimed compound was known to, or rendered obvious by, the state of the art (Thomas, p. 181).

<sup>227</sup> See above, Section 2.4.1.2.

“Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”<sup>228</sup>

This provision allows the Indian authorities to challenge any given derivative on a number of alternative grounds. For example, the derivative compound may be faulted for lack of novelty, because it is based on salts that were previously claimed and disclosed. Alternatively, it may be rejected on subject matter grounds (as constituting a mere discovery, as opposed to an invention) if the derivative fails to add the requisite degree of efficacy. Section 3(d) of the Indian Patents Act has been challenged for alleged inconsistencies with the TRIPS Agreement. Box 4 reviews and dismisses these challenges.<sup>229</sup>

#### **Box 4: Alleged TRIPS-inconsistency of Section 3 (d) of the Indian Patents Act**

##### **Additional grounds for the exclusion of patentability**

The Indian Patents Act’s use of a specific clause to address multiple grounds for excluding derivatives has been challenged for failing to comply with the TRIPS Agreement because it allegedly adds criteria for exclusions that are not recognized in Articles 27 and 30 of the TRIPS Agreement.<sup>230</sup> However, this argument appears spurious on closer examination. On its face, the statute simply restates the principles of invention, novelty and inventive step by expressly excluding that which is not an invention, novel or unobvious, for lack of efficacy. These negative exclusions are a necessary and inherent component of the positive eligibility requirements themselves and they constitute no new or enlarged set of exclusions to those already allowed. The fact that the language used in Section 3(d) of the Patents Act speaks of “exclusions”, which indirectly evokes Article 30 of the TRIPS Agreement, is inconsequential for the reason that **all** compounds that are not inventions, or not novel, are **automatically** “excluded” from patentability by definition. The efficacy criterion is used as an element of the invention or novelty test. Under TRIPS, members are free to define these terms according to their policy preferences. As to pharmaceutical substances, it is inherent in their nature as medicinal cures that their novelty and/or inventive character are measured in terms of their enhanced efficacy. The efficacy criterion thus helps define what the terms invention, novelty and inventive step mean in the pharmaceutical context, and does not constitute an additional patentability requirement.

##### **Non-discrimination requirement**

Another critique regarding Section 3(d) of the Indian Patents Act has focused on the requirement under Article 27, TRIPS Agreement, to make patents available for any invention, whether product or process, *in all fields of technology*. As outlined above, India has broadly excluded from patentability many sub-categories of modified pharmaceutical products on the grounds that they lack enhanced efficacy. It has been argued that the enhanced efficacy requirement, as applied to pharmaceutical products under Indian law,

<sup>228</sup> See Section 3 (d) of the Patents Act, 1970 (2005).

<sup>229</sup> It has also been noted, in the literature on the topic, that the drafting of Section 3(d) could be improved. For details, see S. Basheer/T. P. Reddy, “The ‘Efficacy’ of Indian Patent Law: Ironing out the Creases in Section 3(d)” [hereinafter Basheer/Reddy] (available at [www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.pdf](http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.pdf)).

<sup>230</sup> See “Report of the Technical Expert Group on Patent Law Issues” (“Mashelkar Report”), December 2006 (this report was later withdrawn for separate reasons). The same view is still upheld by other stakeholders and was part of Novartis’ challenge of Section 3(d) before the Madras High Court, see discussion above. For a different view on the statute’s TRIPS-compliance, see Abbott, *The Definition of Pharmaceutical Substance*.

makes it more difficult to obtain a patent in the pharmaceutical area than in other fields of technology.<sup>231</sup> Such view, however, does not take appropriate account of the fact that due to important differences between areas of technology, differential treatment of these areas may be justifiable on public interest *bona fide* grounds, such as the promotion of generic pharmaceutical competition. In addition, it is even questionable whether the Indian law actually treats pharmaceuticals differently from other fields of technology. Section 3 (d) of the Indian Patents Act emphasizes the need for enhanced efficacy. As explained above, this does not constitute an additional requirement of patentability, but an element of the invention, novelty or inventive step test in the particular field of pharmaceuticals. Other fields of technology serve other purposes and will therefore rely on different criteria to determine the meaning of novelty and inventive step. Using such criteria arguably does not represent discrimination between different fields of technology, but is instead a necessary tool to ensure that patent grants take account of the particularities of a given technological area and are limited to those products that bring a genuine benefit to society.

Despite some methodological differences in approach, both the Indian and the United States legislation (and case law) treat structural similarities occurring in product derivatives as undeserving of product patent protection, unless the structural modifications result in new, improved or unexpected properties (United States law) or in significantly enhanced efficacy (Indian law).<sup>232</sup>

### Policy options under patent law

The above approaches within Indian and United States law provide useful examples for developing countries to determine how to address the patentability of derivatives. Whether to emphasize the definition of “invention”, or the novelty requirement, as under Indian law, or the inventive step test, as under United States law, is up to a member’s discretion. Any of these requirements may be used to filter out insignificant and trivial derivatives of known

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<sup>231</sup> See, e.g., R. Bate in IP Health Digest, Vol 1, No. 2318, message no. 3.

<sup>232</sup> As discussed above, it is for the time being not clear how United States case law will evolve in the area of incremental pharmaceutical inventions. In the area of small molecules, the CAFC appears to insist on the requirement of precise prior art leads for a finding of *prima facie* obviousness (teaching, suggestion or motivation (TSM) to combine test), in addition to structural similarities. The KSR decision, on the other hand, waives this requirement and could be interpreted as softening the TSM test. Section 3(d) of the Indian Patents Act, by contrast, does not imply any requirement of precise prior art leads; structural similarity alone will suffice to trigger a *prima facie* denial of the eligibility of a given substance as an “invention” (i.e. patentable subject matter). However, the issue of prior art leads and their required degree of precision is likely to come up under the inventive step examination, after an applicant has cleared the Section 3(d) hurdle. A potentially more important difference between the United States and the Indian approaches could arise on the issue of how to rebut the *prima facie* cases of obviousness (United States law) or lack of invention (Indian law). Under United States case law, *prima facie* obviousness may be rebutted by the patent applicant/holder through a showing of “unexpected or surprising results” (Thomas, p. 180, citing the CAFC decision *In re Dillon* of 1990). This may encompass structurally similar substances that, even though behaving in an unexpected way, are not more efficacious than the previously known substance. Indian case law has recently relied on a narrow definition of the efficacy criterion, defining the latter as “therapeutic” efficacy (see the Madras High Court decision of 8 June 2007 in *Novartis AG v. Union of India et al*; see the decision of the IP Appellate Board on the same case, at pages 154/155; see also the decision of the Indian Patent Office of 19 June 2008 in *Boehringer Ingelheim Pharmaceuticals v. Indian Network for People Living with HIV/AIDS & Positive Women’s Network*. The same reference to “therapeutic use” may be found in the 2008 draft Manual of Patent Practice and Procedure (Chapter IV, para. 4.5.6), which, however, is not intended to have any legally binding force on patent examiners (available at [http://ipindia.nic.in/ipr/patent/DraftPatent\\_Manual\\_2008.pdf](http://ipindia.nic.in/ipr/patent/DraftPatent_Manual_2008.pdf)), pg. 3. Under this narrow definition, incremental innovations such as new drug delivery forms and increased heat stability properties would not qualify as patentable inventions (see Basheer/Reddy, p. 260).

products on a case-by-case approach. For example, domestic regulations could provide that structural similarities create a presumption of lack of novelty or inventive step (for the latter taking into account the typical level of creativity and insight of the person with ordinary skills in the art). The burden of proof would then lie on the patent applicant to demonstrate the significantly superior properties or efficacy of the variant, or show that the prior art substance taught away from the created variant in some important respect (bearing in mind the premise in *KSR* that in order to arrive at a finding of obviousness, there is no need for a specific and precise prior art lead).

However, it should be acknowledged that developing country patent examiners may have difficulty assessing the requirement of superior efficacy. The authorities may wish to invoke high level expert opinion, or even establish a board of distinguished external advisers. Reliance on Patent Cooperation Treaty (PCT) examiners has been questioned due to the considerable increase in their work load<sup>233</sup> and should therefore not be considered a substitute for due diligence by national authorities. Moreover, care must be taken to maintain strict standards consistently over time, lest inconsistent decisions lead to premature lowering of standards.

In sum, pharmaceutical derivatives may be approached either under the novelty requirement or under the inventive step test. Developing countries with existing expertise in patent examination could use the above analysis as policy guidance when examining an application on a case-by-case basis. Countries using a pure registration system might need more clearly-defined legislation to approach the patentability of pharmaceutical derivatives.

As regards the codification of domestic legislation on the patentability of derivatives, governments have the following broad options:

1. **Avoid any reference to the issue in the Patents Act.** In this case, national patent examination guidelines should address pharmaceutical product variations in detail.<sup>234</sup>
2. **Provide broad standards on the issue in the Patents Act,** leaving the details up to the patent examination guidelines.
3. **Codify detailed rules directly in the Patents Act.** The inconvenience with this approach is that technical details sometimes need to be modified to reflect changes in the technological environment or government policy. In particular, developing countries that lack experience in the patenting of pharmaceutical products might wish to keep some flexibility in order to rapidly readjust their patent policy if early experience shows that the existing scheme is not working properly. For that purpose, it might prove more practical to regulate the details on pharmaceutical variants in administrative guidelines that the government is able to change without going through a Parliamentary approval procedure, a process that could possibly generate external lobbying pressures.

### **Policy options outside of the patent system**

Members that choose to follow the above recommendations on policy options under patent law may nevertheless wish to promote the development of useful product derivatives through alternative forms of protection. Members are free to provide protection under a system of

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<sup>233</sup> Personal communication from Mr. Malcolm Spence, Technical Advisor – Intellectual Property/SPS, Caribbean Regional Negotiating Machinery, Bridgetown, Barbados.

<sup>234</sup> For an overview of the most important patent examiners' guidelines in the public health context as used by the major developed country patent offices, see UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*. See same for a discussion on how developing countries could design their own patent examination guidelines.

utility models or compensatory liability. Structural similarity between the original, patented product and the derivative does not necessarily prevent the latter from being eligible for utility model protection, if domestic utility model law considers the derivative as new and industrially applicable and waives the inventive step requirement (thus ignoring structural similarity). However, the implication would be that any commercially-oriented follow-on improvements could be blocked by the holder of the utility model. This concern could be addressed through a regime of non-exclusive compensatory liability, which appears to be the more appropriate option and has been described in some detail under Section 2.3.2.1, above.

### **2.4.2.3 Selection patents**

#### **Background**

The life of a patent covering a pharmaceutical substance may also be extended by means of claiming “selection patents”. The latter have been defined as follows:

“A “selection patent” is a patent under which a single element or a small segment within a large known group is “selected” and independently claimed based on a particular feature not mentioned in the large [and previously patented] group.”<sup>235</sup>

As opposed to the new use issue, selected segments (or “species”) are often claimed for the same medical purpose as the prior art large group (or “genus”), but for improved properties. Unlike in the case of product derivatives, the selected segment does not differ from the prior art, but is part of it.

In the area of pharmaceuticals an example for claiming selection patents is the frequent practice of seeking a patent on an enantiomer<sup>236</sup> in cases where the racemate<sup>237</sup> is already part of the prior art. The question arises as to whether previous disclosure of the genus (i.e. the prior art racemate) anticipates later claims to a particular enantiomer (novelty issue) or renders them obvious (inventive step issue). In some cases, an enantiomer may have useful and unpredictable properties which differ from those of the (larger) racemate, and which, prior to the isolation from the racemate, were masked by the other enantiomer.<sup>238</sup>

WTO members are free under the TRIPS Agreement to decide to what extent selection inventions should be patentable, as long as the patentability criteria of novelty, inventive step and industrial application are respected. Applied strictly, the novelty requirement could be used to exclude the patentability of selection inventions, based on the understanding that the newly claimed selection was part of the earlier disclosed genus (i.e. prior art).<sup>239</sup> For example, an enantiomer not expressly mentioned in the earlier disclosure of a racemate could be regarded as nevertheless being part of the prior art. However, many countries seem to consider selection patents as an issue of inventive step, rather than novelty. For example, the EPO patentability guidelines state that “a generic disclosure does not usually take away the

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<sup>235</sup> UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, p. 14.

<sup>236</sup> “Enantiomers (or optical isomers) behave in relation to one another as an image does to its mirror image. In organic chemistry, enantiomers spontaneously occur, for example, in compounds that comprise a carbon atom with four different substituents.” (UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, p. 16; footnotes omitted).

<sup>237</sup> A racemate comprises “an equal mixture of *dextro* and *levo* enantiomers”, see Thomas, p. 91.

<sup>238</sup> UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, footnote 81.

<sup>239</sup> See South Centre Guide, p. 73.

novelty of any specific example falling within the terms of that disclosure”.<sup>240</sup> The EPO guidelines treat those selected compounds that are not specifically disclosed in a prior art document as new in the patent sense and therefore subject them to the inventive step examination.<sup>241</sup> In the United States, the Court of Customs and Patent Appeals (CCPA) held that a disclosure of a racemate does not anticipate a later claim to a separated enantiomer.<sup>242</sup>

For the inventive step requirement the treatment of selection claims varies among WTO members. The essential and common denominator seems to be the question of whether the claimed improved properties of the new element selected from the prior art group could have been expected by an average person skilled in the art.<sup>243</sup> Some countries have developed rather strict case law in this regard. For instance, in Germany, the BGH has held that a prior art disclosure of a large generic group of compounds is, to the skilled chemist, fully equivalent to the disclosure of each specific element within this group.<sup>244</sup> The opposite approach has been followed in the United States, where the Court of Appeals for the Federal Circuit (CAFC) has decided that broad prior art references do not disclose the claimed species in a selection invention, especially where the disclosed genus leads away from the claimed compound.<sup>245</sup>

Another criterion for assessing inventive step may be whether the claimed selection has a special character or quality that it does not share with the other prior art components of the previously known larger group. The higher the number of non-selected components that share the claimed properties, the higher the likelihood that the claimed selection will be considered obvious.<sup>246</sup>

In the specifically relevant area of enantiomers, it should be mentioned that the testing of improved pharmaceutical efficacy of an isolated enantiomer as compared to the racemic mixture of both enantiomers is part of the routine of chemists and pharmacists.<sup>247</sup> For a pair of enantiomers, it is typical that one has a higher activity than the other, which means that for at least one of the isolated enantiomers, a higher activity may be expected than for the racemate.<sup>248</sup> For this reason, the Indian draft guidelines for patent examination considers enantiomers as *prima facie* obvious from the prior art racemate.<sup>249</sup>

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<sup>240</sup> Ibid, p. 75, citing EPO Examination Guidelines chapter IV 7.4.

<sup>241</sup> See UNCTAD-ICTSD-WHO, Pharmaceutical Patents, p. 15, quoting EPO Examination Guidelines Part C, Chapter IV 3.1.

<sup>242</sup> Thomas, p. 91. The CCPA's successor, the CAFC, has not yet pronounced itself on the novelty of enantiomers as compared to prior art racemates (ibid.). In any case, Thomas points out that prior art disclosure of a racemate may nevertheless result in a finding of obviousness of enantiomers under United States patent law (ibid.).

<sup>243</sup> See for example, EPO Examination Guidelines Part C, Chapter IV 3.1, as quoted in UNCTAD-ICTSD-WHO, Pharmaceutical Patents, p. 15 (Box 8).

<sup>244</sup> See UNCTAD-ICTSD-WHO, Pharmaceutical Patents, p. 14 (referring to a publication by Grubb). Thus, the BGH appears to consider that the selection of the claimed specific compound is obvious to a skilled chemist, as taught by the prior art larger group of compounds. At the same time, the BGH could also be understood as denying the novelty of the claimed selection, which is already part of the prior art generic group of compounds.

<sup>245</sup> See South Centre Guide, p. 79, with references to the *Jones* and *Baird* cases.

<sup>246</sup> See Paragraph 24 of the United Kingdom Patent Office Examination Guidelines for Patent Applications relating to Biotechnological Inventions, Section 3 of the Manual of Patent Practice, as quoted in UNCTAD-ICTSD-WHO, Pharmaceutical Patents, p. 15 (Box 9).

<sup>247</sup> UNCTAD-ICTSD-WHO, Pharmaceutical Patents, p. 17.

<sup>248</sup> Ibid.

<sup>249</sup> Draft Manual of Patent Practice and Procedure, Patent Office of India, 2005, Annexure 1, paragraph 5.1.4: “ [...] Once a racemic compound is known, its enantiomers are obvious because a person skilled in the art knows



## Policy options

The patenting of selection inventions may extend the life of a patent on a substance that is covered by both an earlier patent on a group of compounds (e.g. as admitted through Markush-type of claims, see below, Section 2.5) and a subsequent patent on a specific element of that group. For instance, in the United States, Federal Circuit case law has stated that the grant of a patent on a species does not limit the scope of an earlier patent that claims the genus.<sup>250</sup> In the event that both patents belong to the same holder, the later patent effectively extends the exclusive rights in the species. In case the patents belong to different parties, “each patent owner can exclude the other from practicing the species. The result is that without some sort of agreement between them, neither would be legally free to manufacture and sell the species.”<sup>251</sup> Depending on the scope of the domestic research exception, such cumulative patents could also pose serious obstacles to the development of follow-on innovation on the protected species, obliging interested researchers and competitors to navigate through a dense web of patents (“patent thicket”) by paying royalties or challenging the patents through triggering infringement litigation.

WTO members that wish to avoid such anti-competitive effects are free to limit the patenting of selection inventions, through a tight application of the patentability criteria. The following options may be considered:

- **Option 1: Apply a strict standard of novelty.** The disclosure of the prior art broad group of compounds may be considered as anticipating all of the specific elements that are included in the group, thus destroying their novelty in later, separate patent applications. This may be based on the concept of implicit teaching (see above, Section 2.4.1.1). In addition, it is common sense that the disclosure of a group of compounds comprises all of the group’s elements, even if not specifically mentioned.
- **Option 2: Apply a strict standard of inventive step.** Countries may confirm the novelty of those specific elements that were not expressly mentioned in the prior art group of compounds. Instead of the novelty standard, it would be the inventive step requirement that would act as the principal floodgate against selection patents. The essential issue to examine would be the question of whether the improved properties of the species (as compared to the prior art genus) are beyond what a skilled chemist may expect. In this context, countries may follow the German approach to selection inventions in general (considering them obvious, in light of the disclosed prior art genus) or the Indian approach to enantiomers in particular (regarding them as *prima facie* obvious from the racemate, in light of the typical behavior of enantiomers, as explained above). It should also be noted that denying a patent on the species (i.e. a product patent) on grounds of novelty or inventive step does not exclude the granting of a patent on the method used for isolating the species from the genus (i.e. a **process patent**), provided such method meets the patentability requirements.

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that a compound having a chiral center exists in two optically active forms. Hence product patent may not be granted for the enantiomers. [...]”

<sup>250</sup> Thomas, p. 91, citing CAFC case law (footnote 39).

<sup>251</sup> *Ibid.*, p. 92.

- **Option 3:** Countries that wish to promote follow-on, incremental innovation may choose to protect selection inventions (i.e. the product) through **utility model law**, provided that domestic law does not rule out the possibility of applying for such protection of the specie despite the existence of a parallel patent on the genus, and allows for more permissive novelty and inventive step standards (or even waives the latter). This would provide some incentive for the selection of useful species from a known genus without the need to expand patent protection to known or non-inventive substances. On the other hand, the holder of a utility model could still block access by competitors to the specie, which could have a negative impact on product improvement and competition.
- **Option 4:** As an alternative to option 3, countries wishing to promote follow-on, incremental innovation may choose to protect selection inventions (i.e. the product) through **non-exclusive regimes of compensatory liability** (see above, Section 2.3.2.1). Thus, the party that selected the specie from the genus would be entitled to compensation from any party using the specie for follow-on improvements but would not be in a position to block access to the specie for such purposes.

## **2.5 Patent claims construction**

### **2.5.1 Background**

An invention that covers patentable subject matter and meets the three patentability requirements, discussed above, must in principle be granted patent protection. However, there is a need to delineate the boundaries of the invention so that third parties such as generic producers can be aware of the technological territory that cannot be invaded without risking a suit for patent infringement.<sup>252</sup> To do this is the purpose of the patent claims that each patent application has to contain.<sup>253</sup> There are several ways of construing a claim to determine the literal scope of the inventor's exclusive rights (claims construction). Whether the scope extends beyond the literal meaning of a claim is an issue of claims interpretation, which will be discussed in the next section.

The TRIPS Agreement does not provide any guidance on the issue of claims construction to determine the literal scope of a patent. It only refers to the two basic categories of patent claims, i.e. product and process claims (Articles 27.1; 28.1, TRIPS Agreement). However, a product may be described in many different ways, for instance through its chemical structure, or rather by referring to its functions, or by describing the process through which it has been obtained, or by a combination of these elements. A process may also be defined by various

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<sup>252</sup> UNCTAD-ICTSD Resource Book, p. 449.

<sup>253</sup> Other mandatory elements of a patent application are: 1. the request; 2. the description or "specification" (to disclose the invention in a manner sufficiently clear to be carried out by a person skilled in the art); 3. one or more drawings, where necessary to illustrate the description; 4. an abstract (to serve as a technical information). Under some developed countries' patent legislation, description and drawings must be used for the claims interpretation; see, e.g., § 14, second sentence of the German Patents Act.

means, e.g. by a description of various steps that make up the entire process, or by referring to its functions, or again through a combination of these elements.

The way in which a product or process claim is construed may have significant impact on its literal scope and thus the possibility of generic competitors to access pharmaceutical substances. In the absence of any TRIPS rules on this issue, OECD country practice in claims construction may provide important insights to developing country policymakers and generic producers who consult a published patent document in order to ensure that their own activities do not involve patent-protected substances. Finally, a basic understanding of claims construction is also important for those developing country-based domestic pharmaceutical producers who have acquired an advanced level of know-how and seek patent protection for their own inventions, either in their own country or abroad.

A patent claim usually consists of three parts, i.e. a preamble, a transition phrase, and a body.<sup>254</sup> Regarding claims construction, it is the claims body that deserves most attention.

### ***2.5.1.1 The claims preamble***

The preamble describes the general character of the invention. It may be framed in general terms, referring to, e.g., “a pharmaceutical composition”. It may also be more specific, referring to, e.g., “an antibacterial pharmaceutical composition” or “a naproxen formulation for once-daily oral administration”.<sup>255</sup> As a general rule, the preamble is not considered to limit the scope of a claim. However, an exception is made to the extent that the preamble is necessary to define the claimed invention. For example, a preamble referring to a “sustained release tablet” has been considered by the United States Federal Circuit as providing a meaningful limitation to the respective claim, as “sustained release [of the pharmaceutical substance into the human body] is an essential feature of the invention”, defining the way in which another pharmaceutical substance mentioned later in the claim (bupropion hydrochloride) is absorbed by the human body.<sup>256</sup> In this specific case, the applicant replaced the original reference to “sustained release” by a more specific reference to a particular agent (hydroxypropyl methylcellulose/HPMC) used to generate sustained release of bupropion hydrochloride. In a subsequent infringement suit, the Federal Circuit found that the claim had been narrowed in scope to the use of HPMC as release agent. Generic competitors were free to use bupropion hydrochloride in combination with release agents other than HPMC.

### ***2.5.1.2 The transition phrase***

The transition phrase combines the preamble and the claims body. Patent applicants may usually choose from three different phrases, using the terms:

- “Comprising”; or
- “Consisting of”; or
- “Consisting essentially of”.<sup>257</sup>

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<sup>254</sup> See Thomas, p. 219.

<sup>255</sup> Examples from Thomas, p. 219.

<sup>256</sup> Ibid, referring to Judge Rader.

<sup>257</sup> Ibid, p. 221.

For example, a claim may read:

“A pharmaceutical composition, **comprising** ...”

The choice of the transition phrase may have a significant impact on the literal scope of the patent. A claim “comprising” elements A and B is open in its literal meaning to an additional element C, as long as C does not modify the overall character of the invention. Third parties producing a generic substitute comprising elements A, B, and C are therefore likely to be held liable for infringement of the literal scope of the patent. This can only be avoided where element C modifies the overall character of the invention, which basically requires the development of a new product or process (i.e. within the “novelty” meaning of patent law).

By contrast, a claim reading:

“A pharmaceutical composition, **consisting of** elements A and B”

is limited in its literal scope to the expressly named elements. Third parties producing generic substitutes using elements A, B, and C are therefore outside the literal scope of the patent. If this principle were applied strictly, third parties using the patented substance and adding a trivial element would be allowed to avoid claims of literal infringement. For example, a generic producer who copies previously claimed chemical substances A and B and markets them in a kit adding a spatula (element C) not contained in the original product would not be considered to be inside the literal scope of the patent claim.<sup>258</sup>

In order to improve the patentee’s ability to sue third parties for literal patent infringement, the United States Federal Circuit has established that, where the added element (i.e. the spatula in the above example) has a different character from the elements expressly mentioned in the claim (i.e. pharmaceutical substances A and B), does not interact with them and does not contribute to the overall goal of the invention, the added element will not save the third party from infringing upon the literal scope of the patent.<sup>259</sup> A similar outcome would result if the product comprising the trivial element (i.e. the spatula, in the above example) were considered *equivalent* to the product containing the expressly mentioned elements (i.e. A and B). Such interpretation goes beyond the literal scope of the claim and is considered further in the next section on patent claims interpretation.

Patent applicants will normally be hesitant to employ a “consisting of” transition phrase, due to the narrow character of the claim, and the relative ease with which others may avoid legal claims of infringement. For this reason, many claims employ a transition phrase referring to “consisting essentially of”, which makes clear that by adding trivial elements to expressly claimed elements, third parties would still infringe the literal scope of the patent. The “consisting essentially of” version is thus comparable in effects to the “comprising” version of a transition phrase.

### **2.5.1.3 The body**

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<sup>258</sup> Example from Thomas, p. 223.

<sup>259</sup> Federal Circuit 2004, *Norian Corp. v. Stryker Corp.*, cited by Thomas, p. 222.

The claims body is the main text of the patent claim, containing the core description of the invention. Variations in the construction of the body may have significant effects on the literal scope of a patent claim.

Developed countries have traditionally applied a number of different ways of how to describe the invention in the claims body. In brief, most claim formats relate to:

- The **function** of the invention (i.e. what it does); or
- The **structure** of the invention (i.e. what it is); or
- The **process** of making the invention (i.e. how it is made).

The claim formats of most relevance to pharmaceutical inventions are the following:

- Structural claims: A structural claim describes the chemical composition of a product. Protection is provided to the described chemical structure, encompassing all methods of producing that structure. Unless there is a requirement for the patent applicant to specify, along with the structure, the particular purpose the invention should serve, the scope of protection could arguably cover uses of the described structure for any purpose. This is the approach followed in a number of developed countries and the EPO in particular has extended this broad scope to cover even those uses unknown to the inventor at the time of filing the application.<sup>260</sup>
- Markush claims: A Markush claim is a sub-form of a structural claim. Markush claims refer to a family of compounds by defining the structure that is commonly shared by all members of the family.<sup>261</sup> These claims allow patent applicants to claim “hundreds of closely related compounds”,<sup>262</sup> without the need to actually define the structure of each compound, nor to test all of their properties.<sup>263</sup> The fact that a Markush claim refers to a chemical structure common to a great number of chemical variants may not be relied upon to demonstrate the obviousness of the claimed variants.
- Jepson claims: A Jepson claim defines an invention (product or process) through the reference to obvious (and thus non-patentable) elements. The preamble admits the existence of prior art, on which the actual invention in the claims body is based in the form of an improvement of the prior art. For patent examiners this represents an easy way of identifying those elements of the claim that are new and inventive. For this reason, the EPO strongly encourages the use of this claim format.<sup>264</sup>

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<sup>260</sup> See above, Box 1, and case T128/82, OJ EPO 1984, p. 164, as cited by South Centre Guide, p. 140; see also R. J. Young, “The construction of product-by-process claims”, in *The construction of product-by-process claims*, 11th European Patent Judges’ Symposium, Copenhagen, *Official Journal of the EPO* 2003, Special Edition, No. 2 [hereinafter Young]

(available at [http://www.european-patent-office.org/epo/pubs/oj003/07\\_03/se2\\_07\\_03.pdf](http://www.european-patent-office.org/epo/pubs/oj003/07_03/se2_07_03.pdf)), pp. 20-75, p. 20; Scuffi, p. 60; both with references to EPO decision (Enlarged Board of Appeal) G 2/88, OJ EPO 1990, 93 (No. 2 of the Reasons, second sentence of third paragraph). Concerning new uses of known products, the new EPC makes available for first medical uses product claims that cover all possible medical uses, while still leaving the possibility to claim another product patent on subsequently discovered uses, see above, Box 2. Under the TRIPS Agreement, Members are not obligated to adopt such extensive protection of a product with respect to its uses.

<sup>261</sup> For details, see Thomas, p. 227; and UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, p. 12.

<sup>262</sup> Thomas, p. 227. According to UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, p. 12, the number of claimed compounds may be sometimes millions.

<sup>263</sup> UNCTAD-ICTSD-WHO, *Pharmaceutical Patents*, p. 12.

<sup>264</sup> Thomas, p. 231.

- Functional claims (also known as “means-plus-function” claims): Functional claims do not relate to the structure of the invention, but to its functions. They are generally admitted in the United States.<sup>265</sup> The EPO, by contrast, does not accept such claims unless a more precise delineation of the invention is impossible.<sup>266</sup> Under United States law, functional claims may not refer to a function alone, but must describe the function in combination with the corresponding structure, material, or acts described in the patent specification (35 U.S.C. § 112, paragraph 6). The reason for this requirement was the concern expressed by the United States Supreme Court that the sole reference in the claims to function would result in overly broad claims, as there are a multitude of different devices that may be used to carry out the claimed function, including those unknown at the time of patent application. All of these potential ways to carry out the claimed function would be covered by the patent, which would have a chilling effect on competitors’ efforts to invent such new devices.<sup>267</sup>
- Product-by-process claims: Product-by-process claims define a product by the process used to obtain it.<sup>268</sup> The scope of these claims is controversial. On the one hand, it is argued that use of such a claim format results in a product claim, encompassing all ways of making the product.<sup>269</sup> The opposite view considers that such claims are restricted in their scope to the particular manufacturing method as recited in the claim and the end product as a result of this particular method, even where the end-product is known (but provided that the method of production is new, inventive and industrially applicable).<sup>270</sup> Two different panels of the United States Federal Circuit have, in two decisions, expressed both views.<sup>271</sup> The EPO considers the scope to cover the end product, provided the product itself meets the patentability criteria.<sup>272</sup> This distinguishes product-by-process claims as admitted by the EPO from the process claims TRIPS standard under Article 28.1 (b). Under the latter, products as directly obtained through a patented process are also protected, irrespective of their novelty.<sup>273</sup> The EPO admits product-by-process claims only if it is impossible to define the product by reference to its composition, structure or other testable parameter.<sup>274</sup>
- Skuballa claims: Skuballa claims are process claims that refer to numerous potential uses of medical compounds. Rather than claiming the specific dosage for each medical indication individually, Skuballa claims are limited to reciting each of the potential uses, based on the assumption that establishing specific dosages for each use could easily be done by a person skilled in the art.<sup>275</sup>

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<sup>265</sup> Thomas, p. 231, referring to 35 U.S.C. § 112, para. 6.

<sup>266</sup> South Centre, 2000, p. 33.

<sup>267</sup> Thomas, p. 232, referring to the *Halliburton Oil Well Cementing Co. v. Walker* Decision, quoting the Supreme Court: “Unless frightened from the course of experimentation by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose.”

<sup>268</sup> Scuffi, p. 68.

<sup>269</sup> This is the situation under German patent law, see Young, p. 26.

<sup>270</sup> Ibid., referring to the situation under United Kingdom patent law.

<sup>271</sup> Thomas, p. 229.

<sup>272</sup> See Young, p. 32, who observes that the special features of a process used for defining the product may form the basis for the recognition of novelty and inventive step of the product itself. See also Scuffi, p. 70.

<sup>273</sup> See Young, on p. 28, paragraph 4.3, referring to process claims as linking “patent protection for a (**possibly known**) product to a patentable process, without requiring any particular additional category of claim (or indeed, any claim at all to the product itself) to obtain the protection conferred.” (emphasis added).

<sup>274</sup> EPO decision T 150/82, OJ EPO 1984, 309.

<sup>275</sup> Thomas, p. 235, referring to the United States Board of Patent Appeals and Interferences.

## 2.5.2 Policy options

The TRIPS Agreement leaves members entirely free regarding their domestic rules on patent claims formulation. Rules regarding formulation may be included directly into the Patents Act or into subsequent administrative implementation guidelines. The advantage of the latter is that it allows the government to quickly adapt its policy on claims formulation to changing needs and experiences. It is not the objective of this Guide to provide for detailed rules on claims construction. The objective of this section is to provide developing countries with some guidance in respect of possible approaches to claims construction, taking examples from OECD country legislation and practice.

In this respect, it should be remembered that domestic rules on the formulation of patent claims will generally have to be applied to all fields of technology, not only pharmaceuticals. The TRIPS Agreement provides that patents shall be available and patent rights enjoyable without discrimination as to the field of technology.<sup>276</sup> This being said, a WTO panel has clarified that “discrimination” in this sense “extends beyond the concept of differential treatment”.<sup>277</sup> This has been interpreted as suggesting that governments are permitted to adopt different rules for particular product areas, as long as the differences are adopted for *bona fide* purposes.<sup>278</sup> Differential treatment of pharmaceutical patents *vis-à-vis* other patents could therefore be justified to the extent that this is conducive to the promotion of public health (i.e. through the production of low-priced, locally produced drugs, or the importation of low-priced generics).<sup>279</sup>

### Structural claims:

- Countries seeking to preserve a broad public domain in pharmaceutical substances are free to obligate patent applicants to specify the particular purpose the invention should serve in addition to the structure. Without this specification, patent protection could possibly cover uses of the described structure for any purpose, even those unknown to the inventor at the time of filing the application. Thus, if a Government wishes to keep the scope of the patent rather narrow, it could adopt, in the Patents Act or the Examination Guidelines, a requirement to limit structural claims to expressly indicated purposes (“use-bound claims”).<sup>280</sup> But even the limitation of patent claims to specific uses will not alter the fact that the same claims cover all possible ways of making a product, as opposed to process claims, which only encompass the indicated way of manufacture (see above, box 1). Thus, for example, in case a drug is patented only for its use against cancer, competing producers may **use** the original substance for the purpose of fighting HIV/AIDS, but would still need a license from the patentee to **make** that substance. To the extent that the competitor holds a patent (product or process) on the new use, s/he may apply for a compulsory license for dependent patents, Article 31(1), TRIPS Agreement. Where the new use is off-patent, producers seeking to market the new use could invoke the public interest in making available new cures to obtain a public interest compulsory license, or a compulsory license to

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<sup>276</sup> Article 27.1, second sentence. Adopting different rules on claims formulation in different areas of technology may lead to different scopes of patent claims, depending on the area of technology.

<sup>277</sup> See *Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R of 17 March 2000, para. 7.94.

<sup>278</sup> See UNCTAD-ICTSD Resource Book, p. 481.

<sup>279</sup> While public health arguably constitutes a *bona fide* purpose in this respect, the above WTO panel did not specifically address this issue.

<sup>280</sup> This option has already been analyzed in the overall discussion of new medical uses of known products, in the context of patentable subject matter, see above, Section 2.3.2.

rectify an abuse of the original patent, arguing that the latter was being used to prevent the marketing of new cures not encompassed by the original patent claims.

- As it has been observed in the discussion of new uses of known products, follow-on uses of a patented drug are most likely to be discovered by the patent holder himself. In that case, the holder of the original patent could add another period of protection of twenty years on the underlying substance (provided product patent protection is available for new uses under domestic legislation). A better approach may therefore be the adoption of non-exclusive incentive regimes (i.e. compensatory liability) for new uses of known products, as discussed above.
- By contrast, unlimited structural claims could potentially prevent the extension of the patent term on the same substance by the patent holder. The original patent would comprise all uses, even those not known to the patentee at the time of filing the application. While this approach would automatically exclude third parties from exploiting new uses of the same substance during the life of the original patent, it would treat any later discovered new use of the underlying product as being covered by the original structural claims, thus rendering impossible any extension of the patent on such basis.<sup>281</sup>
- Whether a country tailors its structural claims as limited to the claimed uses or as unlimited depends, *inter alia*, on the potential of its local generic producers. In countries where generic producers are capable of discovering new uses of patented pharmaceuticals, a government may favour the implementation of use-bound claims to provide generic producers some freedom to operate outside the original patent claims, in combination with provisions on “dependent patent” or public interest compulsory licenses, as outlined above. In addition, in order to minimize the risk of blocking effects, the protection of new uses of known products could be limited to non-exclusive models, such as a compensatory liability regime, recommended above. Where the discovery of new uses by local producers seems unlikely, governments may consider structural claims that encompass all possible uses, thereby preventing an extension of the original patent by the original patentee.<sup>282</sup>
- Regarding patented processes, the claims could be required to refer to the various steps needed to complete the process, as well as the purposes for which the process will be used. Due to the fact that such process claims may not cover all possible ways of manufacturing the resulting product, competitors are free to make the (pharmaceutical) product through a process that has not been claimed.

#### Functional claims:

- Governments seeking to avoid overly broad claims could consider a rejection of unlimited functional claims altogether, unless the reference to the function of the invention is the only possible way of describing the invention (EPO approach).
- Alternatively, functional claims could be generally admitted, but could be limited to those chemical structures that are specified in the patent application. An example for this approach can be found in United States law, where functional claims may not

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<sup>281</sup> This presupposes, however, that countries do not apply the legal fictions employed under the EPC, where new use product patents are admitted on the same substance despite the fact that the original patent already covered all possible uses of the compound. See Article 54(4) and (5), EPC, and discussion on new uses, box. 2, above.

<sup>282</sup> There is a close connection between claims construction and the patentability criteria: unlimited structural claims should logically be supported by a novelty standard that excludes product patents for new uses, as those uses are already included in the prior art patent on the original substance. An exception are the legal fictions employed under the EPC, see above.



refer to a function alone, but must describe the function in combination with the corresponding structure, material, or acts described in the patent specification.

Product-by-process claims:

- Governments seeking to limit the scope of patent claims to the greatest possible extent could interpret product-by-process claims as being restricted to the particular manufacturing method recited in the claims and the resulting end product, so that competitors would avoid patent infringement by manufacturing the product through a different process. This would limit the invention to an ordinary process patent (Article 28.1 (b), TRIPS Agreement). This approach was followed in a 1992 opinion in the United States Federal Circuit.<sup>283</sup>
- Further options exist with regard to the extent to which the end product is protected:
  - Claims may cover a product *as actually obtained* through the specified process;
  - Alternatively, claims could cover *any product obtainable* through that process. This latter claim would be much wider, covering more than just one product.<sup>284</sup> Competitors seeking to manufacture different end products would not have the legal security of knowing the exact scope of the patent;
  - Where considered necessary to preserve the public domain, reference in a claim to the production process could be combined with a reference to a particular function that the end product is meant to serve.

Markush claims:

- This specific format of structural claims is appropriate in situations where a government seeks to provide for strong proprietary rights. The public domain available for generic competitors is considerably restricted in a scheme where Markush claims are allowed.
- Governments seeking to maintain a strong public domain may consider rejecting Markush claims entirely.
- Where domestic producers have acquired an advanced level of expertise in pharmaceutical production, Markush claims could facilitate the domestic producers' task of applying for patents on a family of compounds sharing a common chemical structure. Governments wishing to take advantage of this option but who are concerned about the public domain available for domestic competitors could seek to limit Markush claims to those compounds that share a common purpose in terms of medical use. This is the approach taken under the USPTO Patent Examination Guidelines, which make Markush claims dependent on a shared common utility.<sup>285</sup> However, this would not address one of the fundamental concerns with this claims format, i.e. the lack of disclosure of the particular structure and properties of all of the claimed chemical alternatives.<sup>286</sup>

Jepson claims: this claims format can be recommended in general, as it clearly establishes existing prior art and thus facilitates the task of patent offices to distinguish genuine inventions from trivial modifications. As indicated by the EPO's preference for this claims format, this is an option that is also of interest to developed countries.

Skuballa claims:

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<sup>283</sup> *Atlantic Thermoplastics Co. v. Faytex Corp.*, cited in Thomas, p. 229, fn. 146.

<sup>284</sup> See Correa, 2000, p. 33, with reference to Grubb.

<sup>285</sup> See UNCTAD-ICTSD-WHO Pharmaceutical Patents, p. 13.

<sup>286</sup> *Ibid*, p. 12.

- This claims format waives the requirement to specifically claim individual dosages of pharmaceutical substances needed for certain uses and therefore may only be appropriate for those developing countries where pharmaceutical producers and scientists have acquired the necessary level of know-how to infer required dosages from the patent claim.
- Countries lacking such expertise should consider whether the Skuballa format is appropriate. It may be preferable to require disclosure in the claims of each dosage required for a particular medical use.

In sum, countries are free to tailor the above claims formats to their specific needs and national priorities. Different claims formats may be combined where considered necessary to preserve the public domain.

## **2.6 Patent claims interpretation**

### **2.6.1 Background**

The claims set out in a patent application define the technological area that may not legally be invaded by third parties. Depending on the way the claim is formulated, the patent holder may prevent others from using a product or a process for certain purposes (see above). When a claim of infringement arises, a court must interpret the claims set out in the patents with a view to determining their scope and meaning. Then the claims as interpreted must be compared to the product or process accused of infringement.<sup>287</sup>

A literal infringement occurs (in United States law) when the accused product or process “included every element ... as recited in at least one of ... [the patentee’s] claims.”<sup>288</sup> Under United States law, an accused product or process that includes fewer elements or steps than those recited in claims will not infringe the literal scope of the patent. Whether an accused technology can include more than the listed elements without literally infringing a patented product or process depends on how the drafters have initially chosen to describe their invention in the language of the claims, i.e. in the transition phrase.<sup>289</sup>

Under United States law, claim construction is a matter of law, not fact.<sup>290</sup> However, in most developed countries the scope of protection is not necessarily limited to cases of literal infringement. Rather, courts may invoke a “doctrine of equivalents” to reach beyond acts of literal infringement in order to prohibit accused products or processes that present trivial or “insubstantial” differences from the claimed invention. As *Thomas* has observed, when courts “apply the doctrine of equivalents they attempt to balance fair protection for the patentee with appropriate notice to competitors of the scope of the patentee’s exclusive rights.”<sup>291</sup> Phrased differently, the doctrine of equivalents serves to demonstrate the zone in which second comers can freely “work around” or “invent around” the claims of the patent without fear of

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<sup>287</sup> Thomas, p. 455.

<sup>288</sup> Ibid, pp. 456-57.

<sup>289</sup> Ibid, p. 456, and above, Section 2.5.

<sup>290</sup> Ibid, p. 458, with reference to *Markman v. Westview Instruments, Inc.* (Federal Circuit).

<sup>291</sup> Ibid, p. 464.

infringement. The broader the concept of equivalence, the wider is the scope of the patent, encompassing a multitude of elements not expressly referred to in the patent claims.

As opposed to the above discussion on derivatives of known substances (Section 2.4), which examines to what extent structural modifications warrant an *additional* patent, the purpose of patent claim interpretation under the doctrine of equivalents is to determine to what extent structural and other modifications are encompassed by the *original* patent. How the doctrine of equivalents is applied in practice varies from country to country and from period to period within any given country. It can also vary from one subject matter to another, and it raises particularly complex technical questions in the chemical and pharmaceutical fields.

Historically, countries whose technological development originally focused on reverse engineering, notably Japan, tended to rely on literal infringement, without much recourse to a doctrine of equivalents, in the early stages. This strategy tends to narrow the scope of protection when foreign patentees dominate the landscape, without discrimination, while freeing up more room for follow-on innovation by local inventors who may work around these patents without literally infringing them. However, once that same country has begun to invest heavily in basic research it may choose to embrace a broader doctrine of equivalents in order to maximize potential returns to investors who have assumed proportionately greater risk in bringing so-called “pioneer inventions” to the market.

Developed country patent law concerning the doctrine of equivalents is technically complex and subject to discordant interpretations of ambiguous and sometimes conflicting precedents. As a general rule, according to the “Function - Way - Result” standard laid down by the United States Supreme Court Decision in *Graver Tank v. Linde Air Products Co.*, the accused technology infringes the patent *if it performs the same function in the same way to achieve the same result*.<sup>292</sup> As emphasized under German patent law, this similarity in function, way and result has to be *obvious* to a person skilled in the art, based on the information contained in the patent claims. Non-obvious variations of the claimed invention thus fall outside the claims and might warrant a separate patent.<sup>293</sup>

Against this background, some general trends in the use of the doctrine of equivalents in the United States may be identified.<sup>294</sup> Before 1982, for example, when the non-obviousness standard was relatively high and patents were routinely invalidated by the federal appellate courts, those patents that survived judicial scrutiny may have attracted a broader scope of equivalents. After 1982, when the CAFC was installed, the eligibility criteria have arguably been lowered, and it has become much harder to judicially invalidate issued patents. At the same time, more attention has been paid to narrowing the scope of patents that increasingly reflect merely incremental innovation. In this area, the range of equivalents tolerated by the courts has accordingly attracted considerable attention, and may shrink under the application of various limiting doctrines as the jurisprudence on the matter continues. As opposed to this development regarding trivial changes, equivalents are being used more generously to protect pioneering advances.

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<sup>292</sup> 339 U.S. 605, 85 USPQ2d 328 (1950).

<sup>293</sup> See Ensthaler, pp. 123/124, for Germany.

<sup>294</sup> See Thomas, pp. 464 ff.

## **2.6.2 Policy options**

As developing countries familiarize themselves with the patenting of pharmaceuticals, they will have to formulate policies and doctrines to deal with the question of equivalents beyond literal infringement.

In general, a country with limited manufacturing capacity is initially well served by a doctrine of literal infringement with little room for appeal to the doctrine of equivalents. This strategy maximizes the room for generic producers and improvers to work around existing pharmaceutical patents. Countries with growing capacity, such as Brazil, China and India, may also benefit from a narrow doctrine of equivalents, especially because it may help to enable them to develop incremental improvements and adaptations of foreign products without literally infringing them, and also because it helps to reduce patent thickets and blocking effects in delicate upstream research sectors, particularly biotechnology. Where blocking effects occur because a locally developed improvement cannot be practiced without infringing a dominant patent, a compulsory license for so-called “dependent patents” should be readily available under legislation implementing Article 31(1) of the TRIPS Agreement. In order to avoid the patenting of trivial improvements, patentability criteria may be applied strictly, as outlined in Section 2.4, above.

Nevertheless, States with growing technical capacity and a narrow doctrine of equivalents will increasingly experience negative tradeoffs if that doctrine of equivalents is uncritically applied to major technical or medical advances that may emerge from their universities and research institutes. In that case, OECD country law provides an arsenal of technical interpretations that permit courts to expand the doctrine of equivalents in appropriate cases, without violating norms against discrimination, to adjust the doctrine of equivalents to the weight of the technical advance in any given patent. The flexibility in the design of the doctrine of equivalents, which is not regulated by the TRIPS Agreement, must be used with caution. It cannot become an excuse to condone piracy or discrimination against foreign patentees. At the same time it is a useful and important tool in adjusting a country’s patent policy to evolving technical capabilities.

## **2.7 Disclosure of patented inventions**

### **2.7.1 Background**

The TRIPS Agreement provides that members shall require an applicant for a patent to disclose the invention in a sufficiently clear and complete manner so that the invention may be carried out by a person skilled in the art (Article 29). This obligation reflects the basic concept of patent law: in exchange for receiving a temporary exclusive right, the patent holder makes his/her invention available to the public at large. Disclosure of the invention is made through the description or “specification”, which a patent application has to contain, in addition to the patent claims (see above, Section 2.5). The scope of the patent claims cannot reach beyond the scope of the specification.<sup>295</sup>

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<sup>295</sup> Thomas, p. 206.

Despite the disclosure requirement, patent applications are often not sufficiently detailed or self-explanatory for persons skilled in the art to be able to utilize the disclosed information for future follow-on innovation, particularly in developing countries. The TRIPS Agreement provides some flexibility on how developing country governments may respond to this situation.

### **2.7.2 Policy options**

The TRIPS Agreement provides some leeway for governments to improve the effective value of patent application documents to their local researchers and scientists. In particular:

- The person skilled in the art to whom the disclosure must be sufficiently clear and complete may be defined as a local developing country expert, rather than a scientist with expertise representing OECD country standards. In addition, skills may be defined as representing the national average, rather than the top standard. This will require the patent applicant to provide a more complete, comprehensive disclosure. In the pharmaceutical context, this could mean that all elements of claimed compositions would have to be disclosed and explained.
- The TRIPS Agreement authorizes members to require the applicant to indicate the *best mode* known to her/him for carrying out the invention (Article 29.1). This is an important contribution for helping local innovators and researchers fully understand the technology claimed in the patent. Many areas of today's technologies are so complex that patent applications alone are often not comprehensible to potential competitors of the patentee. A best mode requirement would thus be an important step toward the creation of a pro-competitive environment for technology development and follow-on innovation. Major developed countries such as the United States have chosen to implement the best mode requirement in their domestic patent law.<sup>296</sup> The usefulness of this option may be limited in cases where the best mode for the manufacture of pharmaceutical products is not known at the time of filing the application, as production has not commenced on that date.<sup>297</sup>
- The TRIPS Agreement also authorizes members to require that a patent applicant provide information concerning the applicant's corresponding foreign applications and grants (Article 29.2). This could provide important guidance for inexperienced developing country patent examiners regarding the patentability of the invention in question and the actual scope of the patent. At the same time, it should be kept in mind that the design of developed country patentability criteria corresponds to these countries' particular state of technological development and might not be appropriate for countries depending on a broader public domain. This being said, information on foreign applications and grants could also help a developing country patent examiner to better identify those particular elements of an invention that do not deserve patent protection.

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<sup>296</sup> Thomas, p. 208, citing 35 U.S.C. §112.

<sup>297</sup> South Centre, 2000, p. 60.

### 3. Post-grant flexibilities

#### 3.1 Exceptions to patent rights

##### 3.1.1 Introduction

Once a patent has been granted, the scope of the exclusive rights conferred may be limited for certain public interest reasons considered superior to the interests of the patent holder. “Where the line is drawn between those areas that are the preserve of the patent holder to control, and those areas [i.e. of exceptions and limitations] which the patent holder may not control, is therefore a very important policy question for members.”<sup>298</sup> Conceptually, one must distinguish the topic of this section from exceptions to patentability that result in the *non-granting* of a patent (e.g. substances found in nature, see above). Exceptions to exclusive rights as considered here apply *after* a patent *has been granted*.

Before the TRIPS Agreement was adopted in 1994, when States were relatively free to adopt exceptions to patent law as they wished, a group of exceptions that were established in state practice became widely recognized in multilateral negotiating forums. These exceptions are listed in table 3 below.

**Table 3: Overview of established exceptions under national patent laws**

Exception to patent rights	Nature of policy problem addressed
Private & Non-commercial Use	<i>De minimus</i> activity should be shielded from patent infringement
Experimental Use	Scientific/technical progress must not be hindered by the patent system
Prior Use	Prior users should be treated fairly vis-à-vis patent holders
Pharmacy	Pharmacists should be free to make medicines for supply to patients on the basis of individual medical prescriptions submitted to them by doctors without fear of patent infringement

<sup>298</sup>See Garrison, p. ix.

<b>Exception to patent rights</b>	<b>Nature of policy problem addressed</b>
Foreign vessels	Freedom of international movement of foreign vessels must not be hindered by patent
International civil aviation (Chicago)	Freedom of international movement (and maintenance) of foreign aircraft must not be hindered by patents
Regulatory review (Bolar)	Competition between patented medicines and generic medicines must be enabled as swiftly as possible after the expiry of the medicine patent
National exhaustion*	Once a patent holder has sold a patented product, they ought not to be able to control subsequent dealings with the product, e.g., resale or repair
European regional exhaustion*	Once a patented product has been sold on the European market, freedom of movement of goods throughout the rest of the market must not be hindered by patents

Source: Garrison, p. x.

\*Note that the classification of patent rights exhaustion as a form of exception is not imperative; it may also be argued that, since exhaustion terminates the exclusive distribution rights, it goes beyond the scope of a mere exception. Note also that the doctrine of international patent rights exhaustion has also been widely accepted; see the discussion of parallel imports, below.

Of these exceptions, an early draft of the TRIPS Agreement (i.e. the Anell Draft of 23 July, 1990) listed the following exceptions for consideration in the negotiating text:<sup>299</sup>

1. Rights based on prior use;
2. Acts done privately and for non-commercial purposes;
3. acts done for experimental purposes;
4. Preparation of prescription medicines in a pharmacy;
5. Certain acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent changed in accordance with procedures for effecting changes to patents after grant; and
6. Acts done by government for purposes merely of its own use.

<sup>299</sup> See UNCTAD-ICTSD Resource Book, p. 432.

Eventually, however, when consensus on a complete list of exceptions became impossible, this list was withdrawn and in its place Article 30, TRIPS Agreement adopted a three-step general standard on all exceptions to patent rights as follows:

“Members may provide [1] limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions [2] do not unreasonably conflict with a normal exploitation of the patent and [3] do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>300</sup>

This text was based on Article 9 (2) of the Berne Convention regarding reproduction rights under copyright law. As compared to the latter, Article 30 of the TRIPS Agreement makes at least one important modification concerning the third testing criterion that expressly refers to the public interest as an element to be taken into account when assessing the prejudice caused to the legitimate interests of the patent holder.

Despite the adoption of a standard in Article 30, the above-mentioned exceptions (table 3) are thought to be consistent with the TRIPS Agreement, since they were widely practiced at the time of its adoption and no objections to them were raised.<sup>301</sup> In practice, however, any of these pre-existing exceptions may be adopted by domestic laws in narrower or broader forms, and would be ultimately tested for compliance with the standard adopted in Article 30, TRIPS Agreement through WTO dispute settlement proceedings.

Three further considerations are worth noting. First, the pre-existing limitations have not stood still even in states that had previously adopted them. Rather, they continued to evolve, growing broader or narrower depending on the jurisdiction. For example, the common law research exemption in the United States was recently narrowed so drastically by the Court of Appeals for the Federal Circuit that it no longer allows university scientists to use patented inventions for pure research purposes without risk of liability for infringement (see Section 3.1.2, *infra*). Efforts to override this decision by statute have so far not succeeded. In contrast, the research exemptions in some other developed countries remain broad to permit research by commercial firms, even for purposes of working around a patented invention.

Second, since the implementation of Article 30, TRIPS Agreement, a number of States have adopted new exceptions, often prompted by the expansion of patent protection into new fields. Table 4 provides a summary of these new exceptions, whose validity has not yet been challenged.

**Table 4: Post-TRIPS patent exceptions under national patent laws**

Exception to patent right	Nature of policy problem addressed
Business method prior use	Prior users of business methods should be treated fairly vis-à-vis patent holders.

<sup>300</sup> Numbers added to indicate the three steps.

<sup>301</sup> Garrison, p. 2.



Exception to patent right	Nature of policy problem addressed
Medical practitioner	Freedom for medical practitioners to carry out medical treatments
Farmers privilege	Need for farmers to be able to harvest and re-sow their own seeds
New variety breeding	Need for breeders to be able to use present varieties as a basis from which to breed new varieties
Teaching	Freedom to teach students

Source: Garrison, p. xii.

Third, the one WTO panel decision interpreting the three-step test of Article 30, TRIPS Agreement (*Canada - Patent Protection of Pharmaceutical Products*<sup>302</sup>) has been criticized on numerous grounds, especially for insufficient attention to the public interest inherent in the third prong, the Preamble, and Articles 7 and 8 of the TRIPS Agreement.<sup>303</sup> Moreover, this decision dealt with pharmaceutical products before the Doha Declaration on TRIPS and Public Health was adopted. Even then, the panel decision upheld a member's right to allow the reverse-engineering of patented products for the purpose of obtaining early regulatory approval of generics, while denying members the right to stockpile those generics, prior to patent expiry, for sale after patent expiry.<sup>304</sup>

The rest of this section will focus on a limited number of exceptions thought to be of particular relevance to pharmaceutical production in developing countries. The "policy space" for additional exceptions will be briefly explored.

### 3.1.2 The experimental use exception

#### 3.1.2.1 Background

Under the TRIPS Agreement, the stated objective of IPR protection and enforcement is to:

“contribute to the promotion of technological innovation and to the transfer and dissemination of technology [...]” (Article 7).

While the availability of exclusive rights provides an important incentive for inventors to engage in inventive activity and to disclose the results of their efforts to the public, exclusive

<sup>302</sup> WT/DS114/R (hereinafter *Canada - Generics*).

<sup>303</sup> See Garrison, Section 3 (pp. 19 ff.).

<sup>304</sup> For a detailed discussion of the *Canada - Generics* panel report, see Garrison, pp. 19-43.

rights in certain substances and processes may also hinder scientific progress to the extent that scientists must experiment on and with existing inventions in order to prove new scientific theories and to develop new research tools (**fundamental or basic research**). A research exemption ought to carve out a “safe harbour” for scientific activities that might otherwise be blocked by patents. The problem that blocking patents pose has become particularly acute in the realm of biotechnology, where the line between theoretical and applied research has disintegrated and where many inventions of great commercial value serve a dual purpose as research tools for the scientific community. As explained above, such research tools may pass the “industrial application” or “utility” test and thus be patentable to the extent that a **specific function** of the research tool has been identified.

Beyond the need to preserve space for scientific researchers to develop new knowledge, there are related questions pertaining to the ability of researchers in commercial enterprises to conduct research on or with patented inventions for the purpose of making additional inventions based on the protected subject matter, such as improvements or adaptations of existing products or processes, or for discovering ways to “invent around” the patented invention (**commercial research**). Here, the research in question potentially has a more direct commercial outcome, yet it serves an important public purpose. Indeed, scientific and technological progress of a society depends to a large extent on such “follow-on innovation”, for which inventors and/or scientists need access to patented subject matter.

For local pharmaceutical producers, moreover, the purpose of commercialization is obviously of key importance. Therefore, a question arises concerning the extent to which generic producers and/or researchers are authorized to use patented substances for the development of new products.

In some developed countries’ legislation on patent exceptions, the distinction between scientific research purposes on the one hand and commercial purposes on the other hand is not always very clear. For instance, the German Patents Act broadly provides that the scope of the patent shall not extend to acts relating to the protected subject matter done for experimental purposes.<sup>305</sup> The reference to “experimental purposes” is rather vague and arguably encompasses those cases where commercial interest is one of the driving forces behind experimental activities. Accordingly, the German BGH ruled that in cases where the experiments in question are intended for the purpose of gaining new knowledge about the patented subject matter, including its uses, or to promote technological progress, any activity on the patented subject matter may be justified under the experimental use exemption, even where there is an ultimate commercial objective in addition to the purpose of knowledge generation.<sup>306</sup> Along the same lines, the International Association for the Protection of Intellectual Property (AIPPI) adopted its Resolution Q 202 (“The impact of public health issues on exclusive patent rights”) in September 2008, which states that:

“1.1) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorization of the patentee, experiments relating to

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<sup>305</sup> See § 11, No. 2 of the German Patents Act.

<sup>306</sup> See BGH decision of 11 July 1995, *Klinische Versuche*, Pressemitteilungen des Bundesgerichtshofs 1995, p. 274; cited in H. Schubert (University of Erlangen-Nürnberg), “Nutzung von Patenten zu Versuchszwecken”, who provides a detailed analysis of the decision (available at: <http://www.uni-erlangen.de/einrichtungen/WTT/erfinderberatung/versuchsprivileg.shtml>).

the subject-matter of the invention, irrespective of whether the ultimate aim of the experiments may be commercial. [...]"<sup>307</sup>

The Australian Law Reform Commission (ALRC) has suggested altering Australian patent law to include a statutory provision on an experimental use exception, which emphasizes the experimental character of the exception, but does not exclude the existence of additional commercial motivations:

- “The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

(a) the exemption is available only if study or experimentation is the sole **or dominant purpose** of the act;

(b) **the existence of a commercial purpose or objective does not preclude the application of the exemption; [...].**"<sup>308</sup>

An interesting example of a statutory experimental use exception is provided under the new Swiss Patents Act. Article 9 of the law exempts any research done to obtain new knowledge about the patented subject matter, including its uses.<sup>309</sup> This provision is similar to the jurisprudence of the German BGH (see above) and has been interpreted as allowing research activities for both non-commercial and commercial purposes, as long as the objective of the research is to reveal new knowledge about the patented invention.<sup>310</sup> Thus, the patented substance may be used to generate new knowledge that may be necessary for the development of a new product, provided that the latter is not covered by the literal scope of the original patent nor equivalent to its literal scope. The exception obviously does not authorize the mere reproduction of the original product as covered by the original patent claims.

In focusing on the generation of new knowledge rather than on the commercial/non-commercial dichotomy, the above approaches more appropriately accommodate the main rationale for the experimental use exception, i.e. to prevent patents from blocking the advancement of technological innovation. This being said, it is true that the above-mentioned research exemptions refer, above all, to the objective of gaining new knowledge on the patented invention. This has to be the main objective of any activity claiming justification under this exception. The mere promotion of a competitor's commercial activities alone will not fall under this exception.

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<sup>307</sup> AIPPI, Resolution Question Q 202 “The impact of public health issues on exclusive patent rights”, 10 September 2008 (available at [www.aippi.it/docc/RS202English.pdf](http://www.aippi.it/docc/RS202English.pdf)).

<sup>308</sup> Garrison, Section 4.3.1, quoting Recommendation 13-1 of the ALRC Final Report on “Genes and Ingenuity: Gene Patenting and Human Health” (emphasis added).

<sup>309</sup> See Article 9 I (b) of the Swiss Patents Act, as entered into force on 1 July 2008 (French language version available at [www.admin.ch/ch/f/rs/232\\_14/](http://www.admin.ch/ch/f/rs/232_14/)).

<sup>310</sup> See N. Thumm, “A statutory research exemption for patents”, in *Healthy IPRs. A Forward Look at Pharmaceutical Intellectual Property*, edited by M.P. Pugatch and A. Jensen, Stockholm Network, London, 2007, pp. 116-129 [hereinafter Thumm].

Further guidance in this context may be had from a 2009 decision by the United Kingdom High Court regarding the scope of the United Kingdom experimental use exception. The High Court expressed the view that a commercial purpose behind a competitor's use of patented substances does not automatically rule out the possibility of invoking the experimental use exception. Most pharmaceutical research is driven by commercial considerations. However, the purpose of the experimental use exception is not to promote competitors' commercial activities, but to enable the generation of new knowledge on the protected substance. Thus, the defendant in a patent infringement suit needs to show that the immediate purpose of his activities is not to generate revenue, but to gain new knowledge on the patented product (e.g. to enable future modifications of a drug). Where the defendant's activities have mixed purposes, the generation of new knowledge must be shown to be the preponderant purpose, while the generation of revenue may constitute a secondary purpose.<sup>311</sup>

In the context of generic pharmaceutical production, it is important to note that the experimental use exception alone will not authorize the sale and other commercialization of a product that was lawfully developed under the exception. The purpose of the experimental use exception, even in its wider forms as discussed above, is to enable activities related to the use of the patented substance for the generation of new knowledge, which could result in the development of a new product. However, the sale of such a new product constitutes a separate activity, which is no longer part of the experimental activity, even if the latter had a commercial objective.<sup>312</sup> It follows that a producer who intends to market a product that was legally developed on the basis of a patented product under an experimental use exception still needs authorization from the holder of the original patent. This authorization would relate to the use of the originally patented product for the production and sale of the newly developed product, which may be granted a patent in itself. This constitutes a typical case of dependent patents. The TRIPS Agreement under Article 31(l) authorizes Members to grant a compulsory license to the holder of the subsequently developed patent. Under such a license, the follow-on innovator would be authorized to use the original patent for the production and sale of his improved substance, whereas the original innovator would equally be authorized to use the invention claimed in the follow-on patent.

Another important qualification must be made with respect to the Swiss and German experimental use exceptions: they only apply to research "on" (Article 9 I (b) of the Swiss Patents Act; § 11, No 2 of the German Patents Act) the patented invention. Acts undertaken for research "with" (see Article 40.b of the Swiss Patents Act) the invention (i.e. use as research tool) are not covered. In this context, we should note the importance for researchers, especially in biotechnology, to have the right to use the patented invention not only to gain new knowledge on the subject matter of the invention (i.e. to experiment "on" the patented invention, as covered by the German and Swiss experimental use exceptions), but also to use the patented invention as an instrument or research tool to undertake further research (i.e. to experiment "with" the patented invention). For example, the sole authorization to experiment "on" the patented polymerase chain reaction would allow a researcher to find out more about this procedure used in gene technology. However, it would not authorize her/him to actually

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<sup>311</sup> See *CoreValve Inc v Edwards Lifesciences AG & anr* [2009] EWHC 6 (Pat) (for a brief analysis of this decision, see SJ Berwin, "High Court considers scope of experimental use defence to patent infringement" (available at: [http://www.sjberwin.com/html\\_newsletters/ebf/pharma/pharma\\_update/March2009/article2.html](http://www.sjberwin.com/html_newsletters/ebf/pharma/pharma_update/March2009/article2.html)).

<sup>312</sup> Note that this is an important difference between patent law/utility model law, on the one hand and the protection of plant varieties under UPOV (1991 Act), on the other hand: according to Article 15 of UPOV 1991, the breeder's right shall not extend to acts done for experimental purposes, acts done for breeding other varieties, and acts related to, *inter alia*, selling and other marketing of these other varieties. See Article 15(1)(ii), (iii) of UPOV 1991.

use this procedure as a tool to develop increased amounts of nucleotide sequences.<sup>313</sup> In order to ensure access to patented research tools, the Swiss Patents Act provides a right to claim a non-exclusive license to use a patented biotechnological invention as a research tool.<sup>314</sup> Where the parties cannot reach agreement on the fees, this issue may be decided by the courts.<sup>315</sup> The justification for treating experimental uses “on” the invention differently from experimental uses “with” the invention may be justified by the fact that experiments “on” the invention do not affect the normal exploitation of the patent by the right holder, while experiments “with” the invention may be the only purpose of a patented research tool. In that case, expanding the experimental use exemption to research tools would render impossible the normal exploitation of the patent.

In the United States, by contrast, the CAFC has narrowed the common law experimental use exception, limiting it to acts performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”.<sup>316</sup> The CAFC considered the United States common law experimental use exception as not encompassing any activities conducted with a commercial aim, and even non-commercial academic research could be said to further the “legitimate business objectives” of the university, “including educating and enlightening students and faculty participating in these projects”, “increas[ing] the status of the institution and lur[ing] lucrative research grants.”<sup>317</sup> According to *Garrison*, such a narrow view - if sustained by the Supreme Court - “can clearly be expected to have a significant adverse impact on the ability of researchers to operate in the United States.”<sup>318</sup>

In contrast, some developing countries have adopted broader termed experimental use exceptions, although their application in the courts as well as their ability to remain broad over time remains to be seen. China, for example, has adopted a potentially broad research exemption. This may, however have been narrowed by subsequent regulations that distinguish between experimentation **on**, and experimentation **with** a patented product (as do the Swiss and the German laws). This distinction still permits experimental use to develop improvements to the patented inventions.<sup>319</sup>

### **3.1.2.2 Policy options**

The above review of national legislation illustrates the discretion available to governments to design an experimental use exception. While national legislation in this regard has to respect the boundaries for patent exceptions set up by the TRIPS Agreement (Article 30), no WTO panel has thus far provided any authoritative interpretation of the extent to which Article 30,

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<sup>313</sup> Example taken from Thumm, pp. 120-121. According to this author, “the polymerase chain reaction is an essential procedure of gene technology that allows small amounts of nucleotide sequences to increase. It also allows for better approval and analysis of material and is therefore an important tool for research in many laboratories.”

<sup>314</sup> See Article 40 (b) of the Swiss Patents Act.

<sup>315</sup> Thumm, p. 121.

<sup>316</sup> *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), quoted by F. Abbott, “Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law”, UNCTAD-ICTSD Issue Paper No. 12, February 2006, p. 8 [hereinafter Abbott, 2006].

<sup>317</sup> *Madey v. Duke University*, quoted by Garrison, p. 47.

<sup>318</sup> Garrison, p. 47.

<sup>319</sup> *Ibid.*, p. 48.

TRIPS Agreement covers the experimental use exception.<sup>320</sup> Moreover, it has been observed<sup>321</sup> that the actual application of TRIPS-compliant legislation in a particular case may still result in TRIPS-inconsistency, not of the legislation as such, but of its application by national authorities.

Nevertheless, one should bear in mind that the TRIPS Agreement leaves members considerable leeway to determine the appropriate method of implementing its provisions within their own legal system and practice (Article 1.1, TRIPS Agreement), consistent with their own scientific and technological capabilities. The Appellate Body decision in the *India - Mailbox* case<sup>322</sup> has been interpreted by at least one author as suggesting the need for deference to state action under TRIPS once a good faith effort to comply has been demonstrated.<sup>323</sup> As found by *Correa*:

“The analysis of the legislation in developing countries and economies in transition indicates that the research/experimentation exception has been widely recognised in patent law both before and after the TRIPS Agreement. Many countries – including the most technologically advanced – have not used, however, the full room for manoeuvre left by the Agreement to legislate on the matter.”<sup>324</sup>

Against the background described above, it seems essential to design a provision that takes account of the main policy rationale behind the experimental use exception, i.e. to ensure that the granting of exclusive rights does not stifle technological progress. In this respect, some of the laws reviewed above, such as the ones of Switzerland and Germany, appear to be promising approaches. They focus on the generation of new knowledge on the invention through experiments “on” the invention, irrespective of the nature of the activity as (non-) commercial, provided the generation of new knowledge constitutes the primary purpose of the activity at issue. Developing countries should consider adoption of a similar approach, in combination with the possibility to grant compulsory licenses to enable the use of dependent patents (Article 31(1), TRIPS Agreement, as explained above). At this point, it should be reiterated that developing countries also have other options beyond patent law to provide incentives for incremental innovation. In particular, a compensatory liability regime would authorize competitors to market the results of their improvement-oriented research in exchange for compensation, without the need to wait for the expiry of any exclusive rights in the underlying product.

As far as experiments “with” the invention are concerned, we have pointed out above that the industrial application standard may be used to limit the patentability of research tools, which should, to the greatest extent possible, be available in the public domain for purposes of follow-on and cumulative research. To the extent that even under a strict standard of industrial application the patenting of a research tool becomes unavoidable, we recommend that

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<sup>320</sup> In *Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R of 17 March 2000, para. 7.69, the Panel referred to the experimental use exception, but did not address the issue of its compliance with the requirements under Article 30, TRIPS Agreement.

<sup>321</sup> See South Centre, 2000, p. 66.

<sup>322</sup> *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* (“India - Mailbox”), AB-1997-5, WT/DS50/AB/R, 19 December 1997.

<sup>323</sup> See J.H. Reichman, “Securing Compliance With the TRIPS Agreement After *United States v India*”, *Journal of International Economic Law*, Vol. 1, No. 4, December 1998, pp. 585-601.

<sup>324</sup> C. Correa, “The International Dimension of the Research Exception”, AAAS/SIPPI Paper, January 2004.

developing country policy makers consider the approach taken under the Swiss Patents Act, as described above. The Swiss approach to patented research tools effectively modifies the exclusive rights character of the research tool patent, turning it into some form of “use and pay” or “compensatory liability” regime, as advocated by *Reichman* (see above, Section 2.3.2). This non-exclusive approach rewards the inventor and at the same time avoids abusive “blocking patents” on research tools that stifle technological innovation and progress. The Swiss Patents Act provides the right to claim a non-exclusive license for a patented research tool.<sup>325</sup> This may have advantages for both the public and the inventor. The competitive use of the patented research tool through a multitude of capable licensees (e.g. universities) is likely to result in a rather quick development of new products and will thereby increase the market value of the respective licenses, thus generating revenues that are possibly higher than those gleaned under an exclusive license, where the development of new products may be slower due to lack of competition.

In sum, governments, when designing a scientific research exception that meets the requirements of Article 30, TRIPS Agreement, may consider looking at some OECD legislation/proposals (in particular the Swiss Patents Act), which do not necessarily preclude an application of the exception to acts done for commercial purposes, as long as the activity serves the purpose of generating more knowledge “on” the invention. For experiments “with” the invention, the first option should always be the exclusion of research tools from patentability, to the greatest possible extent, through a strict industrial application requirement. Where patenting becomes unavoidable, a compensatory liability (“use and pay”) system involving non-exclusive licenses appears an appropriate way of providing a pro-competitive environment for the development of new products through the use of patented research tools.

### **3.1.3 The regulatory review (“Bolar”) exception**

#### ***3.1.3.1 Background***

A patent confers upon its holder the right to exclude others from making, using, selling, etc. the protected product or process. The patent, however, does not authorize the right owner to put the patented product on the market. With respect to pharmaceutical products, such authorization may often be obtained from a specialized government body, hereinafter referred to as Drug Regulatory Authority (DRA).

Obtaining approval from a DRA for the marketing of a drug might take a considerable amount of time, sometimes up to several years.<sup>326</sup> Generic producers, in order to obtain marketing approval, often depend on the use of essentially the same substance or active ingredients as those used in a patented drug for which the originator has already received marketing approval, based on clinical trial data. Such use of the patented substance may consist either of submitting the proposed generic substitutes to the DRA for bio-equivalence testing, or of using the substance for the production of the generic producers’ own test data to prove to the DRA that the generic version of the drug meets certain safety and efficacy standards.<sup>327</sup> From

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<sup>325</sup> See Article 40 b of the Patent Act, and Thumm, p. 122.

<sup>326</sup> For more details on the drugs approval process, see M. Pugatch, “Intellectual Property, Data Exclusivity, Innovation and Market Access”, in *Negotiating Health*, pp. 97 ff. [hereinafter Pugatch].

<sup>327</sup> For more details on these different marketing approval procedures, see Section 3.5.

the point of view of a generic competitor, regulatory approval processes thus require considerable time, effort and money invested in reverse-engineering the patented product/compound, as well as formulating an equivalent product, and they may require substantial amounts of test production to demonstrate reliable manufacturing.<sup>328</sup>

If the patent holder could use his/her exclusive right to prevent generic producers from using the patented substance in these ways in order to obtain marketing approval a generic producer could only prepare to submit a request for marketing approval after the patent has expired. Considering the time required for the approval process, marketing of the generic drug would thereby be delayed to well after the expiry of the patent, thus extending, *de facto*, the exclusive position of the patented drug on the market. From a public health perspective, delayed market entry of generic competitors is likely to delay any possible decrease of drug prices.

For these reasons, it is advisable for WTO members, from a public health perspective, to include a regulatory review exception in their patent legislation,<sup>329</sup> as many OECD countries have done. While some of them, like Germany under its experimental use exception, proceeded “a long way down the road to permitting the sorts of activity that is enabled under a separate Regulatory Review exception”,<sup>330</sup> the United States and Canada were the first countries to introduce a stand-alone regulatory review exception into their domestic laws.<sup>331</sup> The WTO Panel in *Canada–Patent Protection of Pharmaceutical Products* ruled that such provisions fall within the room for exceptions that Article 30, TRIPS Agreement allows. The Panel stressed that so long as the patented product is produced for the sole purpose of obtaining marketing approval, and no commercial use is made of the resulting final products until after expiry of the patent, such production efforts would satisfy the TRIPS Agreement conditions for patent exceptions.<sup>332</sup> However, the Panel made it clear that a “stockpiling” provision authorizing generic producers to manufacture, during the patent term, an unlimited stock of generic copies to be sold immediately after patent expiry would not satisfy the requirements for patent exceptions under Article 30, TRIPS Agreement.<sup>333</sup> Whether this part of the Panel’s decision would withstand re-examination under the Doha Declaration on TRIPS and Public Health remains to be seen.<sup>334</sup>

Since the WTO Panel’s ruling in 2000, the European Union, which previously opposed a regulatory review exception, has adopted a version of its own.<sup>335</sup> Developing countries, such as Brazil, China, Egypt, India, and Kenya have also introduced regulatory review exceptions in their domestic laws.<sup>336</sup>

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<sup>328</sup> *Canada - Patent Protection of Pharmaceutical Products*, Report of the Panel, para. 7.45.

<sup>329</sup> The regulatory review exception is also referred to as “Bolar” exception, named after the first court case on this exception in the United States (*Roche Products Inc. vs. Bolar Pharmaceutical Co.*; 733 F. 2d. 858, Fed. Cir., cert. denied 469 US 856, 1984).

<sup>330</sup> Garrison, p. 58.

<sup>331</sup> *Ibid.*, pp. 14 (United States), 19 (Canada).

<sup>332</sup> See Report of the Panel, para. 7.45. The Panel considered such an exception as “limited” in terms of Article 30, as a production limited to regulatory approval purposes would leave the bulk of the patentee’s exclusive rights (i.e. production, use and sale for commercial purposes) untouched.

<sup>333</sup> Report of the Panel, para. 7.34. As opposed to the case where production is limited to marketing approval purposes, an unlimited stockpiling authorization entirely removes the patentee’s exclusive right to make and to use the protected product during the patent term.

<sup>334</sup> See Garrison, pp. 40-42.

<sup>335</sup> Directive 2001/83/EC as amended by Directive 2004/27/EC.

<sup>336</sup> For details, see Garrison, pp. 58 ff.



When formulating such provisions, members must decide whether to allow such exceptions to cover activities relating to any compound for which it could reasonably be believed that approval might be sought, or to limit the exception to compounds for which approval is actually sought. A Supreme Court decision in the United States<sup>337</sup> authorized the broader option (i.e. for both pre-clinical and clinical research), and developing countries should seriously consider following suit (see Section 3.1.3.2). These countries will also wish to evaluate Canada's even broader (and WTO-approved) version of the exception, which allows activity for regulatory review **in foreign countries**, unlike the United States form of the exception.<sup>338</sup>

In this context, it is important to note that laws protecting the use of clinical test data (both in the domestic OECD context and as spread among developing nations through bilateral and regional free trade agreements) can interfere with the generic producer's ability to reap the full benefits of an existing regulatory review exception. While the latter exception authorizes a generic producer to use a patented substance for purposes reasonably related to the granting of marketing approval through a DRA, some countries' laws on clinical test data prevent the DRA from relying, for a certain period of time, on the originator's previously submitted clinical data for the purpose of approving a bioequivalent generic product. The only way for generic producers to receive marketing approval for their product before the expiry of the data exclusivity period is then through the generation of their own test data, which requires them to repeat the same clinical trials already undertaken by the owner of the exclusive test data rights, despite the fact that safety and efficacy of the generic product may simply be established by showing its equivalence with the originator drug.<sup>339</sup> Undertaking their own clinical trials is too costly and time consuming for most generic producers, who will in that case await the expiry of the period of test data exclusivity. This wait will cause a considerable delay in the granting of regulatory approval for the generic drugs, which is contrary to the purpose of the regulatory review exception.

In addition, even in cases where the generic producer could effectively produce his own trial data, certain provisions in FTAs obligate the DRA to refrain from granting marketing approvals on generic drugs as long as the original version is protected under a domestic patent (so-called "linkage" of patent law and drug regulation). Rather than leaving the task of patent enforcement up to the patentee, these laws turn the DRA into a patent enforcement authority, despite the fact that many of these authorities, especially in developing countries, do not have the expertise to verify the patent status of a drug. As observed by *Abbott*, even developed country DRAs may face serious problems when seeking to verify the patent status of a drug.<sup>340</sup>

As a result of patent linkage provisions, a generic producer will receive marketing approval only after the expiry of a patent on the originator drug, despite the existence of a regulatory review exception. The TRIPS Agreement, by contrast, would not prevent the DRA from granting marketing approval during the term of the patent, thus providing the generic producer with the legal security needed to invest into the establishment of manufacturing facilities to ensure timely commencement of production right after expiry of the patent on the

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<sup>337</sup> *Merck v. Integra Lifesciences*, 125 S. Ct. 2372 of 13 June 2005.

<sup>338</sup> Garrison, p. 58.

<sup>339</sup> For more details, see the discussion on test data protection, Section 3.5, below.

<sup>340</sup> F.M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements", *Quaker United Nations Office Occasional Paper* 14, April 2004, p. 8 [hereinafter Abbott, Contradictory Trend].

originator drug. In addition, “linkage” provisions, as discussed above, prevent generic producers from challenging poor quality patents in patent infringement litigation, after bringing their generic copy to the market prior to the expiry of such patents.<sup>341</sup> The above concerns may explain why some important WTO members such as the EU and India have so far refused the adoption of patent linkage provisions in their domestic laws.<sup>342</sup>

Implementing a scheme in which marketing approvals are dependant on the term of the patent may have other implications outside the scope of the regulatory review exception (particularly in the area of compulsory licenses). These will be discussed in the context of clinical test data protection (see Section 3.5).

### **3.1.3.2 Policy options**

Should a government decide to include in the domestic patent legislation an express regulatory review exception, the following observations apply:

A regulatory review provision generally must remain limited to regulatory approval purposes, as authorized by the WTO panel (see above). For LDCs, which are not restricted before 2016 by Article 30, TRIPS Agreement and related WTO jurisprudence (as regards pharmaceutical products), it is advisable that they design their regulatory review exceptions in a TRIPS-compliant manner, so as to avoid complicated rewriting of these provisions after 2016.

Provisions allowing for the use of patented inventions for regulatory approval purposes may be given various scopes. In particular:

- The exception could be limited to marketing approval requests in the national market only. Alternatively, it could extend to requests made within a certain region (such as a regional trade agreement) or even the entire world. This would authorize production of medicines samples in the domestic territory to be used for approval purposes abroad.<sup>343</sup> The bigger the geographical area covered, the higher the economic incentive for a domestic generic producer to engage in large-scale production for possible exportation of pharmaceuticals after expiry of the respective national patents.
- The exception could be limited to acts directly related to the actual marketing approval request. Alternatively, it could also cover uses of the patented substance in the course of the pre-clinical trial phase (referring to acts “reasonably related to”

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<sup>341</sup> In this context, it should again be noted that as of June 2002, 73 per cent of patent invalidation claims initiated by generic producers in the United States had been successful, see United States FTC Study, p. 16. Between 2000 and 2007, generic competitors prevailed in 62 per cent of the final judgments rendered by European courts in patent litigation cases between originator and generic companies. The vast majority of these cases were initiated by originator companies. See EC Pharmaceutical Sector Inquiry, Executive Summary, p. 11.

<sup>342</sup> Under Regulation (EC) No. 726/2004 and Directive (EC) No. 2001/83, patent linkage is considered unlawful in the EU. Absent any express provisions in Indian domestic law, the New Delhi High Court in August 2009 in *Bayer Corp. & others vs Union of India & others* (WP(C) No. 7833/2008) decided that there was no linkage requirement in Indian law, and that the Indian drug regulatory authority may therefore grant marketing approval for generic products without verifying the patent status of the approved drug. The decision is available at <http://lobis.nic.in/dhc/SRB/judgement/18-08-2009/SRB18082009MATC78332008.pdf>.

<sup>343</sup> For the use of the produced substance in the territory of the other country, the generic producer would have to rely on a corresponding regulatory review exception in that country’s domestic law, if the substance is on-patent in that country.

marketing approval procedures). As indicated above, the United States Supreme Court in its *Merck v. Integra Lifesciences* Decision<sup>344</sup> interpreted the United States regulatory review exception as authorizing the use of patented inventions for the purpose of conducting research with respect to drugs as to which there is some reasonable prospect that an application for marketing approval may be submitted, regardless of whether an application is, in fact, eventually submitted or successful.<sup>345</sup> This option has important implications for generic producers, who may depend on the availability of patented materials not only for the purpose of proving bioequivalence but also during the early phases of pharmaceutical R&D. For example, competitors may be interested in identifying the potential of a patented compound for new medical indications (provided the original patent does not cover all possible uses of a compound).<sup>346</sup> In amending their patent legislation, WTO members could therefore be guided by the United States regulatory review provision as interpreted by the United States Supreme Court.<sup>347</sup>

### 3.1.4 Other possible exceptions

A number of other possible exceptions, relevant to the promotion of local pharmaceutical production, may be interesting to some developing countries and to LDCs. We will note these in passing.

- **Medical practitioner exception:** as noted above, Article 27.3 (a) of the TRIPS Agreement authorizes members to exclude methods of treatment from patentability, and developing countries will want to seriously consider this option. An alternative view, however, favoured by the United States and the Australian Law Commission, is to hold that patent incentives to medical treatments are too important to exclude them from eligibility. Instead, while broadly allowing the patentability of medical tools and techniques to encourage investment in R&D, the United States has adopted a narrow exception to shield medical practitioners (and, for example, the hospital employing them) from patent infringement when carrying out “pure medical methods”.<sup>348</sup> This exception would “cover an act such as making a surgical incision at a particular location but would not cover the use of a patented tool for making that same incision.”<sup>349</sup> In Australia, questions have also been raised concerning the need for a “new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment.”<sup>350</sup> It is worth noting that the United States approach assumes that patients are able to afford the patented tools and interventions that a practitioner might wish to use. The opposite may be true in

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<sup>344</sup> 125 S. Ct. 2372 of 13 June 2005.

<sup>345</sup> See Abbott, 2006, p. 8.

<sup>346</sup> In the *Merck v. Integra Lifesciences* case, Merck used compounds patented by Integra Lifesciences in order to find out more about potential new medical indications, but abandoned these activities as the patented substance revealed unpromising in this regard. Integra sued Merck for patent infringement. See Garrison, p. 58. A more narrow reading of the United States regulatory review exception would have found Merck liable for patent infringement, as its use of the patented substance never actually contributed to a request for regulatory approval.

<sup>347</sup> See 35 USC§ 271(e) of the United States Patent Act.

<sup>348</sup> Garrison, p. 61.

<sup>349</sup> Ibid.

<sup>350</sup> Ibid, p. 62, quoting the Australian Law Reform Commission.

developing countries, where competition would lower prices.<sup>351</sup> In any event, the United States has justified its use of this exception (in Section 287 (c) of its patent law) under Article 30 of the TRIPS Agreement in response to questions at the Council for TRIPS.<sup>352</sup> Presumably, this option remains open to interested developing countries as well.

- **Teaching exception:** An exception for teaching purposes has been integrated into the laws of Argentina, Brazil and India that deal with experimental use.<sup>353</sup> Other developing countries may wish to consider this example.
- **Stockpiling for medical emergencies:** A policy proposal has been made to enable countries facing the threat of pandemic diseases to import and stockpile generic versions of patented medicines in case of future need. Under this proposal, importing countries would pay little more than the marginal cost of production for the privilege of stockpiling emergency supplies. “If the generic medicines did ever actually have to be used though, then the proposal requires that adequate compensation be paid to the patent holder.”<sup>354</sup> The objective here would be to prepare for public health emergencies while ensuring that patent holders would receive proper compensation if the emergency materialized. The view has been expressed that such a provision could be reconciled with some existing precedents that are deemed valid under Article 30, TRIPS Agreement.<sup>355</sup> Developing countries may accordingly wish to take this proposal into consideration.
- **Humanitarian use:** Proposals have also been made to allow States to limit the rights of patentees to commercial activity, while establishing a carve-out for certain not-for-profit activities such as humanitarian emergencies, to be carried out under an appropriate exception.<sup>356</sup> University technology transfer offices in some developed countries have already begun to reserve rights to the results of government-funded research, patented by the universities and licensed to the private sector, in order to preserve opportunities for licensing to developing countries on differential and preferential terms. Whether these or other practices will evolve into a formal exception adopted by governments remains to be seen.

## 3.2 Parallel imports

### 3.2.1 Background

Pharmaceutical companies often sell their products at different prices in different areas of the world, depending to a large extent on what the market will bear. Parallel importers take advantage of the price difference between countries. They purchase certain IPR-protected products at low price in a low-price country and import them into high price countries,

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<sup>351</sup> Ibid, p. 61.

<sup>352</sup> Ibid, p. 62.

<sup>353</sup> Ibid, p. 66.

<sup>354</sup> Ibid, p. 76, citing a proposal of J. Love in the *Financial Times* of 28 October 2005.

<sup>355</sup> Ibid, p. 76, with further explanation.

<sup>356</sup> Ibid, p. 77.

undercutting the local price set by the IPR holder. The low-priced products are imported in parallel to the official channels of distribution established by the IPR holder (in this context the holder of a pharmaceutical patent). It is important to note that parallel imports are not counterfeits; they are original products of the patent holder sold by himself or an authorized person on a given market, and purchased and subsequently re-sold legally by a third party. Upon the first sale of the patented product, the patent holder loses the right to control the further distribution and resale of that particular product; the idea being that through the first sale, the patent holder has been sufficiently rewarded for his/her inventive efforts and his/her exclusive selling and using rights in the product are therefore exhausted (commonly referred to in EU countries as “exhaustion doctrine”, or “first sale doctrine” in the United States).<sup>357</sup>

During the Uruguay Round of Multilateral Trade Negotiations, some developing countries adopted the position that exclusive distribution rights should also be exhausted in case the protected product is put on the market on the basis of a compulsory license, i.e. without the authorization of the patent holder.<sup>358</sup> This is contrary to the understanding of IPR exhaustion in developed country legal traditions, which make exhaustion dependent on the right holder’s consent.<sup>359</sup> On the other hand, this approach has been followed by a number of developing countries in recent domestic IP legislation.<sup>360</sup>

The first sale of a patented product could occur either in the country for which the patent has been granted, or abroad. Domestic marketing of the patented product will in any case exhaust the domestic exclusive using and selling rights. An important issue arises when the first marketing occurs abroad. In this case, the concept of “international exhaustion” prescribes that the using and selling rights available under the domestic patent will be exhausted as in the case of domestic marketing.<sup>361</sup> By contrast, the concept of “national exhaustion” limits

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<sup>357</sup> A patent confers upon its holder a bundle of different exclusive rights: the rights to exclude others from making, using, offering for sale, selling, or importing the patented product (Article 28.1, TRIPS Agreement). As a result of patent exhaustion, the patent holder only loses those exclusive rights related to the distribution of the particular product he has marketed; he may no longer exclude others from **using, offering for sale, selling, or importing** that particular product. By contrast, he may still exclude others from **making** the product: exhaustion does not affect his exclusive right in the invention as such (as opposed to the distribution of a particular product). Purchasers of patented products may therefore resell them, but not copy them for commercial purposes.

<sup>358</sup> See UNCTAD-ICTSD Resource Book, p. 102. Due to such fundamental differences in opinion, the TRIPS Agreement contains no binding definition of what constitutes “exhaustion”.

<sup>359</sup> This approach has also been adopted under the 1989 Treaty on Intellectual Property in Respect of Integrated Circuits (Article 6.5, referring to marketing activities by, or with the consent of the right holder). See also footnote 13 to Article 51, TRIPS Agreement, on the obligation to adopt certain border measures in cases of trademark counterfeiting and copyright piracy. Exempted from this obligation are goods put on the market in another country by or with the consent of the right holder. There is no reference to goods put on the market in another country on the basis of a compulsory license.

<sup>360</sup> See, for example, India’s Patents Amendment Act (2005), No. 15 OF 2005, Section 58, introducing the following amendment:

“In section 107A of the principal Act,—

(b) in clause (b), for the words “who is duly authorised by the patentee to sell or distribute the product”, the words “who is **duly authorised under the law** to produce and sell or distribute the product” shall be substituted.” (emphasis added).

See also comparable legislation in Kenya (Section 37 of the Industrial Property Regulation 2002); Lao PDR (Article 100 of the Decree Of the President Lao People’s Democratic Republic On the Promulgation of the Intellectual Property Law); Viet Nam (Article 125.2/b, Law on Intellectual Property, No. 50/2005/QH11); and Tanzania-Zanzibar (Section 12 (4)(a) (i), Act No. 4 of 2008).

<sup>361</sup> Under the international exhaustion doctrine, the first sale of a product abroad will only exhaust the domestic patent if the respective product is protected by a corresponding patent in the country of first sale. Otherwise, the patent holder enjoys no exclusivity in the country of first sale, thus the first marketing there cannot be treated as

exhaustion to the domestic market and first sales outside the country for which the patent has been granted will not affect the existence of the domestic patent. Finally, the concept of “regional exhaustion” as practiced in the EU provides that first sales of the patented product in any EU member State will exhaust a national patent; first sales outside the EU will not.

Thus, parallel imports are only possible if the patentee’s use and sales rights are exhausted in the country destined for importation. In the pharmaceutical context, where price differences between countries may be considerable, parallel imports constitute an important means to provide access to low-priced medicaments by developing countries. In addition, they may provide an important source of affordable pharmaceutical substances needed by generic manufacturers for their own production. For example, the exhaustion of patents rights in active pharmaceutical ingredients (APIs) will enable local manufacturers to use these APIs in the production of pharmaceutical end products.<sup>362</sup> This being said, producers using APIs to copy existing products still need to avoid infringements of any separate patents existing on the finished product, despite the exhaustion of the patent on the APIs.

It has been argued that the authorization of parallel imports would discourage patent holders from selling their products at lower prices in developing countries, for fear of importation of such products into developed country markets. However, this can be avoided by the adoption in developed countries of a regime of regional or national patent and trademark exhaustion, thus providing the patent holder the right to prevent cheap imports from developing countries. Most developed countries have such mechanisms in place.

It is true that the existence of parallel imports among developing countries may encourage patent holders to phase out differential pricing and instead resort to uniformly high prices for the entire developing country market, thus limiting drugs affordability to the affluent parts of these countries’ populations. The objective would be to prevent parallel imports to developed countries, where such imports would prevent the patent holders from reaping their main benefits. While the legal assessment of such behaviour would to a great extent depend on the merits of the individual case, a July 2010 judgment by the European General Court (EGC)<sup>363</sup> put severe limitations on market-dominant companies in the use of their dominant position to curtail parallel imports.<sup>364</sup> The judgment, which is explained in Section 3.4 (Control of patent

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equivalent to the first sale on the domestic market. Note that the European Court of Justice (ECJ) has admitted parallel imports within EU member States even where the product at issue was not patented in the (EU) country of first sale. See joint cases C-267/95 and C-268/95 *Merck & Co Inc. and others v Primecrown Ltd. and others and Beecham Group plc. v Europharm of Worthing Ltd.* of 5 December 1996. The rationale for this approach, which deviates from classical patent law, has been the overall importance attached by the ECJ to the principle of free circulation of goods in a common market. The same could apply to some developing country regional agreements, such as, for instance, the East African Community (EAC), which is scheduled to form a common market as of 2010. See UNCTAD, “Comparative Study of Provisions of EAC Partner States’ Patent Laws Reflecting TRIPS Flexibilities Relevant for the Access to Medicines”, Geneva, 2008 (on file with the authors). The study was prepared for Germany’s technical cooperation agency GTZ, upon request from the Secretariat of the EAC.

<sup>362</sup> Note that patent exhaustion in this case would not enable the local producer to start making its own APIs as a copy of the imported API, because the exclusive right of “making” (see Article 28.1(a), TRIPS Agreement) is not affected by exhaustion. By contrast, the imported APIs as such may be used in the pharmaceutical production process.

<sup>363</sup> Until the entry into force of the EU’s Treaty of Lisbon on 1 December 2009, this court was known as “Court of First Instance”.

<sup>364</sup> See EGC, Case T-321/05 of 1 July 2010, *AstraZeneca v. European Commission* (available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=T-321/05&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>).

abuse and anti-competitive licensing practices) below, makes clear that dominant companies, while they cannot be expected to protect the interests of their competitors, must nevertheless base their actions on legitimate interests and competition “on the merits”.<sup>365</sup> The sole purpose of limiting competition through the exclusion of parallel imports may constitute an abuse of dominance under European law. There should be a legitimate reason for any activity of a dominant market player, such as the wish to increase the competitiveness of its own product (rather than reducing the competitiveness of others’ products).

Another argument advanced against the use of parallel imports has been that parallel trade will deprive needy patients in the low-price country of essential medicines.<sup>366</sup> However, there do not seem to be any reasons why the patent holder could not simply replenish the market of the low-price country by delivering greater quantities of her/his products, unless there is an exceptionally difficult infrastructure. Another point of criticism is that parallel traders would pocket the majority of the price difference rather than offering genuinely lower prices to patients.<sup>367</sup> The risk of such practice is reduced by the number of parallel traders competing in the market. The higher their number, the lower is the probability that parallel importers will pocket the bulk of the price difference, as such practice undermines the very basis of their competitiveness in the high-price market.

The most serious problem linked to the authorization of parallel imports is that it may open up ways for abuse. Channels of delivery that are not sufficiently supervised by the patent holder may be used not only for the delivery of high quality originator drugs, but also for counterfeit products to reach the target country’s patients. This is particularly problematic for many developing countries where there are sizeable informal markets for pharmaceuticals. Seeking to monitor the quality of incoming parallel trade may strain the capacities of authorities in developing countries and particular in LDCs.<sup>368</sup> The question arises to what extent these potential abuses outweigh the potential benefits generated by parallel imports in terms of medicines availability. There is no general answer, as the result of this cost-benefit analysis depends on the gravity of the counterfeit problem in a given country and the country’s ability to monitor the quality of imported drugs. In addition, developing countries and LDCs should make effective use of technical assistance programs to fight counterfeit drugs.

Considering the downward effect of parallel imports on drugs prices, the London-based, independent Commission on Intellectual Property Rights (IPR Commission) in its 2002 report recommended that developing countries seeking to promote access to medicines “should aim to facilitate parallel imports in their legislation.”<sup>369</sup> The Commission also recommended that “developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries.”<sup>370</sup> Similar recommendations with respect to the treatment of parallel imports in developed and developing countries were subsequently adopted in the 2006 CIPIH Report.<sup>371</sup> Under Article 6 of the TRIPS Agreement and Paragraph 5 (d) of the Doha Declaration on the TRIPS

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<sup>365</sup> See Freshfields Bruckhaus Deringer LLP, “AstraZeneca: the EU General Court extends categories of abuse”, Briefing, July 2010 (available at <http://www.freshfields.com/publications/pdfs/2010/July10/28415.pdf>).

<sup>366</sup> See Noehrenberg, pp. 181-182.

<sup>367</sup> Ibid, p. 181.

<sup>368</sup> Noehrenberg, p. 181, referring to an October 1997 letter from the Director of the Kenyan National Quality Control Laboratory to the Director of the South African Medicines Control Council.

<sup>369</sup> See Commission on Intellectual Property Rights, p. 42.

<sup>370</sup> Ibid, p. 41.

<sup>371</sup> CIPIH Report, p. 124, paragraph 4.19.

Agreement and Public Health, WTO members are free to admit or to prohibit parallel imports in their domestic legislation, subject to non-discriminatory treatment.<sup>372</sup>

Even where parallel imports are authorized, patent holders may still seek to prevent them through contractual obligations. For example, patent holder A authorizes his distributor B to sell the patented product only to authorized retailers/pharmacies in B's home country and not to sell the product to parallel trader C. Such contractual limitations of parallel importations have been expressly referred to in Free Trade Agreements, such as the United States FTAs with Australia and Morocco, respectively.

### **3.2.2 Policy options**

The TRIPS Agreement contains no binding definition of parallel imports/exhaustion. A WTO member government is free to allow or disallow parallel imports, taking into account the following:

- Parallel imports may contribute to the availability of affordable end products as well as pharmaceutical ingredients, such as APIs, which local producers may need in their production process. Producers using APIs to copy existing products still need to avoid infringements of any separate patents existing on the finished product, despite the exhaustion of the patent on the APIs.
- In order to enable parallel imports, Governments may provide that the rights under the patent shall not extend to articles put on the market anywhere in the world with the consent of the patent holder.
- Countries seeking to promote parallel imports through systems of international or regional exhaustion of patent rights need to be aware of some potential non-patent issues that could affect the effectiveness of their legislation. In particular, it may be advisable to also design a regime of international or regional trademark exhaustion. Otherwise, imports of a drug in which the domestic patent distribution rights have been exhausted might still be rejected at the border for lack of trademark exhaustion (where only national exhaustion is provided for). To avoid such problems, the importer may obviously repackage the imports, and possibly even use his own brand to indicate the importer.<sup>373</sup> But the economic feasibility of such strategy will depend on the awareness among consumers that the new package actually contains originator drugs at the usual quality, which are being distributed by a competitor.
- Countries authorizing parallel imports need to be aware of the potential difficulties in differentiating high quality parallel imports from counterfeit drugs. Customs authorities need to have the capacity to detect counterfeit products and prevent their marketing.
- Finally, governments need to be aware that the parallel importation of affordable finished pharmaceutical products may undercut efforts to promote local producers, to the extent that the latter cannot afford production at competitive prices. Governments should carefully consult with stakeholders to examine possibilities, through tariff measures, to lower the costs of imported raw materials and APIs used by local producers.

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<sup>372</sup> For further discussion, see UNCTAD-ICTSD Resource Book, pp. 92 ff.

<sup>373</sup> A trademark gives its holder the right to prevent the use by a competitor of identical or similar signs, but may not prevent the competitor from using his own distinct trademark. See Article 16.1 of the TRIPS Agreement.



### 3.3 Compulsory licenses, including government use

#### 3.3.1 Background

The term “non-voluntary,” or “compulsory” licensing refers to the practice by a government to authorize itself or third parties to use the subject matter of a patent without the authorization of the right holder for reasons of public policy. In other words, the patentee is forced to tolerate, against his/her will, the exploitation of his/her invention by a third person or by the government itself. In these cases, the public interest in broader access to the patented invention is considered more important than the private interest of the right holder to fully exploit his/her exclusive rights.<sup>374</sup> Compulsory licensing is addressed under Articles 31 and draft 31*bis* of the TRIPS Agreement.

Existing WTO jurisprudence suggests that when tensions arise between the members’ efforts to provide domestic public goods, such as the need to maintain an adequate public health system, and the private rights of patentees, members should look to both the codified exceptions to those rights under TRIPS Article 30 and to the broad possibilities for imposing compulsory licenses under TRIPS Articles 31 and 31*bis*, before invoking still untested claims for waivers under Articles 7 and 8.1.<sup>375</sup> In addition, Articles 8.2 and 40.2 of the TRIPS Agreement leave WTO members broad latitude to regulate the interface between their domestic competition laws and international standards of intellectual property protection.<sup>376</sup>

This framework means that policymakers responsible for the provision of such essential public goods as education, public health, the environment, competition, and scientific research need to understand the full range of options available under Articles 31 and draft 31*bis* of the TRIPS Agreement.<sup>377</sup> These provisions regulate the grounds for, and conditions of, imposing compulsory licenses on patented products and processes.<sup>378</sup>

Long before the negotiation of the TRIPS Agreement, State practice developed at least six prototypical types of compulsory licenses that are widely recognized around the world in one form or another, and they are all fully consistent with Articles 31 and draft 31*bis* of the TRIPS Agreement. They are:

1. Compulsory licenses imposed to rectify *violations of competition law* (antitrust law).
2. Compulsory licenses imposed to rectify *abuses of the patentee’s exclusive rights*, which may or may not rise to the level of antitrust violations.

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<sup>374</sup> J.H. Reichman with C.H. Hasenzahl, “Nonvoluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the United States of America”, *UNCTAD-ICTSD Issue Paper* No. 5, Geneva 2003, p. 1. [hereinafter Reichman/Hasenzahl, Overview].

<sup>375</sup> See e.g., *Canada - Patent Protection of Pharmaceutical Products*, Report of the Panel.

<sup>376</sup> See generally K.E. Maskus and J.H. Reichman (editors), “International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime”, Cambridge University Press, 2005, and in particular chapters by Drexler, Ullrich, Fox, Fink, Janis, and Ghosh on “The Role of Competition Law”.

<sup>377</sup> See generally K.E. Maskus and J.H. Reichman, “The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods”, in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*, pp. 3-45.

<sup>378</sup> See generally Reichman/Hasenzahl, Overview; “Nonvoluntary Licensing of Patented Inventions: The Canadian Experience”, *UNCTAD-ICTSD Regional Research Agenda*, Geneva, 2002 [hereinafter Reichman/Hasenzahl, Canadian Experience] (available at [www.iprsonline.org/unctadictsd/docs/reichman\\_hasenzahl\\_Canada.pdf](http://www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl_Canada.pdf)).

3. Compulsory licenses issued in the *public interest*, to address environmental, public health, national security or economic development concerns by promoting third-party production of the patented products at lower prices and/or greater quantities than are otherwise available.
4. Compulsory licenses issued on behalf of owners of *dependent patents*, that is, to allow holders of improvement patents to make use of dominant patents that would otherwise block technical progress.
5. Compulsory licenses imposed by governments to permit them and their contractors to make non-commercial public use of the patents without the consent of the rights holders (*government use*).
6. A new compulsory license for the *exportation of pharmaceutical products* to countries that lack the capacity to manufacture needed drugs under their own compulsory licenses (draft Article 31*bis* of the TRIPS Agreement).<sup>379</sup>

Sometimes these rationales are combined in a single statutory formula, as for example, when a country combines the public interest rationale with abusive conduct as grounds for a compulsory license.<sup>380</sup>

The six types of compulsory licenses listed above represent current State practice, but constitute by no means an exhaustive list of substantive grounds upon which members may base a decision to grant a compulsory license. Members are in principle free under the TRIPS Agreement to issue a compulsory license on grounds not included in the above categories. In this context, the question has arisen whether under the TRIPS Agreement, a member may grant a compulsory license in cases where the patent holder fails to work the patent in the territory of the country for which the patent is granted, but chooses to supply the local market through imports (“local working requirement”). This issue is controversial.<sup>381</sup> The Paris Convention in Article 5A(2) authorizes countries of the Union to provide for compulsory licenses in case of failure by the patentee to work the patent (e.g. to produce medicines locally, rather than importing them<sup>382</sup>). The question at issue is whether the non-discrimination requirement under Article 27.1, TRIPS Agreement was intended to supersede the authorization of local working requirements under Article 5A(2) of the Paris Convention.<sup>383</sup> The negotiating history of the TRIPS Agreement indicates that countries participating in the

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<sup>379</sup> See J.H. Reichman, “Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement”, paper presented to the American Association of Law Schools Mid-Year Workshop on Intellectual Property, Vancouver, Canada, June 14, 2006.

<sup>380</sup> See e.g., Reichman/Hasenzahl, Canadian Experience.

<sup>381</sup> See UNCTAD-ICTSD Resource Book, pp. 480-482. For an overview of the literature, see M. Halewood, “Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law”, *Osgoode Hall Law Journal*, Vol. 35, No. 2, 1997, pp. 243-287 [hereinafter Halewood], p. 250, fn. 9. The basic argument against the TRIPS-conformity of local working requirements is that such requirement would discriminate against patent holders who choose to supply the local market through importation of the patented product, rather than local production, in alleged contradiction of the non-discrimination requirement in Article 27.1, TRIPS Agreement.

<sup>382</sup> See G.H.C. Bodenhausen, “Guide to the Application of the Paris Convention for the Protection of Industrial Property”, United International Bureaux for the Protection of Intellectual Property, Geneva, 1968 [hereinafter Bodenhausen], p.71: “Normally, working a patent will be understood to mean working it industrially, namely, by manufacture of the patented product, or industrial application of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as ‘working’ the patent.”

<sup>383</sup> See UNCTAD-ICTSD Resource Book, p. 482.

Uruguay Round negotiations did not agree on this issue.<sup>384</sup> By contrast, the history of patent law reveals that patents were traditionally seen as a vehicle to promote a country's domestic industries.<sup>385</sup> The exclusion of a local working requirement through the TRIPS Article 27.1 non-discrimination requirement has been criticized in the literature as reversing this patent objective, resulting in the protection of foreign assets at the cost of domestic technological development.<sup>386</sup> In addition, it has been pointed out that Article 2.1, TRIPS Agreement, obligates members to comply with the substantive provisions of the Paris Convention, *inter alia* its Article 5A(2), which qualifies failure to work a patented invention as a way of IP abuse, which in turn may be addressed through appropriate measures under Article 8.2, TRIPS Agreement.<sup>387</sup> While such measures must not be in contradiction with the TRIPS Article 27.1 non-discrimination requirement, the use of a local working requirement to ensure the production of affordable medicines does not appear to be based on an improper purpose as implied by the term "discrimination". Where local production of a patented drug promises to be cheaper than importation (at least in the medium term), thus enhancing the population's access to that drug, it would seem inappropriate to consider the different treatment of imports and locally produced drugs as "discrimination" within the meaning of TRIPS Article 27.1. Different treatment of importing patent holders on the one hand and locally producing ones on the other hand seems justified for *bona fide* purposes.<sup>388</sup>

It needs to be highlighted that the above arguments have not as yet been tested before a WTO panel.<sup>389</sup> The United States in 2000 initiated WTO dispute settlement proceedings against Brazil on the basis of the latter's domestic industrial property law, which subjects patents to compulsory licensing if the patented invention is not manufactured locally, but imported. But the United States later withdrew the complaint, agreeing with Brazil on bilateral consultations in case the Brazilian Government intends to invoke the local working ground against a United States patent holder.<sup>390</sup> Thus, countries that are decided to introduce a local working requirement need to be aware of the risk of facing WTO dispute settlement proceedings for alleged infringement of Article 27.1, TRIPS Agreement, despite the fact that a number of solid arguments seem to support the legality of such a requirement for public health purposes.

Members' freedom to determine the grounds upon which compulsory licenses may be granted has been reiterated in the Doha Declaration on TRIPS and Public Health, which states in its paragraph 5 (b) that

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<sup>384</sup> Ibid, pp. 464-465.

<sup>385</sup> See Halewood, p. 260; UNCTAD-ICTSD Policy Discussion Paper, pp. 33-34.

<sup>386</sup> Halewood, *ibid*.

<sup>387</sup> Ibid, p. 257.

<sup>388</sup> For this line of argumentation, see UNCTAD-ICTSD Resource Book, p. 481, referring to a WTO panel according to which "discrimination" is a "normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment" (*Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R, Report of the Panel of 17 March 2000, para. 7.94). This definition does not apply to measures taken to promote access to life-saving medicines. Some of the stakeholders present at the UNCTAD peer review meeting did not agree with this interpretation of Article 27, TRIPS Agreement, referring to the proviso in Article 27 that there should be no discrimination as to whether products are imported or locally produced. However, Article 27 does **not** contain a positive obligation to treat imports and local products equally; it merely stipulates a negative obligation to abstain from **discriminating** between local products and imports. To the extent that a state intervention is non-discriminatory (e.g. where justified through *bona fide* purposes), it may well apply different treatments to local products on the one hand and imports on the other.

<sup>389</sup> The *Canada - Patent Protection of Pharmaceutical Products* Panel did not specify what it meant by "*bona fide*" purposes.

<sup>390</sup> For details, see UNCTAD-ICTSD Resource Book, pp. 481-482.

“Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”

Rather than imposing substantive limitations, Article 31 sets up procedural requirements that members need to follow when issuing a compulsory license. In general, all compulsory licenses are subject to the same procedural requirements (see Section 3.3.2 for details). However, these requirements may be relaxed for the following types of compulsory license as mentioned by the TRIPS Agreement:

- Compulsory licenses used to rectify *violations of competition law*;
- Compulsory licenses addressing cases of *national emergency*;
- Compulsory licenses addressing *other cases of extreme urgency*; and
- Compulsory licenses issued for *public non-commercial use*.

The following should be noted in this context:

- Compulsory licensing to remedy *abuses of patent rights or competition law violations* is subject to a number of procedural and administrative requirements that require time and effort, but such licenses are then exempt from other restrictions under Article 31, TRIPS Agreement, such as a duty to negotiate with the patentee, and may result in little or no compensation for the patentee.<sup>391</sup>
- Cases of public non-commercial use are also referred to as “government use” licenses, a term which is not expressly used under Article 31 of the TRIPS Agreement.<sup>392</sup> In the case of a government use license, the licensee may be a government agency or a private contractor acting for or on behalf of the government.<sup>393</sup> By contrast, in other cases, which may include licenses issued to promote the public interest, the compulsory licensee is an independent party acting on his/her own behalf and on his/her own account.
  - For example, if a government intends to increase the availability of otherwise unaffordable medicines, it may choose to invoke the public interest of health to justify the grant of a compulsory license to a private party manufacturing the needed drugs on his/her own behalf and for his/her own account and benefit, at the royalty rate agreed in the license. This would be an “ordinary” compulsory license issued to an independent private party in the public interest. The government may alternatively choose to hire a private contractor who will produce the drugs for the government’s own public health programme. This would constitute a government use license issued to a contractor who acts for or on behalf of the government, thus relaxing the requirements for the granting of the license (Article 31 (b) of the TRIPS Agreement). For example, in October 2009, the President of Ecuador issued a decree declaring access to priority medicines to constitute a matter of public interest.<sup>394</sup> This declaration under Decision 486 of the Andean Community opens up the possibility for the government to issue compulsory licenses on certain medicines, on a case-by-case basis, and against the payment of royalties to the patent holder. At the time of writing, the Government of Ecuador had not yet specified the nature of the envisaged licenses (i.e. on public interest grounds or for government use).

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<sup>391</sup> TRIPS, Article 31 (k).

<sup>392</sup> For details, see below Section 3.3.2.

<sup>393</sup> UNCTAD-ICTSD Resource Book, p. 471.

<sup>394</sup> See Ecuador Decree No. 118 of 23 October 2009 (available at: <http://www.sigob.gov.ec/decretos/>).

- Under a government use license, the private contractor working for the government is not precluded from making a profit.<sup>395</sup>
- The reason for these relaxed requirements may be explained by the *rationale* behind the concept of government use licenses: the sovereign power inherent in every nation state, represented by the government of that state, may not be blocked in its own activities by private property rights. This being said, the TRIPS Agreement obligates members to make available to the aggrieved patent holder remedies to challenge the validity of the decision to grant a compulsory license, including government use licenses, and an obligation to provide adequate remuneration for the use of the patent (for details, see Sections 3.3.2.7 and 3.3.2.8).

Recourse to compulsory licensing typically occurs when governments perceive that patent holders have not satisfied the market demand for a given product by supplying sufficient quantities at prices that broad sectors of the public can afford. Remedying such problems can be seen as meeting both public interest goals and problems of abuse, both of which derive their roots from Article 5A of the Paris Convention, as incorporated into TRIPS.<sup>396</sup> In this connection, a respected commentator on Article 5A, Paris Convention has observed that, besides a failure to work the patented invention, member States are free to issue a compulsory license “in other cases where the public interest is deemed to require such measures”, such as public health.<sup>397</sup> Other examples of abuses recognized by state practice “may exist in cases where the owner of the patent [...] refuses to grant licenses on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of the patented product, or demands excessive prices for such products, the member State [of the Paris Convention] are free to define these, and other, *abuses*.”<sup>398</sup> Finally, another ground for abuse that has recently been used to trigger compulsory licensing is a patentee’s refusal to deal.<sup>399</sup>

It bears emphasizing that in most cases the mere threat of a compulsory license when backed up with political will and the capacity to procure the drugs in question through alternative means, often suffices to persuade patentees to negotiate a significant price reduction.<sup>400</sup> In that event, the outcome may be characterized as a semi-voluntary form of price discrimination or as a form of price control, rather than a case of compulsory licensing as such. The Brazilian experience in this regard may prove instructive for other developing countries, in that – until recently – the Government managed to obtain favourable terms without imposing such a license.<sup>401</sup>

At the same time, however, the Brazilian Government has shown that in case it deems the mere threat of a compulsory license as insufficient to meet public health objectives, it is ready

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<sup>395</sup> For details, see below Section 3.3.2.

<sup>396</sup> Bodenhausen, pp. 67-73 TRIPS Article 2.1.

<sup>397</sup> Ibid, p. 70.

<sup>398</sup> Bodenhausen, p. 71 (italics provided).

<sup>399</sup> See below, Section 3.4.2.3.

<sup>400</sup> See Reichman/Hasenzahl, Overview.

<sup>401</sup> See, for instance, A. Jack, “France healthcare: Cut-price HIV drugs drive may spur patents clash”, *The Financial Times* (online edition) 11 August 2006 (available at: [http://www.eiu.com/index.asp?layout=ib3Article&article\\_id=200927405&country\\_id=1350000135&pubtypeid=1152462500&industry\\_id=620001062&category\\_id=&rf=0](http://www.eiu.com/index.asp?layout=ib3Article&article_id=200927405&country_id=1350000135&pubtypeid=1152462500&industry_id=620001062&category_id=&rf=0)), referring to a 2005 agreement between the Brazilian Government and Abbott Laboratories to provide the second-line AIDS therapy Kaletra at a lower price than the company had originally planned.

to actually issue a compulsory license, as was done in April 2007 with respect to Merck's HIV drug Efavirenz. The Government justified the compulsory license with Merck's refusal after negotiations to lower the price for Efavirenz from \$1.57 per patient to 65 cents, the price at which it sells the same drug in Thailand.<sup>402</sup> This was the first time the Brazilian Government actually issued a compulsory license for a patented pharmaceutical product.

One should note that developed countries have made and continue to make extensive use of compulsory licenses to regulate competition, ensure affordable prices, and promote an array of national interests, including security interests. Some developed countries, such as Canada, used systematic grants of compulsory licenses in the past to promote the establishment of a national generic pharmaceutical industry,<sup>403</sup> although the TRIPS Agreement and regional trade agreements have now made such a broad brush approach difficult if not impossible. France has adopted proceedings for expedited compulsory licensing to export patented pharmaceuticals in case of need.<sup>404</sup> The Italian Competition Authority between 2005 and 2007 issued three compulsory licenses on patented pharmaceutical products.<sup>405</sup> Finally, the United States continues to make extensive use of such licenses, particularly for governmental uses of patented inventions.<sup>406</sup>

From a developing country perspective, compulsory licenses may become an important instrument both to promote the wider availability of medicines at affordable prices and to promote the establishment of a generic pharmaceutical industry. One way of using this instrument is to combine procurement activities and/or compulsory licenses of several importing countries for the same essential medicines to create promising opportunities to achieve economies of scale, which is facilitated for LDC-dominated regional trade agreements under draft Article 31*bis*, TRIPS Agreement. This may be of interest to foreign generic suppliers and even to patent holders willing to cooperate with regional agencies in return for reasonable royalties and assured market share.<sup>407</sup>

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<sup>402</sup> A. Jack and R. Lapper, "Brazil Spurns Patent on HIV Drug", *The Financial Times* (online edition), 5 May 2007 (available at: <http://lists.essential.org/pipermail/ip-health/2007-May/011120.html>).

See also Abbott/Reichman.

<sup>403</sup> Canada changed its policy after the entry into force of the North American Free Trade Association (NAFTA) and the TRIPS Agreement. For details, see Reichman/Hasenzahl, Canadian Experience.

<sup>404</sup> The French Parliament has approved the implementation of EC Directive 2004/48/EC on the enforcement of IP rights. Through this implementation, the mechanism of export compulsory licenses defined by EC Regulation 816/2006 has been introduced in the French IP code. This Regulation concerns the exportation of pharmaceutical products to third countries. Apart from this new compulsory license for export purposes, French law provides for two other types of compulsory license that limit distribution of products to the domestic market, see Article L613-16, Loi no. 2004-800 du 6 août 2004 art. 18 Journal Officiel du 7 août 2004.

<sup>405</sup> See the respective press releases available at <http://www.cptech.org/ip/health/c/italy/>, and IP Health Newsletter of 31 March 2007, Vol. 1, No. 2300, Messages 4, 6 and 7. In 2005, the Italian Competition Authority obliged Merck, by way of an injunction, to grant licenses for the manufacture of the active ingredient *Imipenem Cilastatina* (used in treatment of serious hospital infections). The Authority considered the patentee's refusal to grant a license to an Italian domestic producer as an abuse of the patentee's dominant position, because it would delay the market entry of Italian generic producers in other EU members States, where the patent on *Imipenem Cilastatina* had already expired. In 2006, the Authority granted a compulsory license for the production of an active ingredient *Sumatriptan Succinate* (used to treat migraine headaches), considering as abusive the patentee's refusal to grant a license to a domestic producer for the manufacture in Italy of *Sumatriptan Succinate*. Finally, in 2007, the Authority accepted and rendered mandatory a commitment offered by Merck to grant free licenses for the manufacture and sale in Italy of the active ingredient *Finasteride* (used in the treatment of hypertrophy of the prostate). The Authority had considered Merck's original refusal to grant licenses as an abuse of a dominant position. By presenting the above commitment, Merck avoided the imposition of a penalty.

<sup>406</sup> See generally Reichman/Hasenzahl, United States Experience.

<sup>407</sup> For details, see J.H. Reichman, "Procuring Essential Medicines Under the Amended TRIPS Provisions: The Prospects for Regional Pharmaceutical Supply Centers", paper presented to the *Seminar on Intellectual Property*

Key stakeholders in the public health debate, including the European Parliament,<sup>408</sup> stressed the importance of improved implementation of TRIPS flexibilities in respect of compulsory licensing.<sup>409</sup> In addition, the difficulties of those WTO members with insufficient domestic pharmaceutical manufacturing capacities to make effective use of compulsory licenses or government use licenses in the past were addressed by a Decision of the WTO General Council in 2003,<sup>410</sup> on the basis of which the same body, in 2005, agreed to a formal amendment to the TRIPS Agreement.<sup>411</sup> This decision has to be ratified by at least two thirds of WTO's 153 members to make it a permanent amendment of the TRIPS Agreement, replacing the Paragraph 6 Decision.<sup>412</sup> The implications of these decisions are addressed in Section 3.3.2.6.

If the legal constraints and obligations under Articles 31 and draft 31*bis* of the TRIPS Agreement pose no serious obstacles to a government determined to impose a compulsory license on a patented medicine, a potentially far more serious practical limitation could be the fact that the R&D-based pharmaceutical industry in developed countries reportedly relies increasingly on key active ingredients that are produced under outsourcing contracts in developing countries such as China and India. To that extent, the availability of comparable active ingredients may paradoxically be artificially limited, because the potential supplier countries could be unwilling to undermine their profitable relations with the R&D-based pharmaceutical companies, and no other sources of key active ingredients may possess the technical skills and abilities to produce them. At least one practitioner believes this

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*Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines*, UNCTAD, Geneva, 18 Oct. 2006 [hereinafter Reichman, UNCTAD paper].

<sup>408</sup> The European Parliament, in a resolution, encouraged developing countries to use all TRIPS flexibilities, especially referring to compulsory licenses (see No. 8 and 9 of the Resolution P6\_TA-PROV (2007) 0353 of 12 July 2007).

<sup>409</sup> See, for example, A. Jack, "WHO urges poor nations to push for cheaper Aids drugs", *The Financial Times* (online edition), 16 August 2006, referring to a top WHO official addressing the August 2006 International Aids Conference at Toronto. Also, WTO Director-General Pascal Lamy in a keynote speech to the 23rd Assembly of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) on 11 October 2006 said: "[...] Together with the new WTO provision on access to medicine allowing for compulsory licenses by poor countries that do not have any manufacturing facilities, these initiatives [i.e. to waive import duty tariffs on pharmaceutical products] can make an important difference in saving people's life or in ensuring that more people can afford minimum medical treatment. [...]"

<sup>410</sup> "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", Decision of 30 August 2003, General Council, WT/L/540 of 2 September 2003 [hereinafter Paragraph 6 Decision]. This Decision was based on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, which refers to the difficulties of those WTO members with insufficient domestic pharmaceutical manufacturing capacities to make effective use of compulsory licensing.

<sup>411</sup> "Amendment of the TRIPS Agreement", Decision of 6 December 2005, General Council, WT/L/641 of 8 December 2005 [hereinafter TRIPS Amendment Decision]. Until the entry into force of the amendment, the Paragraph 6 Decision will remain a valid legal basis for the facilitated export of drugs to countries in need. It is important to note that from a substantive point of view, the Paragraph 6 Decision and the TRIPS Amendment Decision are essentially the same.

<sup>412</sup> WTO members at the TRIPS Council meeting of October 2009 extended the deadline for such ratification until December 2011. For each of the remaining Members, the Paragraph 6 Decision will continue to apply until each of those Members ratifies the amendment. For an overview of Members that have so far accepted the amendment, see [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

phenomenon to pose a major impediment to the use of compulsory licenses,<sup>413</sup> and more research into this problem and possible remedies seems advisable.<sup>414</sup>

This very issue has become particularly relevant since the compulsory licenses issued by Brazil and Thailand in 2006/07 have elicited threats by the affected pharmaceutical companies to not register their new products in these countries.<sup>415</sup> The impact of such a threat, if carried out, depends on the ability of the authorities in these countries to obtain either the original product, or bioequivalent substitutes of the key active ingredients by their own means or from external sources – such as generic suppliers or a network of universities willing to collaborate in this area – using the flexibilities of the TRIPS Agreement, including draft Article 31*bis*, if necessary and feasible.<sup>416</sup> In this context, one can envision circumstances in which the ultimate costs of obtaining reverse-engineered substitutes for key active ingredients that meet international quality standards could push up the price to be charged consumers near to the levels that might have been negotiated with the patent holder. Here once again, as explained in Section 3.3.3.2, adroit use of pooled compulsory licenses by several cooperating states might attenuate these problems by fostering a negotiated settlement that satisfies all stakeholders.<sup>417</sup>

As to the impact of compulsory licensing, a growing number of developing countries have joined Brazil in integrating the use or threat of compulsory licensing into their national health strategies. These countries include Ecuador, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, South Africa, and Thailand.<sup>418</sup> The Government of Thailand has moved with particular zeal in this direction by issuing a government use compulsory license on a remedy for heart disease in addition to HIV/AIDS drugs (see box 5).

#### **Box 5: Compulsory licensing in Thailand**<sup>419</sup>

In November 2006 and January 2007, the Thai Government announced that it would issue three compulsory licenses for the following pharmaceutical products:

- *Efavirenz* (HIV), patented by Merck;
- *Kaletra* (HIV), patented by Abbott;

<sup>413</sup> See communication from A. Engelberg to J.H. Reichman, 26 October 2006 (on file with the authors).

<sup>414</sup> In order to boost the availability of key active ingredients under such a scenario, S. Chaudhuri underlines the importance of ensuring the presence of sustainable generic production, including inter-generic competition (S. Chaudhuri, “Comments on the UNCTAD draft Reference Guide”, p. 3; on file with the authors).

<sup>415</sup> In early 2007, Abbott Laboratories withdrew applications in Thailand for the registration of a new formulation of the HIV-fighting drug Kaletra (i.e. a heat-resistant version of that drug); the painkiller Brufen; the antibiotic Abbotix; the anti-blood clotting medicine Clivarine; the anti-arthritis drug Humira; the anti-high blood pressure drug Tarka; and the anti-kidney disease drug Zemplar. See A. Ahuja (Associated Press), “Thai Health Groups Urge Abbott Boycott”, IP health newsletter of 21 March 2007. For a critical assessment of such actions from a competition law standpoint, see S. Flynn, “Considering Competition Complaints Against Abbott in Thailand - A Brief Explanation of Potential Legal Arguments”, 23 March 2007 (available at <http://www.wcl.american.edu/faculty/flynn/>); and “Thailand’s Lawful Compulsory Licensing and Abbott’s Anticompetitive Response”, 26 April 2007 [hereinafter Flynn, Thailand’s Lawful Compulsory Licensing] (available at <http://www.wcl.american.edu/faculty/flynn/>). In December 2007, the Thai Trade Competition Commission found that Abbott’s withdrawal of drug registration applications did not constitute a violation of the Thai Trade Competition Act.

<sup>416</sup> See Abbott/Reichman, p. 49, referring to increased difficulties in obtaining the patented ingredients through reverse engineering due to legal restrictions on national research exemptions in the home countries of potential foreign suppliers.

<sup>417</sup> For details, see Reichman, UNCTAD paper.

<sup>418</sup> For a list of countries having issued a compulsory license for public health purposes

<sup>419</sup> See, *inter alia*, ICTSD, BRIDGES Weekly Trade News Digest Vol. 11, No. 3, 31 January 2007.



- *Plavix* (heart disease), patented by Bristol-Myers Squibb & Sanofi-Aventis.<sup>420</sup>

The reason for the authorization of these licenses was the Government's perception that the respective drugs were not made available at affordable prices by the patent holders. According to Thai health officials, the grant of the compulsory license on *Efavirenz* has resulted in important price decreases for the patented medicine, from 58 baht/month (price of the patented drug before the compulsory license was granted) to 24 baht/month (price of the patented drug after the compulsory license was granted). The compulsory license also enabled the introduction of a generic version of *Efavirenz*, at only 7.5 baht/month.<sup>421</sup> The patent holders receive a remuneration of 0.5 per cent of the total sales value of the generic copies.

Unlike most other cases, the compulsory license on *Plavix* covers a non-communicable disease. Governments have heretofore generally focused on using compulsory licenses to promote competition and reduced prices for drugs needed to treat epidemics, such as HIV/AIDS and tuberculosis. However, neither the TRIPS Agreement nor the Doha Declaration on TRIPS and Public Health restrict the use of compulsory licenses to epidemics.<sup>422</sup> The affected pharmaceutical companies criticized the Thai Government for not respecting the obligation provided under Article 31, TRIPS Agreement to enter into negotiations for voluntary licenses prior to the issuance of the compulsory licenses. According to the Thai Government, however, the generic drugs obtained under the licenses are being used for its non-commercial public health programmes. Under Article 31 (b), TRIPS Agreement, the prior negotiations requirement may be waived by a member, *inter alia*, in case of public non-commercial use. While the Thai Government in January 2008 announced the granting of another series of compulsory licenses for medicines to treat various forms of cancer (i.e. *Letrozole* of Novartis for breast cancer; *Docetaxel* of Sanofi-Aventis for breast and lung cancer; *Erlotinib* of Roche for lung, pancreatic and ovarian cancer; and *Imatinib* of Novartis for leukemia),<sup>423</sup> it has at the same time indicated its willingness to collaborate with the pharmaceutical companies, provided the latter lower the prices of a number of the drugs in question.<sup>424</sup> As of December 2008, the compulsory licenses had resulted in price decreases for patented *Docetaxel* (400 baht/month after the grant, as compared to 900 baht/month before the grant) and the availability of a generic version for 37 baht/month, as well as a decrease in the price for patented *Letrozole* (from 7 baht/month pre-grant to 2 baht/month post-grant) and a generic version for 0.1 baht/month.<sup>425</sup>

<sup>420</sup> The text of the licenses may be found at [http://www.wcl.american.edu/pijip/thai\\_comp\\_licenses.cfm](http://www.wcl.american.edu/pijip/thai_comp_licenses.cfm).

<sup>421</sup> For these figures, see "Thailand's Experience with Government-Use Licenses", presentation by S. Wibulpolprasert, Senior Advisor on Disease Control, Ministry of Public Health, Thailand, made at the UNCTAD Symposium on flexibilities in the International Intellectual Property Rules and the Local Production of Medicines for ASEAN Countries, 16-19 December 2008, Arnoma Hotel, Bangkok (on file with the authors) [hereinafter Suwit].

<sup>422</sup> In particular, the Doha Declaration in its paragraph 1 refers to "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." The term "especially" indicates that the scope of diseases covered by the Declaration is not restricted to epidemics.

<sup>423</sup> See "Chaiya gives nod to drug licensing", online news of the Bangkok Post of 11 March 2008.

<sup>424</sup> In the negotiations between the Thai Government and the patentees since late March 2007, the Government has been asking to lower the prices to a maximum of 5 per cent above the price for the generics (IP health newsletter of 26 June 2007, Message 1).

<sup>425</sup> Suwit.

After announcing the grant of the compulsory licenses, Thailand was placed on the Office of the United States Trade Representative's (USTR) Priority Watch List, which leaves it subject to trade reprisals.<sup>426</sup>

Nevertheless, compulsory licensing represents but one tool among several others for addressing public health problems. For example, many developed countries rely primarily on price regulation rather than compulsory licensing to address access to medicines issues.<sup>427</sup> There are also proposals to enable governments or other entities to "buy out" foreign rights to medicines for use in developing countries at prices that would protect all the stakeholders' interests.<sup>428</sup>

Clearly, "selected non-voluntary licenses can yield positive results when used to address emergencies or to remove specific [...] supply bottlenecks. They can [also] be used to prod particular foreign companies into negotiated transactions [...] that adequately respect local needs and conditions."<sup>429</sup> It is finally up to each government to decide on how best to use this instrument while bearing in mind the need to attract private investments in tropical and other so-called "neglected" diseases of particular interest to developing countries. In this context, care must be taken not to ignore the risk premiums that such research-based pharmaceutical development must recoup in order to remain profitable.<sup>430</sup>

In short, "more social benefits may accrue, when foreign and local interests bargain around the TRIPS Agreement to mutually satisfactory, win-win deals" than when either side acts unilaterally.<sup>431</sup> For these and other reasons, it seems advisable for governments to provide for the possibility of issuing compulsory licenses, but to accompany this option with careful negotiating strategies, effective pre-grant patent policies and appropriate use of other public-health related patent exceptions. All of these instruments should be considered of equal importance, rather than relying exclusively on any one of them.

### **3.3.2 Technical Legal Infrastructure**

#### ***3.3.2.1 Grounds for the issuance of a compulsory license***

According to the TRIPS Agreement as interpreted by the Doha Declaration, members are free to determine the *substantive grounds* for issuing a compulsory license. Hence the prior stated practice as summarized above should remain fully applicable, with the reservation that the precise legal status of a compulsory license for local non-working is not altogether certain, as discussed above.

It is particularly important to emphasize the fact that the right to grant such licenses does not depend on a state of emergency or other circumstances of urgency. The TRIPS Agreement in

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<sup>426</sup> For the 2007 USTR Priority Watch List, see <http://www.ustr.gov/sites/default/files/2007-301-PRIORITY%20WATCH%20LIST.pdf>.

<sup>427</sup> See, e.g., Reichman, UNCTAD paper.

<sup>428</sup> See, e.g., Outterson.

<sup>429</sup> Reichman/Hasenzahl, Overview, p. 24.

<sup>430</sup> See, e.g., A.O. Sykes, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha 'Solution'", *Chicago Journal of International Law*, Vol. 3, No. 1, 2002, pp. 47 ff.

<sup>431</sup> Reichman/Hasenzahl, Overview, p. 24.

Article 31 does impose minimum standards concerning certain *procedures and formal requirements* that a member has to respect when intending to issue a compulsory license. These rules will be addressed in the course of the following sections.

### **3.3.2.2 Prior negotiations with the right holder**

Under normal circumstances, the TRIPS Agreement requires a member to make the issuance of a compulsory license dependent on unsuccessful attempts by the applicant for a license to obtain, within a reasonable period of time, the patent holder's consent for the use of the patented invention on reasonable commercial terms and conditions. To define what is "reasonable" in these respects is up to each member and has to be considered by the authority granting the compulsory license. In particular:<sup>432</sup>

- As to reasonable commercial terms and conditions: Questions concerning reasonable terms and conditions turn in the first instance on the amount of the royalty payable to the patent holder; but also on an unreasonably short duration of the license terms; non-disclosure by the patentee of additional technology needed to work the invention; grant backs; tying arrangements and export restrictions imposed upon the licensee.<sup>433</sup>
- As to reasonable period of time: For how much the right holder may prolong the negotiations will depend, *inter alia*, on the purpose of the licensed activity. In cases regarding the production of life-saving drugs, negotiations for a voluntary license may be considered unsuccessful after a shorter period of time than in other cases, such as the production of items for the tourism sector. In the public health context, a negotiation period of 90 days has been suggested.<sup>434</sup>

The requirement of prior negotiations does not apply in the cases of national emergency (including health emergencies<sup>435</sup>), other situations of extreme urgency, in the case of public non-commercial use through government entities ("government use"), and where a compulsory license is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

- Cases of national emergency are usually declared by the government in an official communication. This usually provides the government with the power to rule by decree in areas where it normally depends on parliamentary consent. The reference under TRIPS to "other situations of extreme urgency" makes clear that in order for the prior negotiations requirement to be waived, there is no need for a formally declared state of national emergency.<sup>436</sup> Members are free to provide in their domestic

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<sup>432</sup> See UNCTAD-ICTSD Resource Book, pp. 469-470.

<sup>433</sup> For details on grant backs and tying arrangements see Section 3.4.

<sup>434</sup> See Third World Network, "Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws", Penang, 2003, p. 69 (hereinafter TWN Manual). Some stakeholders at the UNCTAD peer review meeting did not consider 90 days as being a reasonable period of time.

<sup>435</sup> For example, the United States Government in the fall of 2001 considered the production under compulsory license of the anti-anthrax drug Cipro, on which the German pharmaceutical company Bayer holds a patent. Bayer and the United States Government quickly came to an agreement enabling the low-cost mass production of Cipro.

<sup>436</sup> For more details, see UNCTAD-ICTSD Resource Book, p. 471.

legislation that a lack of access to medicines may constitute the basis for a situation of extreme urgency.<sup>437</sup>

- In the absence of an emergency or other situation of extreme urgency, a government is still authorized under the TRIPS Agreement to issue compulsory licenses for public health purposes to meet any public health need as stated under the Doha Declaration on TRIPS and Public Health. In short, no state of emergency is ever needed as a procedural requirement for the issuance of any given compulsory license.<sup>438</sup> A state of emergency constitutes one of the situations that will waive the prior negotiations requirement.
- Public non-commercial use of a patented invention through government entities (“government use”) should not be hampered by protracted negotiations with the patent holder. It has been observed that the terms “public non-commercial use” may be defined in many ways, providing governments with a “flexible concept” of granting compulsory licenses without requiring prior commercial negotiations with the patent holder.<sup>439</sup> The term “public” may refer to the use by, for or on behalf of a government, as opposed to use by an independent private entity. The TRIPS Agreement itself in its Article 44.2 (for details see Section 3.3.2.8) refers to “use by governments” in the context of injunctive relief against compulsory licenses for public non-commercial use. The term “public” may equally refer to the *purpose* of the use, i.e. use for “public” benefit. Uses for private benefit, by contrast, are not encompassed by a government use license; for instance, a license for public, non-commercial use does not limit the patent holder’s exclusive right to sell his drugs to private pharmacies, as opposed to his right to sell exclusively to a country’s public health system. “Non-commercial” may be understood as characterizing the *nature* of the transaction as “not-for-profit” use. It may also be interpreted as referring to the *purpose* of the use, such as the supply with medicines of public institutions that do not function as commercial enterprises. Accordingly, the supply of public hospitals operating on a non-profit basis may be considered “non-commercial” use.<sup>440</sup> This may include cases where the entity working for or on behalf of the government makes a profit. Where this entity is a private operator, it cannot be expected to carry out its activities without any commercial benefits. Otherwise, it would appear difficult for the government to identify a producer that is willing to produce the needed drugs. The right to issue a public non-commercial use license would thus be rendered useless. What is decisive in this context is not the (commercial) **intermediate** activity required to produce the needed drugs, but the non-commercial **end use** of that product by the government, e.g. not-for-profit distribution of medicines through a public health program.<sup>441</sup> From that perspective, it does not make any difference whether the supplier is a private operator or a government-owned entity involved in the production of generic drugs.
- Importantly, prior negotiations may also be waived where a court or administrative body considers a practice by the patent holder as being anti-competitive and has imposed the use of a compulsory license as a remedy. In such a case, moreover, there may be little or no compensation as a penalty.

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<sup>437</sup> J. Love, “Four Practical Measures to Enhance Access to Medical Technologies”, in: *Negotiating Health*, pp. 241-256, p.243.

<sup>438</sup> See UNCTAD-ICTSD Resource Book, p. 471.

<sup>439</sup> *Ibid.*

<sup>440</sup> *Ibid.*

<sup>441</sup> See S. Flynn, *Thailand’s Lawful Compulsory Licensing*, p. 4. Under United States patent law, once the government duly appoints the contractor as its agent, the contractor is insulated from actions for infringement and the patentee must apply to the Court of Federal Claims for compensation. See Act of 25 June 1948, ch. 646, §1, 62 Stat. 941, codified as amended at 28 U.S.C. §1498 (2002).

### **3.3.2.3 Granting authority**

WTO members are free under the TRIPS Agreement to designate an authority for the granting of compulsory licenses. This may be the government or one of its agencies. For example, when Canada allowed licenses of right for the manufacturers of pharmaceuticals, which ended in 1992, application was made directly to the “Commissioner of Patents”.<sup>442</sup>

In the case of compulsory licenses granted in the public interest, the interested party has to file an application for a compulsory license with the designated authority. The authority to issue a compulsory license may also be conferred upon the courts, after litigation between the patent holder and the applicant for a license. From a public health perspective, it seems more appropriate to have a government agency issue the compulsory licenses, as this will save time and resources and involve experts who are familiar with public health issues (such as, for instance, a body in the Ministry of Health, or the competition authority in cases of anti-competitive behaviour).

### **3.3.2.4 Case-by-case approach**

Although members are free to determine the substantive grounds upon which a compulsory license may be granted, the TRIPS Agreement requires that authorization of a compulsory license “shall be considered on its individual merits”. This means that:

- Governments may not grant blanket licenses pertaining to types of industries or enterprises, but must require each individual application to undergo a review process to determine whether the particular procedural and substantive conditions for a compulsory license have been met. For example, a member could not just impose a compulsory license on essential medicines as such, but would have to justify each license in the set.
- This, however, does not prevent a government from establishing a *precondition* enabling the grant of compulsory licenses, which could put a burden on the patent holder to avoid the pre-established condition. For instance, a member may provide in its legislation that the lack of affordable medicines on the domestic market justifies the grant of a compulsory license. The patent holder will then have to demonstrate that a sufficient amount of supplies at affordable prices is actually available to avoid the initiation of the granting procedure for a compulsory license.<sup>443</sup>
- The exact design of the review process is left to a national government’s discretion.

### **3.3.2.5 Scope and duration of the compulsory license**

The TRIPS Agreement provides that the scope and duration of a compulsory license shall be limited to the purpose for which it was authorized. The license shall in general be non-assignable, non-exclusive and shall be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur (Article 31, letters (c) and (g), TRIPS Agreement). In particular:<sup>444</sup>

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<sup>442</sup> See Reichman/Hasenzahl, *Canadian Experience*, p. 8.

<sup>443</sup> See UNCTAD-ICTSD *Resource Book*, p. 468.

<sup>444</sup> *Ibid*, pp. 473-475.

- The fact that the license alone shall be non-assignable does not prevent the licensee from selling or transferring his/her business together with the license.
- The non-exclusiveness of the license means that the licensee may face competition from the patent holder and other (voluntary) licensees.
- The limitation in terms of purpose does not prevent the granting authority from issuing a license of a duration sufficiently long to justify the licensee's investment in production from a commercial standpoint. Otherwise, the purpose of Article 31, TRIPS Agreement, to effectively enable third parties to use the patented substance, would be frustrated.<sup>445</sup> This being said, if during this period the patent holder succeeds in demonstrating that the circumstances which led to the grant of the compulsory license have ceased to exist and are unlikely to recur, the compulsory license would have to be revoked. For example, the initial grant of the license could establish the minimum term necessary for the licensee to recover his/her costs and earn a reasonable return, and also provide for automatic extensions of the license. The patent holder during the minimum term and during the additional period may prove that the circumstances which led to the grant of the compulsory license have ceased to exist and are unlikely to recur.
- National rules on compulsory licensing should include a review mechanism, where both the licensee and the patent holder may submit motivated requests for the (dis-) continuation of the license.

### **3.3.2.6 Rights under a compulsory license – Doha developments**

The licensee is authorized by the government to use the patented invention without the authorization of the patent holder. However, as the license is non-exclusive, the compulsory licensee may face competition in the market from the patent holder and other licensees. This limitation may dampen the generic suppliers' interest in the market, unless the economic prospects are otherwise favourable, as could occur if countries coordinated their procurement strategies and, where necessary, pooled the relevant compulsory licenses.<sup>446</sup>

Another important qualification concerns the exportation of products manufactured under compulsory license: while the patent holder is free to export the entirety of her/his production, the TRIPS Agreement requires the compulsory licensee to use her/his production *predominantly* for the supply of the domestic market (Article 31 (f)). This requirement has been waived, however, for exports to countries with insufficient pharmaceutical manufacturing capacities, as these countries would otherwise be unable to make effective use of compulsory licensing. The waiver, as included in the 2003 WTO Paragraph 6 Decision and the 2005 TRIPS Amendment Decision (draft Article 31*bis*), enables a compulsory licensee to export the entirety of her/his production to a country in need of certain drugs that it cannot produce itself. In order for this waiver to apply, a particular system has been set up, which distinguishes between requirements for importing and exporting members, as explained in the following sections.<sup>447</sup> Attached to both the 2003 Paragraph 6 Decision and draft Article 31*bis*,

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<sup>445</sup> Ibid, p. 473. Some stakeholders at the UNCTAD peer review meeting expressed the view that the duration of the compulsory license should not be linked to the commercial interests of the compulsory licensee.

<sup>446</sup> For details on such pooled procurement strategies in the context of regional cooperation, see Section 3.3.3.

<sup>447</sup> See P. Roffe, C. Spennemann and J. von Braun, "From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health", in *Negotiating Health*, pp. 9-26 (in particular pp. 20-22). See also WHO, "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", by C. Correa, *WHO Health Economics and Drugs EDM Series* No. 16, Geneva,

TRIPS Agreement is a note from the Chairman of the Council for TRIPS, which elaborates on some of the issues contained in the waiver.<sup>448</sup>

### **Requirements to be observed by the exporting member**

The exporting member has to issue a compulsory license for the pharmaceutical product needed in the importing country when the pharmaceutical product in question is patented in the exporting member (see box 8, below, on the compulsory license granted in Canada for the exportation of medicines to Rwanda). Thus, the system depends on the issuance of two compulsory licenses, i.e. one each in both the importing and the exporting country, if the respective drug enjoys patent protection in both countries. Moreover, the laws of both countries need to establish enabling provisions that fulfil the requirements of the TRIPS Agreement, in particular draft Article 31*bis*.

According to that provision, several conditions govern the granting of the compulsory licence in the exporting member:

- The license must be granted only to produce and export the amount estimated to meet the needs of the importing member, and the entirety of this production shall be exported to the country that has notified the Council for TRIPS of its health needs (Annex to the TRIPS Agreement [hereinafter Annex],<sup>449</sup> paragraph 2 (b) (i)).
- Products made under the license have to be clearly identified through specific labeling or marking, and possibly through differentiated packaging and/or special colouring/shaping (Annex, paragraph 2 (b) (ii)).
- The producer has to post on a website information on the quantities to be supplied to each destination and the distinguishing features of the product (Annex, paragraph 2 (b) (iii)).
- Adequate remuneration has to be paid to the patent holder in the *exporting* country, taking into consideration the economic value of the license to the *importing* country. Where a license is granted for the same products in the importing country, the obligation of the latter to pay compensation is waived for those products for which remuneration is paid in the exporting country (draft Article 31*bis*.2, TRIPS Agreement). This avoids payment of double compensation to the patent holder.<sup>450</sup>
- The exporting member must notify the WTO Council for TRIPS of the grant of the license to meet the needs of the importing country (Annex, paragraph 2 (c)). This notification should include information concerning the beneficiary licensee, the products covered by the license, the quantity(ies) for which the license has been granted, its duration and the name of the beneficiary country(ies). Thus, the drugs produced under a compulsory license in the exporting country may be exported to several countries, provided these are all mentioned in the notification. This is an

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2004 [hereinafter WHO, Implementation of Paragraph 6]; P. Vandoren and J.C. van Eeckhoutte, "The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work", *Journal of World Intellectual Property*, Vol. 6, Issue 6, 2003, pp. 779 ff.

<sup>448</sup> In particular, the statement provides for some best practices developed by companies to prevent the diversion of products to markets they were not destined for.

<sup>449</sup> This Annex is part of the TRIPS Amendment Decision as introduced above (draft Article 31*bis*). The Annex contains a number of procedural requirements for the use of the draft Article 31*bis* system. These requirements were taken from the Paragraph 6 Decision (see above).

<sup>450</sup> For suggested model language for this option to waive remuneration in the importing country, see F. Abbott, R. Van Puymbroeck, "Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision". *World Bank Working Paper* No. 61, World Bank, Washington, D.C., 2005, pp. 41 ff. See also WHO, Implementation of Paragraph 6.

important tool for beneficiary importing countries to engage in the pooled purchasing of drugs, thus creating economies of scale for the producer (i.e. compulsory licensee) in the exporting country. In this context, it should be noted that pooled drugs procurement by several developing countries is generally an important means of attracting pharmaceutical producers' interest in a regional market, and may, under a "carrots and sticks" approach, be used by developing country governments to negotiate favourable schemes of collaboration with the holders of pharmaceutical patents (see Section 3.3.3).

- Drugs produced under the draft Article 31*bis*, TRIPS Agreement system may only be exported to countries mentioned in the notification to the WTO. This follows from paragraphs 2 (c) and 3 of the Annex. Members wishing to (re-) export the products to a country not mentioned in the export notification would need to file a new notification with the WTO, as they would qualify as "exporting member" under paragraph 2 (c) of the Annex. The objective of this rule is to ensure that the products imported under the draft Article 31*bis*, TRIPS Agreement system are used for the public health purposes underlying their importation, as expressed in paragraph 3 of the Annex. According to this provision, separate re-exports of products imported under the system shall be prevented (see below).
- However, the conditions governing the granting of the compulsory license in the exporting member, as discussed above (paragraphs 2 (b) and (c) of the Annex) are waived for those exporting developing countries and LDCs that are parties to a regional trade agreement composed of at least 50 per cent LDC members, provided the importing developing country or LDC members share the health problem in question (see draft Article 31 *bis*.3). While this provision does not state such waiver in express terms, it may nevertheless be inferred from comparing its language with the language under draft Article 31*bis*.1. Draft Article 31 *bis*.1 waives the obligation of exporting members under Article 31 (f), TRIPS Agreement, "in accordance with the terms set out in paragraph 2 of the Annex to this Agreement".<sup>451</sup> Comparable language cannot be found in the special LDC provision under draft Article 31 *bis*.3/paragraph 6 of the 30 August Decision. Thus, it may be inferred that exports within an LDC-dominated trade agreement are not subject to the conditions established under paragraph 2 of the Annex, in particular the requirement that only the amount necessary to meet the needs of an eligible importing member may be manufactured under the license (paragraph 2 (b) (i) of the Annex).<sup>452</sup> In addition, there is no obligation for a producer exporter within the LDC region to meet the specific requirements on labeling and web posting. Finally, exports within LDC-dominated trade agreements do not trigger the export notification requirement under paragraph 2 (c) of the Annex.
- In the case of importation from outside the LDC-dominated trade agreement, the conditions for exports under paragraph 2 of the Annex do apply. Also, the facilitated export possibilities within the trade agreement do not alter the fact that each importing country needs to issue a compulsory license for the importation of drugs protected by a national patent. Box 6 provides an example of an LDC-dominated regional trade agreement and how it could use the new system.

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<sup>451</sup> Comparable language is employed under paragraph 2 of the 30 August Decision.

<sup>452</sup> See also S. Musungu, "The TRIPS Agreement and Public Health", in *Intellectual Property and International Trade: The TRIPS Agreement*, editors C. Correa and A. Yusuf, 2nd edition, The Netherlands, Kluwer Law International, 2008 [hereinafter Correa/Yusuf], p. 421 ff. (455).



**Box 6: How the East African Community could use the WTO waivers on compulsory licensing**

To illustrate the use of the waiver in an LDC-dominated regional trade agreement, note that Kenya, for example, would be entitled under the system to re-export drugs produced under compulsory license and imported from a country such as India to the other Partner States of the East African Community (EAC),<sup>453</sup> even if the compulsory license issued in India only refers to Kenya as the beneficiary country. The Indian producer would have to comply with the export conditions under paragraph 2 of the Annex (regarding the amounts necessary for Kenya and the labeling and web posting requirements). Local producers in Kenya would also have the right to export the bulk of their production manufactured under a compulsory license to Burundi, Rwanda, the United Republic of Tanzania, and to Uganda. As such shipments would only occur within the regional trade agreement, the export notification requirement would not apply, nor would the quantitative limitations and the labeling and web posting requirements (according to the language employed in draft Article 31.3*bis*, see above). Finally, the new rule under Article 31*bis*.3, TRIPS Agreement also means that Kenyan manufacturers may import APIs under compulsory license, formulate these APIs into finished pharmaceutical products and then export the resulting products to the other Partner States of the EAC, without notifying the WTO of such export (provided the other EAC Partner States share Kenya's HIV problem).<sup>454</sup>

- This new arrangement under draft Article 31*bis* (3) of the TRIPS Agreement could provide important incentives in terms of economies of scale for both local producers and foreign pharmaceutical companies and could provide a solid legal basis for regional procurement efforts.<sup>455</sup> In this sense, the new draft Article 31*bis*.3 of the TRIPS Agreement expressly refers to “*harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products*”. On the other hand, as long as the regional trade group at issue has not recognized regional patents, each importing country will still have to issue a national compulsory license for the importation of any drug patented in its territory. The policy option of regional cooperation in the area of compulsory licensing is set out further in Section 3.3.3.

**Requirements to be observed by the importing member**

The importing country has to notify the Council for TRIPS of its intention to use the “system” (i.e. the waiver) as an importer (Annex, paragraph 1 (b)). This requirement, however, does not apply to LDCs, which automatically qualify as eligible importing members (*ibid*). In addition, the importing country has to make a more specific notification, comprising:

- The specific names and expected quantities of the needed product (Annex, paragraph 2 (a) (i)). (For example, see box 8, below, on the invocation of the system by Rwanda for the importation of medicines produced under compulsory license in Canada.)

<sup>453</sup> As a Customs Union, the EAC also constitutes a free trade agreement within the meaning of draft Article 31*bis*, TRIPS Agreement. For more details on the EAC Customs Union, see UNCTAD, “An Investment Guide to the East African Community”, Geneva, July 2005 (available at [http://www.unctad.org/en/docs/iteiia20054\\_en.pdf](http://www.unctad.org/en/docs/iteiia20054_en.pdf)).

<sup>454</sup> See F. Abbott, “The Containment of TRIPS to Promote Public Health: A Commentary on the Decision on Implementation of Paragraph 6 of the Doha Declaration”, draft of 2 July 2004, p. 37 (on file with the authors).

<sup>455</sup> For more details, see J. Reichman, UNCTAD paper. See also Abbott/Reichman.

- Confirmation that the importing member in question has established it has insufficient or no manufacturing capacities in the pharmaceutical sector (except LDCs, which are deemed to have insufficient manufacturing capacities in the pharmaceutical sector) (Annex, paragraph 2 (a) (ii)).
- Confirmation that the importing country has granted, or intends to grant a compulsory license, if the demanded pharmaceutical product enjoys patent protection in its territory (this requirement does not apply to LDCs taking advantage of the 2016 transition period) (Annex, paragraph 2 (a) (iii)). The purpose of the compulsory license is to immunize the licensee from patent infringement through acts of, *inter alia*, importing, using, and selling the protected product (e.g. in the context of re-exportation to other countries under a regional trade agreement meeting the conditions of Article 31*bis* (3), TRIPS Agreement, as described above).
- The above requirements regarding specific notification (Annex, paragraph 2 (a) (i)-(iii)) do not apply to those importing members that are parties to an LDC-dominated trade agreement, to the extent that the imports originate **from inside** the trade agreement.<sup>456</sup> As explained before, the language under the special LDC provision (i.e. draft Article 31 bis.3/paragraph 6 of the 30 August Decision) does not refer to the notification requirements that normally apply to exporting or importing members under this system.
- In case the imports into the LDC-dominated trade agreement originate from **outside** the trade agreement, the special LDC provision (i.e. draft Article 31 bis.3/paragraph 6 of the 30 August Decision) does not apply: the purpose of this provision is to facilitate trade flows *within* a region, not to facilitate trade flows *into* a region.<sup>457</sup> Thus, the import notification requirement under draft Article 31 bis.1 applies, as does the export notification requirement under the same provision.
- In the LDC-dominated regional trade agreement context, notifications of imports (i.e. from outside the region) may be submitted jointly by the regional organization on behalf of eligible importing members using the system that are parties to it, with the agreement of those parties.<sup>458</sup>
- Importing countries must also take reasonable measures “within their means, proportionate to their administrative capacities” to prevent re-exportation of those products imported into their territories under the system (Annex, paragraph 3).<sup>459</sup> The latter obligation does not apply to members of an LDC-dominated trade agreement, as the special LDC provision (i.e. draft Article 31 bis.3/paragraph 6 of the 30 August Decision) expressly authorizes re-exports within an LDC-dominated trade agreement, thus constituting a *lex specialis* that takes precedence over the general prohibition of re-exports.

Finally, the Paragraph 6 Decision/TRIPS Amendment Decision calls on other WTO members to ensure the availability of effective legal means to prevent the importation and sale in their

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<sup>456</sup> See draft Article 31 bis.3/paragraph 6 of the 30 August Decision, referring to pharmaceutical products “produced or imported” in a Member of an LDC-dominated trade agreement.

<sup>457</sup> In this respect, the reference under draft Article 31 bis.3/paragraph 6 of the 30 August Decision to “a pharmaceutical product [...] *imported* under a compulsory license in that member [...]” (emphasis added) is understood as being limited to imports **from within** the LDC-dominated regional trade agreement. Personal communication to the authors from staff of the WTO Secretariat, 6 May 2008.

<sup>458</sup> See footnote 4 to the draft Annex to the TRIPS Agreement.

<sup>459</sup> Developed country members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate the implementation of this obligation.

territories of products produced under the waiver mechanism and diverted to their markets inconsistently with the Decision (Annex, paragraph 4).

Box 7 provides an overview of the system under the TRIPS Agreement for the importation and exportation of generic products produced under a compulsory license.

**Box 7: Comparative legal analysis of exportation/importation of pharmaceutical products patented in both the exporting and the importing member**<sup>460</sup>

- Situation under Article 31, TRIPS Agreement
  - Exporting member: Compulsory license required → **up to 49 per cent of production admitted for export** (Article 31 (f)).
  - Importing member: Compulsory license also required. **Re-exportation: up to 49 per cent of imported medicines** → with each re-export, the amount of exportable products is more than halved.
  
- Situation under the “System” of draft Article 31*bis*, TRIPS Agreement
  - No LDC trade agreement
    - Exporting member:
      - Compulsory license required → **100 per cent of production required for export** (Article 31*bis* (1)).
      - Notification of export to WTO (Annex, para. 2 (c)): export to one or several members designated in notification → **pooled procurement potential** for beneficiary members. **Producer is subject to limitations in quantity** (Annex, para. 2 (b) (i)) **and requirements on labeling** (Annex, para. 2 (b) (ii)) **and publishing information** (Annex, para. 2 (b) (iii)).
    - Importing member:
      - Need for import notification to WTO (Annex, para 2 (a))
      - Compulsory license required. Covers any third party action such as importation, use, and sale of product without authorization of owner of domestic patent.
      - But: re-exportation to countries not designated in original export notification is nevertheless prohibited (Annex, paragraph 3), unless original importing country issues **new export notification to WTO** (Annex, para 2 (c)) → only designated importing countries benefit.
  - LDC trade agreement
    - Exporting member:
      - Compulsory license required → **100 per cent of production required for export** (Article 31*bis* (1)).
      - If exporting member is outside LDC trade agreement: Notification of export to WTO (Annex, para. 2 (c)): export to

<sup>460</sup> The objective of this comparison is *not* to present all elements of the draft Article 31*bis* system, but to highlight the *differences* between the general situation under Article 31, the general situation under draft Article 31*bis*, and the special case of an LDC trade agreement under draft Article 31*bis*. The particular features of each situation are highlighted in **bold**.

one or several members designated in notification → **pooled procurement potential** for beneficiary members. **Producer is subject** to limitations in quantity (Annex, para. 2 (b) (i)) and requirements on labeling (Annex, para. 2 (b) (ii)) and publishing information (Annex, para. 2 (b) (iii)).

- If exporting member is part of the LDC trade agreement: **Obligation to notify export to WTO does not apply** (no reference to notification requirement in special LDC provision, draft Article 31*bis*.3) → Shipment to any of the other trade agreement members → **pooled procurement potential** for beneficiary members. In addition: **producer is NOT subject to limitations in quantity, requirements on labeling, and publishing information** → incentive for regional producers
- Importing member:
  - **Obligation to notify import to WTO does not apply**, to the extent that imports sourced **from within** LDC trade agreement (no reference to notification requirement in special LDC provision).
  - If sourced **from outside** LDC trade agreement, obligation to notify does apply. May be made **jointly** by regional organization on behalf of member states.
  - **Re-exports possible** to other trade agreements parties sharing same health problem (special LDC provision authorizes re-exports, takes precedence over general prohibition of re-exports); no need to notify WTO of re-exports (see above, b.i.3.).
  - But compulsory license required. Covers any third party action such as importation, use, and sale of product without authorization of owner of domestic patent.

#### Observations:

- Under the draft Article 31*bis* (3), TRIPS Agreement system (i.e. LDC-dominated trade agreement), the **exporting** WTO member may be
  - Outside the LDC trade agreement (example: India exports to the United Republic of Tanzania; the United Republic of Tanzania re-exports to Burundi, Kenya, Rwanda, and Uganda)
  - Party to the LDC trade agreement (example: the United Republic of Tanzania produces itself and exports to Burundi, Kenya, Rwanda, and Uganda)
  - A **WTO notification of export** is only needed for those shipments coming from **outside** the LDC trade agreement. **Likewise**, a **WTO notification of import** is only needed to the extent that the shipments come from outside the LDC trade agreement.
  - Conditions regarding necessary amount of production, labeling and web posting **do not apply to producers exporting within** the LDC trade agreement.
- The above analysis is based on the assumption that the exported medicine is patented in both the exporting and the importing country.

- If the exported medicine is not patented in the exporting country, there is no need for the draft Article 31*bis* system, as there are no patent law-related limitations to the exportation of the medicine. The importing country will still need to issue a compulsory license.
- If the exported medicine is not patented in the importing country (or granted patents are not enforced, following the extension of the LDC transition period, such as in the case of Rwanda, box 8, below), the draft Article 31*bis* system is still required (except the granting of a compulsory license in the importing country), as its main purpose is to facilitate exports of patented products produced under a compulsory license. The importing country only needs to notify the WTO (of the names and quantities of the products needed) if it is not party to an LDC-dominated trade agreement, or if imports into the region come from outside of that region. It only has to confirm its insufficient manufacturing capacity for pharmaceuticals if it is no LDC.

**Conclusion:** the effect of Article 31*bis* (3), TRIPS Agreement on a regional trade agreement (RTA) is that:

- Producers within the RTA are not subject to limitations of quantity, labeling and web posting requirements;
- No additional WTO notification is needed on top of original export notification from exporting country outside LDC trade agreement;
- No WTO notification at all is needed for exports originating in a member of the LDC trade agreement destined to other members of this trade agreement;
- No WTO notification at all is needed for imports coming from a member of the LDC trade agreement;
- The prohibition of re-exports does not apply.

Box 8 provides some background on the first-ever use of the new draft TRIPS Article 31*bis*/Paragraph 6 system by Canada and Rwanda.

**Box 8: Rwanda invokes paragraph 6 system for the importation of a fixed-dose anti-retroviral drug made by the Canadian pharmaceutical company Apotex Inc.**

In July 2007, only one week after the European Parliament delayed its ratification of the Paragraph 6 Decision,<sup>461</sup> the Rwandan Government as the first and only country so far, notified the WTO to make use of the Paragraph 6 mechanism. Referring to the 2016 transition period for LDCs, the Government announced that it would no longer enforce patent rights that could have previously been granted on the triple combined fixed-dose anti-retroviral drug TriAvir.<sup>462</sup> Between September 2008 and September 2009, Rwanda imported 260,000 packs of TriAvir as manufactured in Canada by Apotex Inc.<sup>463</sup> As an LDC, Rwanda did not have to prove its lack of manufacturing capacity.

The triple combined drug is patented in Canada by Glaxo Group Ltd., Wellcome Foundation Ltd., Boehringer Ingelheim Pharmaceuticals Inc. and Shire Biochem Inc. Based on a

<sup>461</sup> See Resolution P6\_TA-PROV (2007) 0353 of 12 July 2007.

<sup>462</sup> See “Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, WTO document IP/N/9/RWA/1 of 19 July 2007.

<sup>463</sup> See IP Watch, “Last Cheaper AIDS Medicines For Rwanda Under WTO”, online publication of 17 September 2009 (available at: <http://www.ip-watch.org/weblog/2009/09/17/last-cheaper-aids-medicines-for-rwanda-under-wto/>). On the quantity of imported medicines, see WTO document IP/N/9/RWA/1.

compulsory license, the Canadian manufacturer Apotex was authorized to produce the medicament and export it to Rwanda under Canada's Access to Medicines Regime (CAMR) implemented in Canadian law in May 2004, and the regulation for the Use of Patented Product for International Humanitarian Purposes. Under this regime, Apotex could only start producing upon formal request from a would-be importing country. Furthermore, Apotex was obliged to negotiate with the patentees voluntary licenses for 30 days.<sup>464</sup> As Apotex and the patentees did not reach voluntary licensing agreements,<sup>465</sup> the Canadian Government became the first country to notify the WTO of the grant of a compulsory license for the manufacture of a total of 15.6 million tablets of ApoTriAvir for the export to Rwanda.<sup>466</sup> Information on each shipment, including quantities, was posted on the company's website.

This first use of the Paragraph 6 system has, however, not been suited to calm down public criticism of the system as being too burdensome, due to its onerous reporting rules.<sup>467</sup> Despite the fact that Apotex reportedly offered lower prices than its Indian competitors,<sup>468</sup> the company stated that it would not be ready to use the system again.<sup>469</sup> According to the same sources, Apotex blamed the procedural requirements under the Canadian Paragraph 6 implementation legislation (i.e. CAMR) to represent a major disincentive for developing countries and generic producers to use the Paragraph 6 system.<sup>470</sup> In response to such criticism, current efforts to reform CAMR have resulted in a Bill (C-393) before the Canadian House of Commons. An important question in this context is to what extent the current requirement, under CAMR, for separate negotiations with the patent owner for each purchasing country and each order of medicines may be amended and simplified, along the lines of a "one-license solution".<sup>471</sup>

### **3.3.2.7 Adequate remuneration – models for royalty guidelines**

According to the TRIPS Agreement, the patent holder has to be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". In particular:

- This obligation applies to both compulsory and government use licenses.

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<sup>464</sup> For further details on the Canadian law see South Centre/CIEL, "Rwanda and Canada: Leading the Implementation of the August 2003 Decision for Import/ Export of Pharmaceuticals Produced under Compulsory License", *Intellectual Property Quarterly Update*, Third Quarter 2007, pp. 1 ff. (available at [http://www.ciel.org/Publications/IP\\_Update\\_3Q07.pdf](http://www.ciel.org/Publications/IP_Update_3Q07.pdf)).

<sup>465</sup> See *ibid*, p. 6 for details on the negotiations for voluntary licenses.

<sup>466</sup> Canada granted authorization to Apotex Inc. on 19 September 2007 to make, construct and use the patented inventions solely for the purpose directly related to the manufacture of ApoTriAvir and to sell it for export to Rwanda for a period of two years. See Canada's notification of the TRIPS Council, IP/N/10/CAN/1 of 5 October 2007 (available at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm)).

<sup>467</sup> IP Watch, "Global Access To Medicines Not Improved By TRIPS Waiver, Some Say", online publication, 1 October 2008 (<http://www.ip-watch.org/weblog/2008/10/01/global-access-to-medicines-not-improved-by-trips-waiver-some-say/>), quoting the former MSF Essential Medicine Campaign Canada coordinator as stating that efforts by MSF to assist developing country governments in the use of the Paragraph 6 system were met by a widespread lack of interest on behalf of these governments.

<sup>468</sup> *Ibid*.

<sup>469</sup> IP Watch, "Last Cheaper AIDS Medicines For Rwanda Under WTO", online publication, 17 September 2009 (<http://www.ip-watch.org/weblog/2009/09/17/last-cheaper-aids-medicines-for-rwanda-under-wto/>).

<sup>470</sup> *Ibid*.

<sup>471</sup> *Ibid*.

- It does not apply to the importing country under the 2003 WTO Paragraph 6 Decision/the 2005 TRIPS Amendment Decision: the patent holder is only entitled to remuneration in the exporting country, taking into consideration the economic value of the license to the *importing* country.
- Various sources have recommended the establishment of a Compensation Committee to determine the form and amount of the compensation.<sup>472</sup>
- Members are free to determine what is adequate. This is to be done on a case-by-case basis. The following indicators may provide some guidance:
  - The patent holder usually does not need to recoup his costs for R&D and other investments in developing country markets, as these costs are fully recouped in developed country markets. Looking into the future, however, more medicines may be developed in both developed and developing countries to address specifically diseases prevalent in developing countries in response to TRIPS or other incentives. In these cases, companies will have to recoup their investment made in developing countries, and care must be taken not to disincentivize this type of research.
  - Obtaining transparency regarding the marginal cost of production might prove difficult; in this case, a government is free to make its own estimates and shift the burden of proof to the respective company/patent holder.
  - The economic value of the license for the licensee may be higher where an industrial policy objective is met than where urgent public needs have to be satisfied.<sup>473</sup>
  - In case the compulsory license is issued to remedy anti-competitive behavior on the part of the patent holder, this may be taken into account.
  - The patent holder may be required to present a detailed justification of her/his royalty request, including specific data on her/his R&D costs, the extent of government funding, etc.

On the basis of the above considerations, countries may wish to issue royalty guidelines to specify exact rates of remuneration. Developed country practice indicates that rates range between 1 per cent and 10 per cent of the price of the generic drug.<sup>474</sup> UNDP and WHO have recommended various approaches to calculating royalty rates, as follows:<sup>475</sup>

- UNDP in 2001 recommended a general royalty rate of 4 per cent of the generic price. This rate could be adjusted upward by as much as 2 per cent in case the product has particular therapeutic value, and up to 2 per cent downward in case the product was partly developed through public funds.<sup>476</sup>
- The 1998 royalty guidelines by the Japanese Patent Office (JPO) may be seen as a more elaborate version of the 2001 UNDP guidelines. The JPO guidelines provide royalties between 2 and 4 per cent of the price of the generic product, which may be

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<sup>472</sup>See, e.g., Commission on Intellectual Property Rights, p. 44; TWN Manual, p. 98.

<sup>473</sup>UNCTAD-ICTSD Resource Book, p. 477.

<sup>474</sup>See TWN Manual, pp. 97-98. Other experts have suggested royalties comprising the marginal cost of production plus 5 per cent of the compulsory licensee's selling price, see Reichman, UNCTAD paper, p. 20, quoting A. Engelberg.

<sup>475</sup>UNDP/WHO, "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies", by J. Love, *Health Economics and Drugs TCM Series* No. 18, Geneva 2005 (in particular pp. 83-86) [hereinafter UNDP/WHO Guidelines].

<sup>476</sup>See UNDP, "Human Development Report 2001: Making New Technologies Work for Human Development", New York, Oxford University Press, 2001 (available at: <http://hdr.undp.org/reports/global/2001/en/>); see also UNDP/WHO Guidelines, p. 68.

decreased or increased by up to 2 per cent within a range of 0 to 6 per cent. Taking into account the importance of fixed-dose combination treatments, which may be patented by a variety of different rights holders, the JPO guidelines provide for the possibility of determining different rates for each of the affected patent holders, depending on the extent to which his patent is utilized in the licensed product.<sup>477</sup>

- The Canadian royalty guidelines of 2005, which are part of Canada's legislation implementing the 2003 WTO Paragraph 6 Decision/the 2005 TRIPS Amendment Decision, provide for varying royalty rates according to a country's ranking in the UNDP Human Development Index.<sup>478</sup> The maximum applicable rate is 4 per cent of the price of the generic product, the lowest rate in 2004 was 0.02 per cent for Sierra Leone.<sup>479</sup> The Canadian model differs from the UNDP and JPO approaches in that it seeks to take account of the fact that countries differ in their economic development.
- The fourth model ("Tiered Royalty Method"/TRM) proposed by UNDP and WHO differs from the three approaches mentioned above in two major respects.<sup>480</sup> First, it bases the royalty on the selling price not of the generic product, but the originator product in the United States or the European market. A general royalty rate of 4 per cent is suggested, as representing the average royalty rate for pharmaceutical products in the United States market. Second, the general royalty rate is adjusted according to each country's capacity to pay, as reflected in relative per capita income or, where a disease affects a country in an unusually high degree, the relative income per person needing treatment. As opposed to the UNDP Human Development Index, which comprises many factors not directly related to capacity to pay (such as literacy, enrolment in higher education, etc.), this approach is based directly on capacity to pay. This results in royalty rates that are much lower for low income developing countries and LDCs than they would be under the Canadian model.<sup>481</sup> On the other hand, royalty rates for middle income developing countries and high income OECD countries would be much higher than under the Canadian model, due to the fact that the rate is calculated on the basis of the originator price plus directly on the much higher capacity to pay.<sup>482</sup> In April 2010, Ecuador granted a compulsory license on ritonavir, an antiretroviral (ARV) drug patented in Ecuador by Abbott Laboratories, and calculated royalties payable to Abbott based on the TRM.<sup>483</sup>
- Countries are free to decide how to determine royalty rates; the above proposals are mere suggestions. While the UNDP approach has the merit of simplicity and easy administration, the JPO model provides important assistance in addressing multiple patents within one licensed product. The Canadian approach and the TRM seem to strike a fairer balance between the opposing interests of the patent holder and the general public. It is especially the TRM that favors patients in low income countries,

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<sup>477</sup> For details, see UNDP/WHO Guidelines, pp. 68-72.

<sup>478</sup> For details, see "The TRIPS Agreement and Public Health", Communication from Canada to the WTO Council for TRIPS, WTO document IP/C/W/464 of 14 November 2005, paragraph 17.

<sup>479</sup> UNDP/WHO Guidelines, p. 72.

<sup>480</sup> Ibid, pp. 73, 85.

<sup>481</sup> For example, the annual royalty payable for the drugs Lopinavir and Ritonavir would be USD 1.58 in Zambia under the Canadian model, but only USD 0.06 under the TRM (UNDP/WHO Guidelines, p. 75, Table R-4).

<sup>482</sup> Annual royalties in Brazil for the same drugs would be USD 11.98 under the Canadian approach, and \$14.45 under the TRM. For Germany, the Canadian model would result in an annual royalty rate of \$17.97, while the TRM would propose \$277.31. The TRM approach also provides the option of modifying the 4 per cent basic royalty rate for high income countries in case the originator's price is considered excessive in those countries, or does not properly reflect the therapeutic value of the invention (UNDP/WHO Guidelines, p. 85).

<sup>483</sup> See IP Watch, "Ecuador Grants First Compulsory Licence, For HIV/AIDS Drug", online publication of 22 April 2010 (available at [www.ip-watch.org/weblog/2010/04/22/ecuador-grants-first-compulsory-licence-for-hiv-aids-drug/](http://www.ip-watch.org/weblog/2010/04/22/ecuador-grants-first-compulsory-licence-for-hiv-aids-drug/)).



while it takes account of the need of patent holders to recoup their investment in middle and high income countries.

### **3.3.2.8 Review by judicial or distinct higher authority**

As indicated above, the TRIPS Agreement requires members to review requests for the grant of compulsory licenses on a case-by-case basis. Members have to make available in their domestic legislation means to appeal the decisions taken by the initial granting authority (Article 31 (i), TRIPS Agreement). Such appeals may be filed with a court or an administrative authority distinct from and higher than the initial granting authority. In addition to appeals relating to the *authorization* of a compulsory license, a court or a distinct higher authority shall also review any decision concerning the *remuneration* of the patent holder (Article 31 (j), TRIPS Agreement). The following should particularly be noted:<sup>484</sup>

- A judicial authority does not need to be a specialized court on IP matters. As the issue of compulsory licensing is closely related to non-IP issues such as public health, it might even be more appropriate, from a public policy point of view, to have a general court review the initial authority's decisions on grant and remuneration.
- Members that opt for review by the administration rather than the courts have to make sure the review authority is at a more senior level of government than the initial granting authority. In addition, the review authority must not be subject to control by the authority that initially granted the license and decided on the compensation.
- For government use licenses, the TRIPS Agreement in Article 44.2, **first sentence**, provides governments with the option to bar the patent holder from the possibility to invoke *injunctive relief* against a government use license. This means that a government may not be enjoined from using the patented invention. But this option does not encompass a government's obligation to make available a remedy for *ordinary judicial review* of the legality of the granting decision under Article 31 (i), TRIPS Agreement (i.e. *without* granting injunctive relief).
- As regards other forms of compulsory licenses (i.e. those usable for commercial purposes), Article 44.2 of the TRIPS Agreement, **second sentence**, authorizes members to exclude injunctive relief as an available remedy, *if such remedy is inconsistent with domestic law*. However, like under the first sentence of this provision, this waiver does not include the obligation to make available a remedy for *ordinary judicial review* of the legality of the granting decision (i.e. *without* granting injunctive relief). This provision arguably covers cases where in an infringement proceeding the court refuses the patentee's request for injunctive relief but instead grants a royalty to be paid by the defendant for the continued use of the patented invention until a final decision in the infringement proceeding has been rendered.<sup>485</sup>

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<sup>484</sup> See UNCTAD-ICTSD Resource Book, pp. 477-479.

<sup>485</sup> See J. Love, "Abbott recently sought compulsory license in United States patent dispute", in IP health newsletter of 2 May 2007, referring to a 2006 United States Supreme Court decision (*eBay Inc v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006)). According to the United States Supreme Court, the patent holder in order to be granted injunctive relief in a patent infringement suit has to demonstrate (1) that he has suffered irreparable injury; (2) that other remedies, including the payment of royalties, are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction (see *ibid*). Should the plaintiff be unable to demonstrate these cumulative requirements, he will have to tolerate continued use of the patented invention by the defendant, in exchange of a royalty payment. In practical terms, this situation

### **3.3.3 Policy option: a regional approach to procurement and compulsory licensing**

Regionally coordinated procurement of medicines helps create larger markets and economies of scale for potential suppliers, making developing countries and LDCs more attractive for foreign pharmaceutical producers, both originator and generic firms. Governments interested in promoting local pharmaceutical production may use market incentives to attract foreign patent holders to invest in their domestic pharmaceutical sector.

According to ideas developed by *Reichman*, the first step to be undertaken by those governments willing to collaborate would be the establishment of Regional Pharmaceutical Supply Centers (RPSCs).<sup>486</sup> The RPSCs would be headed by a Board of Directors, which could be made up of the participating countries' health ministers or their representatives. A RPSC's main responsibility would be the procurement of medicines for the entire region.

The RPSC could offer the foreign patent holders to supply the entire regional market, provided the rights holders are prepared to supply the medicines at affordable prices and are willing to assist local producers in the region, for instance through licensing of technology, technical assistance in pharmaceutical production and the provision of key active ingredients that the local producer cannot manufacture himself/herself.

As pharmaceutical companies do not recoup their R&D costs in developing country markets, regulated prices for pharmaceuticals do not need to be based on a Western value system.<sup>487</sup> Instead, the patentee could be required to sell at marginal cost of production plus a certain royalty rate.

For the regional market incentive to become operational, it is important that the participating governments show the political will to harmonize national rules and practices in the areas of price control policies, marketing approval standards, uniform standards for good quality production, and joint R&D in diseases affecting the region. Only then will the promise of a regional market provide a sufficiently realistic incentive for originator companies to agree to make their products available at prices affordable in the region. It will also be important for the countries of the region to agree upon the choice of local producer(s) of any given drug.

The extent to which the foreign investor is prepared to assist local manufacturers in the establishment of sustainable production, such as through licensing agreements, would determine the prices at which the RPSC would purchase the products from the patent holder.

However, should the foreign patentee refuse the offer, the RPSC may seek to purchase the needed medicaments (or their ingredients) from generic producers, such as in India, under the same conditions as previously offered to the originator company. Depending on its patent status in the exporting country, the foreign generic producer may manufacture the drug under a compulsory license and export it under the draft Article 31*bis*, TRIPS Agreement system. Depending on its conferred authority, the RPSC could then issue a multitude of national compulsory licenses for the importation of the needed products, based on the fact that no

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corresponds to a compulsory license issued by the court. For an analysis of the eBay case, see M.J. Jacobs/D.E. Melaugh, "*eBay Inc. v. MercExchange: Copyright's Promise for Patent Injunctions*", at <http://www.techlawforum.net/post.cfm/eBay-inc-v-mercexchange-copyright-s-promise-for-patent-injunctions>.

<sup>486</sup> See Reichman, UNCTAD paper, for details, including a number of potential problems that the RPSCs could face and how to address them.

<sup>487</sup> Reichman, UNCTAD paper, pp. 19-20, with references to Engelberg; Outtersson.

agreement on price was reached with the patent holder. The foreign generic producer would then be able to supply the entire regional market, in collaboration with local manufacturers. In the context of regional trade agreements of at least 50 per cent LDC membership, all involved producers could benefit from the facilitated re-exportation scheme under draft Article 31*bis* (3), TRIPS Agreement.

It bears emphasizing that these suggested RPSCs in order to be operational would by no means require complex bureaucratic structures.<sup>488</sup> What is basically needed is an agreement among concerned governments to pool their procurement efforts and to set up the legal infrastructure to enable efficient decision making by a regional body. Actual distribution of the procured medicines could be facilitated through the assistance of relief agencies and civil society organizations. Over time, regional efforts would also benefit from the creation of an independent science body to establish a list of essential medicines for the respective region.<sup>489</sup>

In conclusion, the regional approach to procurement and compulsory licensing aims at producing “a market-based solution by providing a collective supply and distribution body that would encourage the pharmaceutical industry to engage in more constructive and expeditious price reduction negotiations with developing countries. Essentially, the procurement centers could provide a powerful incentive for patentees to voluntarily bring prices down and thereby avoid compulsory licensing in all but the most critical instances. At the same time, it could put a stop to dilatory action by producers engaging in endless litigation in single territories. Above all, it could provide a major incentive to expand local production capabilities and to channel public and private funds in this direction.”<sup>490</sup>

### **3.4 The control of patent abuse and anti-competitive licensing practices**

#### **3.4.1 Background**

##### ***3.4.1.1 Introduction***

The exercise of exclusive rights such as patents may give rise to abuses and anti-competitive behaviour, whether through abuse of dominance (by individual firms or through collective abuse) or agreements among firms. Local producers of pharmaceutical products in developing countries often depend on collaboration with pharmaceutical companies from developed or advanced developing countries.

Many pharmaceutical substances needed for the production of anti-HIV/AIDS or other drugs will have to be imported, such as APIs. To the extent that a foreign company holds a domestic patent on one or more of these substances, local producers may be interested in seeking a voluntary license from the patent holder. The terms of the license, i.e. the conditions under which the licensee may operate, are determined in negotiations between the licensor and the licensee. The licensing terms are of considerable importance to the local manufacturer, as they can be more or less favourable to sustainable production. Licensors might be tempted to retain

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<sup>488</sup> Ibid, p. 29.

<sup>489</sup> Ibid.

<sup>490</sup> Ibid, p. 30.

most of their protected technology and to reduce the licensee's role to the mere assembly or distribution of the product, without sharing any significant know-how. Patent holders may also refuse entirely to grant licenses to local producers.

In addition, a patent holder's practice of his IP right may also affect local producers outside the IP licensing context, such as, for instance, through predatory pricing. Governments have limited powers to control such business practices, especially as commercial parties should in general be free to determine the content of their contractual arrangements. However, the TRIPS Agreement grants members the freedom to define practices, in their domestic laws, which in particular cases may constitute IPR abuse, and to take the appropriate measures to control such practices. Such control could be exercised in a way that promotes the development of sustainable pharmaceutical production capacities on a national or regional basis.<sup>491</sup>

Under the TRIPS Agreement, abuse of IPRs is a wide concept. It depends on the proper understanding of the objectives of IP protection. IP laws aim at enabling the rights holder to appropriate the full market value of the protected subject matter, thus serving as incentives for the creation, use and exploitation of inventions, works, marks and designs.<sup>492</sup> At the same time, Article 7, TRIPS Agreement states that the protection and enforcement of IPRs should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology [...]". In a well-functioning market economy, IPRs may provide incentives for competition, based on the promise to grant exclusive rights to products or services that bring a new benefit to society.

For this incentive mechanism to function, however, it is essential that existing IPRs are not employed in a way that only benefits their owners, while neglecting their purpose of promoting competitiveness through technology innovation and dissemination. Three types of conflict – abuse, abuse of market dominance and practices restraining trade and technology transfer - may arise between the exercise of IPRs and the pursuit of competitiveness, independently of whether one considers the interface of IP protection and the promotion of competition as mutually supportive or as contradictory.<sup>493</sup>

- The notion of IPR **abuse** under the TRIPS Agreement is a broad one, referring in general to the illegitimate use of an IP right, which is contrary to the objectives of IP protection, such as the promotion of innovation or of dissemination of technology.<sup>494</sup> There may be abuse regardless of whether the IPR holder in question has a dominant market position, or whether he uses his IPR in an anti-competitive way.<sup>495</sup>
- Abuse of a **dominant position** in the relevant market. This is often referred to as "abuse of market dominance". The dominant position is used to extend the protection beyond a legitimate purpose. Dominance may be determined, *inter alia*, by the respective market shares and the ability of the respective IP holder to behave

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<sup>491</sup> See J. Berger, "Advancing Public Health by Other Means: Using Competition Policy", in *Negotiating Health. Intellectual Property and Access to Medicines* (editors Roffe P., Tansey G., and Vivas-Eugui D.), Earthscan, London, 2006, pp. 181 ff. (185) [hereinafter Berger].

<sup>492</sup> See UNCTAD-ICTSD Resource Book, p. 540.

<sup>493</sup> *Ibid.*, p. 541.

<sup>494</sup> *Ibid.*, p. 548.

<sup>495</sup> *Ibid.*

independently of its competitors, its customers, and ultimately its consumers.<sup>496</sup> The dominant position facilitates the abuse of exclusive rights. An example is the case adjudicated by the EGC in July 2010:<sup>497</sup> a multinational pharmaceutical company, which both the EU Commission and the EGC found to be dominant in the market for its anti-ulcer medicine,<sup>498</sup> requested the withdrawal of regulatory approval for a *capsule* formulation of its drug in a number of EU countries, replacing it with a new *tablet* formulation. The sole purpose of this action was to prevent the sale of generic versions and of parallel imports of the capsule formulation.<sup>499</sup> The EGC upheld an earlier decision by the EU Commission, considering that the withdrawal of regulatory approval for the capsule version of the drug constituted an abuse of the company's dominant position in the market for anti-ulcer treatments. The EGC stressed that, while a dominant undertaking is under no obligation to protect the interests of competitors, this cannot "justify recourse to practices falling outside the scope of competition on the merits."<sup>500</sup> In other words, what rendered the company's conduct abusive was the fact that the sole purpose of the withdrawal of regulatory approval was to prevent competition through generic copies and parallel imports. The withdrawal would not have been abusive if there had been some objective reason why such a withdrawal was necessary to improve the competitiveness of the company's own products. Developing countries are encouraged to consider this approach as an important means to address abuse of dominance in the pharmaceutical area. The same rationale could be applied to cases where a holder of a pharmaceutical patent refuses to make available a new drug at a price affordable to a developing country public health service for distribution to the population at large (thereby limiting distribution of the medicament to the affluent parts of society), despite potentially higher gains if the drug could be sold to the public health service.<sup>501</sup> If the sole purpose of such action is to reduce incentives for parallel traders to take advantage of potential price differences between the developing country and high price markets, there would seem to be no legitimate reason for such action, especially if the patent holder renounces the opportunity of higher commercial gains in the developing country market. Abuse of dominance is always regarded as having an adverse effect on competition in the relevant market. This is often referred to as "**anti-competitive conduct**". The TRIPS

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<sup>496</sup> See I. Brinker, T. Loest, "Essential Facilities Doctrine and Intellectual Property Law: Where does Europe stand in the aftermath of the IMS Health case?", on-line publication by Gleiss Lutz Rechtsanwälte, p. 4 [hereinafter Brinker/Loest], referring to European law and jurisprudence (European Court of Justice), according to which market shares in excess of 50 per cent provide in themselves evidence of a dominant position (available at <http://www.gleisslutz.com/de/publikationen/nachanwalt.html?nDisplayJur=41>).

<sup>497</sup> EGC, Case T-321/05 of 1 July 2010, *AstraZeneca v. European Commission* (available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=T-321/05&datefs=&datefe=&nomusuel=&domaine=&mts=&resmax=100>).

<sup>498</sup> Market dominance concerned oral prescription proton pump inhibitors, in particular "Losec". For details, see paragraphs 1-9 and 61-106 of the judgment.

<sup>499</sup> Losec was first patented in Europe in 1979, which explains the existence of generic copies in the market at the time the EU Commission initiated investigations (i.e. in 1999). At that time, generic manufacturers in order to market their products in the EU needed an originator reference product. After the withdrawal of regulatory approval for the capsule version of Losec, generic manufacturers would no longer be able to market their generic copies of these capsules. Parallel importers of Losec capsules would equally be barred from marketing those. By contrast, the dominant company would be the only one marketing the tablet version of Losec. See Linklaters, "EU Court upholds 'novel' approach to abuse of dominance in pivotal pharma appeal", online publication, 1 July 2010 (available at <http://www.linklaters.com/Publications/201007013/Pages/Index.aspx>).

<sup>500</sup> See paragraph 816 of the judgment.

<sup>501</sup> Example from Berger, p. 189.

Agreement refers to this notion in a number of instances.<sup>502</sup> Abuse of dominance plays an important role in the assessment of anti-competitive conduct, but is not defined under TRIPS. Box 9 briefly explains the EU's approach to examining market dominance.

**Box 9: The concept of market dominance under EU competition law**

EU competition law seeks to protect effective and “workable” competition.<sup>503</sup> This basically requires equality of opportunities for all market participants.<sup>504</sup> Market dominance is determined through (a) the ability to behave independently of one's competitors, customers, and ultimately the consumers; and (b) the capacity to prevent workable competition in the market.<sup>505</sup> The relevant market has to be determined through a case-by-case analysis, for which the TRIPS Agreement sets no particular limitations. Depending on individual circumstances, single companies with market shares above 25 per cent may have the capacity to prevent workable competition.<sup>506</sup> Given the technological gap between R&D-based pharmaceutical companies and local pharmaceutical producers in small developing countries or LDCs, foreign patent holders will in many cases have the capacity to prevent competition in the above sense. It is important to note that under the TRIPS Agreement, developing countries are not prevented from applying stricter criteria to determine market dominance and anti-competitive conduct.

- The third type of conflict potentially arising between the exercise of IPRs and the pursuit of competitiveness consists of practices restraining trade or adversely affecting the transfer and dissemination of technology. Such practices may occur through unilateral conduct or contractual agreement.<sup>507</sup> They do not necessarily have to constitute anti-competitive conduct. Again, the TRIPS Agreement provides no definition of what constitutes a restraint on trade or an adverse effect on technology transfer and dissemination. As Article 7 identifies technology transfer and dissemination as one of the objectives of the TRIPS Agreement, use of IPRs that adversely affects this objective may be considered as an IP misuse. Members may subject such practices to appropriate measures of control, provided these are in line with the provisions of the TRIPS Agreement (see in the following section on the TRIPS Agreement framework).

Despite the importance of competition law and policy for the control of exclusive IP rights, the TRIPS Agreement covers competition issues only to a very limited extent. The Agreement

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<sup>502</sup> The TRIPS Agreement authorizes members to address anti-competitive conduct in the particular context of voluntary IP licensing (see Section 3.4.1.2, below, for details). As discussed in Section 3.3.2.2, above, a showing of anti-competitive conduct is required to trigger facilitated procedures for issuing a compulsory license.

<sup>503</sup> Continuous jurisprudence of the European Court of Justice (ECJ), see quotes in M. Zuleeg, “Artikel 3 EG” (commentary on former Article 3 of the EC Treaty), in *Vertrag über die Europäische Union und Vertrag zur Gründung der Europäischen Gemeinschaft*, Nomos, Baden-Baden, 2003, Vol. 1, p. 608, para. 8 [hereinafter EU/EC Commentary].

<sup>504</sup> Ibid.

<sup>505</sup> This is the standard definition used by the ECJ and the EU Commission, see H. Schröter, “Artikel 82 EG” (commentary on former Article 82 of the EC Treaty) [hereinafter Schröter], in EU/EC Commentary, Vol. 2, p. 582, para. 71.

<sup>506</sup> Jurisprudence of the ECJ and practice of the EU Commission with respect to the notion of “dominant position”; see Schröter, p. 597, para. 98.

<sup>507</sup> UNCTAD-ICTSD Resource Book, p. 550.

provides for fairly detailed minimum standards of IP protection without at the same time providing for comparable tools to control the exercise of exclusive rights. In the absence of an international agreement on competition law and policy, there is currently no international framework that could provide developing country policy makers with guidance regarding the control of IP rights.<sup>508</sup>

This lack of international guidance has no major implications in a developed country context, as most OECD countries have implemented in the course of time detailed domestic rules and policies on the control of IP abuses and anti-competitive practices, and have experienced authorities in place to implement these rules and policies. Developing countries, however, often lack the technical expertise to implement complex competition rules. When implementing their obligations under the TRIPS Agreement, they risk implementing exclusive rights without the safeguards that usually accompany them under OECD countries' domestic legislation. Thus, IP systems in developing countries may end up being more restrictive on the public domain than their counterparts in OECD countries.

It is not the purpose of this Guide to provide for detailed advice on the implementation of development-oriented competition law and policy in general. This Guide is limited to presenting the options available under the TRIPS Agreement to control the exercise of IPRs, thereby promoting a pro-competitive environment in the area of pharmaceuticals.

As the pertinent TRIPS provisions on the control of IP abuse and restrictive licensing practices are construed very broadly, guidance may be provided through references to OECD state practice,<sup>509</sup> bearing in mind that the particular situation in poorer countries may require necessary adaptations of such practice.

### **3.4.1.2 The TRIPS Agreement framework**

Under the TRIPS Agreement, there are basically four provisions that deal with IP abuse and anti-competitive conduct on the part of IP holders.

#### **Article 8.1**

Article 8.1 provides that members may “adopt measures necessary to **protect public health and nutrition**, and to promote the **public interest in sectors of vital importance to their socio-economic and technological development**, provided that such measures are consistent with the provisions of this Agreement” (emphasis added). Even though this provision does not expressly refer to IP abuse, it does mention factors such as socio-economic and technological development that are at the heart of many national competition laws.<sup>510</sup> The promotion of competitive local pharmaceutical production that ensures affordable and sustainable access to medicines is an objective of vital importance to a country's socio-economic and technological development and the protection of public health.<sup>511</sup> Members may address IP practices that

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<sup>508</sup> See UNCTAD-ICTSD Resource Book, p. 566. Note that developing countries have so far resisted efforts to include competition rules in the WTO's multilateral trade rules, based *inter alia* on the concern that internationally binding rules would be tailored to OECD countries' standards and needs, potentially taking away important flexibilities for developing countries to deal with competition issues.

<sup>509</sup> See UNCTAD, “The TRIPS Agreement and Developing Countries”, New York and Geneva, 1996, p. 3, para. 20.

<sup>510</sup> See for example Berger, p. 184, for South Africa.

<sup>511</sup> *Ibid.*

hinder the development of such domestic production, provided this is done in a manner consistent with the TRIPS Agreement.

### **Article 8.2**

Article 8.2 authorizes members to adopt “appropriate measures”, consistent with the TRIPS Agreement, “to prevent:

- The **abuse** of intellectual property rights by right holders; or
- The resort to practices which **unreasonably restrain trade**; or
- Practices which adversely **affect the international transfer of technology**” (emphasis added).

This authorization is, as under Article 8.1, contingent upon the TRIPS consistency of the measure taken, and upon the proportionality of such measure (see reference to “appropriate”).<sup>512</sup> The notion of “abuse” under this provision is a broad one, as defined in the introduction to this section (i.e. any illegitimate use of an IPR, which is contrary to the objectives of IP protection).<sup>513</sup> As long as members remain within these boundaries, they are authorized to provide for more specific definitions of “abuse”.

Article 8.2 of the TRIPS Agreement also refers to practices adversely affecting the international transfer of technology. Technology transfer is one of the expressly stated objectives of IPR protection and enforcement (Article 7). Where the exercise of IP rights renders such objective more difficult, it may in some cases be regarded as constituting an abuse in the above sense. However, as Article 8.2 refers to IP abuse and adverse effects on technology transfer as two separate cases, members may under this provision address practices by IPR holders that, without necessarily constituting abuse, nevertheless have an adverse impact on technology transfer.<sup>514</sup>

The same applies to practices by the IP holder which unreasonably restrain trade; these may be addressed by members irrespective of their qualification as abusive. However, the reference to practices which “unreasonably” restrain trade indicates that those IP-related practices that do restrain trade, but are nevertheless inherently beneficial, are to be tolerated (“rule of reason” approach). Examples of trade-restraining but nevertheless beneficial practices are contractual clauses facilitating the productive use of IP, such as confidentiality requirements under trade secret agreements and licenses, or conditioning the grant of sub-licenses by the licensee on the consent by the licensor.<sup>515</sup> By contrast, restrictions such as limitations on a party’s ability to determine its prices would not fall under this category of inherently beneficial practices.<sup>516</sup>

### **Article 40**

While Article 8 of the TRIPS Agreement may encompass any IP abuse or practice (whether unilateral, bilateral, or multilateral) affecting technology transfer or trade, Article 40 deals specifically with the control of **anti-competitive conduct in licensing agreements**, whether

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<sup>512</sup> For details, see UNCTAD-ICTSD Resource Book, pp. 550-554.

<sup>513</sup> Ibid, p. 548.

<sup>514</sup> See Berger, p. 184.

<sup>515</sup> See UNCTAD-ICTSD Resource Book, p. 548.

<sup>516</sup> Ibid, referring to Article 4 of the EC “Commission Regulation (EC) No. 772/2004 on the application of Article 81(3) of the [EC] Treaty to categories of technology transfer agreements”.



these are bilateral or multilateral.<sup>517</sup> Thus, cross-licensing agreements and patent pools may be controlled under this provision.<sup>518</sup> The provision applies where contractual licensing constitutes the centre of gravity of the respective transaction; by contrast, there is no room for Article 40 where the anti-competitive conduct in question relates mainly to other business transactions such as, e.g., assignments, joint ventures, or subcontracting and outsourcing.<sup>519</sup> In the context of the local pharmaceutical production, the first two paragraphs of the provision are particularly relevant.

**Article 40.1** reflects WTO members' agreement "that some licensing practices or conditions pertaining to intellectual property rights **which restrain competition** may have **adverse effects on trade** and may **impede the transfer and dissemination of technology**" (emphasis added). As a consequence of this agreement, Article 40.2 authorizes members to control certain licensing practices and conditions. Article 40.1 covers only cases where anti-competitive conduct results either in adverse effects on trade or in an impediment to technology transfer and dissemination.<sup>520</sup> Members may not have recourse to this provision to control in the abstract the effects of licensing agreements on technology transfer. It must be established that the licensing practice at issue restrains competition and, **due to such restraint**, impedes technology transfer and dissemination, or<sup>521</sup> has adverse effects on trade.

Following the recognition in Article 40.1 of the existence of certain anti-competitive licensing practices, **Article 40.2** authorizes members to adopt "appropriate measures", consistent with the TRIPS Agreement, to prevent or control such practices. To this end, members may specify in their domestic laws licensing practices or conditions "that may **in particular cases** constitute an **abuse** of intellectual property rights having an **adverse effect on competition** in the relevant market" (emphasis added). This means that mere misuse of an IPR (i.e. contrary to the purpose of IP protection) is not sufficient to trigger the application of this provision (as opposed to Article 8.2, see above). Under Article 40 of the TRIPS Agreement, members may only control IP abuses that have anti-competitive effects and thereby a negative impact on trade and technology transfer. Even though Article 40.2 does not expressly refer to an impact on trade or technology transfer, its scope is informed by Article 40.1, which requires a link between the anti-competitive practice and trade or technology transfer and which sets the basic understanding for the authorization provided to members under Article 40.2.<sup>522</sup>

As under Article 8.2, members are free to define "abuse" according to their national laws and practices. But such abuse must in addition have anti-competitive effects, as opposed to the kind of abuse under Article 8.2 (see above).<sup>523</sup>

Article 40.2 by referring to "particular cases" makes clear that the control of IP licensing should be done on a case-to-case basis. Members may not specify anti-competitive practices in the abstract, but "in reasonably detailed circumstantial form and by reference to their actual

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<sup>517</sup> UNCTAD-ICTSD Resource Book, p. 556.

<sup>518</sup> For more details on cross-licensing agreements and patent pools, see below, Section 3.4.2.4.

<sup>519</sup> UNCTAD-ICTSD Resource Book, p. 556.

<sup>520</sup> See also UNCTAD-ICTSD Resource Book, p. 557.

<sup>521</sup> Despite the express language in Article 40.1 ("and"), these negative criteria apply alternatively, rather than cumulatively. This is so because Article 40.1 covers the licensing of any IPR, such as trademarks, which is not necessarily related to technology transfer. See UNCTAD-ICTSD Resource Book, p. 557.

<sup>522</sup> UNCTAD-ICTSD Resource Book, p. 559.

<sup>523</sup> Thus, as compared to Article 8.2, the scope of application of Article 40 is much narrower: it requires more than just any form of abuse; it requires a restraint on competition that in turn affects trade or technology transfer.

impact on the conditions of competition existing in the markets concerned”.<sup>524</sup> As some licensing practices, such as pricing agreements, output limitations or certain allocations of markets or customers may be considered anti-competitive under all foreseeable circumstances, listing these practices as *per se* prohibitions would still be in line with the case-by-case approach required under Article 40.2, provided all potential exceptions to the general prohibition are specified as well. An example of a permissible practice is Article 4 of the EU Commission’s Regulation on Technology Transfer Agreements, which specifies hardcore restrictions in licensing agreements that shall be considered prohibited *per se*, but at the same time lists all the exceptions from this prohibition.<sup>525</sup>

After setting the requirements for members’ control of IP licensing practices, Article 40.2 specifies, in a non-exhaustive manner, practices that may be subject to such control. In particular, reference is made to practices that may potentially be relevant also to local pharmaceutical producers entering into licensing agreements with patent holders, such as:

- **Exclusive grant back conditions:** such clauses relate to obligations on the licensee to grant an exclusive license to the licensor or a third party designated by the licensor in respect of the licensee’s own improvements or new applications of the licensed technology;
- **No-challenges clauses:** such clauses relate to obligations on the licensee not to challenge the validity of IPRs held by the licensor;
- **Coercive package licensing:** such clauses were defined in the UNCTAD Draft Code of Conduct on the Transfer of Technology as restrictions “imposing acceptance of additional technology, future inventions and improvements, goods or services not wanted by the acquiring party or restricting sources of technology, goods or services, as a condition for obtaining the technology required [...]”.<sup>526</sup>

### Article 31 (k)

Finally, governments, when addressing anti-competitive practices by pharmaceutical patent holders, may have recourse to compulsory licensing (see above). Where a court or the administration considers a practice as anti-competitive, procedures for the granting of a compulsory license are, as discussed in this Guide, considerably facilitated. In particular:

- There is no obligation to conduct prior negotiations with the patent holder;
- As opposed to normal circumstances, the full amount of medicines produced under a compulsory license may be exported. Thus, there is no need for the waiver system under the new draft Article 31*bis* of the TRIPS Agreement;
- The royalty rates payable to the patent holder may be lower than under normal circumstances.

Anti-competitive practices may occur in a specific licensing context (Article 40, TRIPS Agreement) as well as within the broader context of patent abuse under Article 8.2, TRIPS Agreement (e.g. predatory pricing). The granting of a compulsory license under the conditions of Article 31 (k), TRIPS Agreement, constitutes a measure “consistent” with the TRIPS Agreement as required under both Articles 40.2 and 8.2.

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<sup>524</sup> UNCTAD-ICTSD Resource Book, p. 559.

<sup>525</sup> Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the [EC] Treaty to categories of technology transfer agreements, Official Journal of the European Union, L 123/11.

<sup>526</sup> Negotiations on the Code of Conduct were conducted under the auspices of UNCTAD between 1976 and 1985, when they came to a halt, due to disagreements on the formulation of a number of international principles on technology transfer.

### **3.4.2 Policy options**

Developing country policy makers and pharmaceutical producers need to be aware of a number of scenarios which may arise in the area of pharmaceutical patent abuse and anti-competitive conduct. The following section explores how the TRIPS provisions mentioned above may be used to address these scenarios.

#### **3.4.2.1 Excessive pricing**

As outlined in the introduction to this section, pricing patented medicines above levels the general public in a developing country can afford may be qualified as abusive, for example where such action serves the sole purpose of preventing parallel imports into other countries and ignores the potential of higher commercial gains through sales to the public at large. Excessive prices may be charged to the end user (i.e. of finished pharmaceutical products) or a licensee (i.e. patented parts/substances needed for generic production):

- Where the excessive price concerns the end product, such practice may be addressed by governments under Article 8.2, TRIPS Agreement. An appropriate measure in this sense could be the **non-enforcement** of the patent at issue, in case of infringement by generic competitors.<sup>527</sup> Alternatively, governments are free to provide for the possibility of **compulsory licensing**, based on the freedom under the TRIPS Agreement to determine the substantive grounds for the granting of a compulsory license.
- Where the excessive pricing concerns a licensed pharmaceutical substance, measures to address such practice could be addressed under Articles 8.2 or 40, TRIPS Agreement. For the latter provision to apply, the practice at issue would have to satisfy the specific requirement of a restraint on competition under Article 40, TRIPS Agreement. This requirement would be met to the extent that excessive prices complicate generic production in the market covered by the patent. Appropriate measures include **non-enforcement** of the patent, but also the granting of a **compulsory license under facilitated procedures**, as provided under Article 31 (k), TRIPS Agreement.
- Finally, it should be noted that a strategy of excessive pricing will only work where the producer dominates the market. In case of a competitive market, excessive pricing will only push consumers toward purchasing the competitors' products. As a general rule, excessive pricing by dominant companies may be considered abusive and thus anti-competitive, opening the possibility to issue a **compulsory license under facilitated procedures**, as provided by Article 31 (k), TRIPS Agreement.

It is important to note that the determination of what is “excessive” lies in the discretion of each WTO member (see box 10 on the experience in South Africa). In many OECD countries, government agencies are authorized to control the prices of medicines. Due to important differences in purchasing power and a frequent lack of health insurance schemes in developing countries, prices that are considered appropriate in developed countries may be

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<sup>527</sup> Non-enforcement is a common remedy under United States law to address cases of patent “misuse”. See Reichman with Hasenzahl, Overview, p. 21. The concept of patent misuse is particular to the United States legal system. In general, it states that an IP holder, who seeks to expand the scope of his right beyond its scope and purpose, does not behave in a legitimate way and will be refused the enforcement of his right. The broad notion of abuse under the TRIPS Agreement encompasses this concept.

deemed excessive in developing countries. Whereas in OECD countries, price controls need to take account of the need by the pharmaceutical industry to recoup their investment in R&D, this does not necessarily apply to the same extent to developing countries. Small developing countries as well as LDCs are not the markets where R&D-based pharmaceutical companies reap major benefits.

**Box 10: The South African experience – addressing excessive pricing of pharmaceuticals**<sup>528</sup>

In September 2002, a number of civil society organizations and individuals lodged a complaint against two multinational pharmaceutical companies with the South African Competition Commission. The complainants alleged violation by some pharmaceutical companies of South African competition law by charging excessive prices to the detriment of consumers for three of their patent-protected ARV medicines. According to South African law (Section 49 B (2) (b) of the Competition Act, No. 89 of 1998), “any person” may “submit a complaint against an alleged prohibited practice”. In the complainants’ view, the drugs prices were excessive because even when taking account of the need to recoup R&D costs and make profits, as well as the obligation to pay certain licensing fees, the prices remained unjustifiably elevated.

The South African Competition Commission endorsed this view and referred the case to the Competition Tribunal. Before the Tribunal could adjudicate on the issue, however, the affected companies agreed to license the right to use the patented substances to a number of local manufacturers. Such agreements had existed before, but under terms and conditions that proved impracticable for the local producers (e.g. sales only allowed to the public sector, at a 30 per cent royalty rate). The new agreements, by contrast, contained much more favourable terms, such as:

- The licensees were authorized to produce for both the public and the private sector;
- The licensees were authorized to produce locally as well as to import the patented substance from abroad (including fixed dose combinations (FDCs));
- The licensees were authorized to export their locally-produced products to all of sub-Saharan Africa;
- The maximum royalty rate was set to be 5 per cent (including FDCs).

What this case shows is:

- The beneficial effects of IP licensing on medicines availability, promotion of local producers and potential win-win collaborative solutions with the patent holder (potential for increased sales in entire region). In this case, the result of increased generic competition was a significant price drop for involved drugs between 58.3 per cent and 93.9 per cent (i.e. prices for patented products prior to the complaint as compared to the cheapest available generic versions produced by local manufacturers on the basis of the new licenses).<sup>529</sup>
- The need to provide for a domestic framework that makes available tools to bring the patent holder to the negotiating table, such as:
  - Legal standing for civil society organizations in competition-related cases;

<sup>528</sup> For details see Berger, pp. 197-199.

<sup>529</sup> Figures from J. Berger, “The role of civil society in the use of TRIPs flexibilities: a focus on South Africa”, presentation made at the *UNCTAD regional workshop on developing local productive and supply capacity in the pharmaceutical sector – the role of intellectual property rights*, 19-23 March 2007, Addis Ababa, Ethiopia (on file with the authors).

- Existing capacity of domestic pharmaceutical manufacturers who could become interesting partners for the foreign patent holder (a “carrot” for the patent holder);
- Regional structures to ensure economies of scale (another “carrot” for the patent holder);
- Availability of compulsory licenses for patent abuse/excessive pricing as a credible threat in case of lack of cooperation (a “stick” for the patent holder).
- The importance of the broad picture: abuse provisions/excessive pricing should be interpreted in the light of a country’s public health emergency and constitutional right to access to healthcare services (where available).

Overall, developing country policymakers should seek to define, in domestic legislation:

- What is “excessive” pricing, taking account of the weak purchasing power and lack of health insurance schemes in many developing countries. Definitions may include references to public health concerns;
- What may be expected of an IPR holder to justify such pricing; and
- What forms of remedy apply after a price has been determined as excessive.<sup>530</sup>
  - The threat of compulsory licensing may be an efficient tool in this respect, as many patent holders prefer lowering their prices rather than seeing generic competitors (i.e. the compulsory licensee) enter the market. The TRIPS Agreement (Article 31) leaves members free to determine excessive prices as a substantive ground for compulsory licensing (see above, the section on compulsory licenses). However, it is important to note that facilitated procedures for the grant of such licenses will only be available to the extent that the patent holder’s behaviour has been characterized as anti-competitive (Article 31 (k), TRIPS Agreement).
  - An alternative to the grant of a compulsory license may be the non-enforcement of the patent right at issue.

### ***3.4.2.2 Predatory pricing***

The practice of selling goods or services below marginal costs, without justification, may be used by patent holders to drive generic competitors out of the market, or to prevent their market entry in the first place. An existing exclusive right may contribute to the establishment of a dominant position in a given market, which in turn may enable the right holder to have recourse to predatory pricing practices.

The latter are particularly relevant in cases where despite an existing patent, the rights holder still faces competition through therapeutically equivalent, off-patent products. Where, by contrast, the patent does result in actual market exclusivity, the rights holder might have recourse to predatory pricing after compulsory licenses have been granted to generic competitors. Finally, predatory pricing practices may even discourage potential generic suppliers from applying for a compulsory license.<sup>531</sup>

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<sup>530</sup> Berger, p. 190.

<sup>531</sup> Ibid, pp. 190-191.

Predatory pricing practices may occur outside or within a licensing context:

- Where a licensor, while claiming the licensing fees, seeks to keep the licensee out of the market, government measures to control such practice must satisfy the conditions under Article 40, TRIPS Agreement (i.e. to show anti-competitive conduct). It should be noted that only dominant firms or cartels are in a position to carry out predatory pricing. Due to its impact on generic competition, predatory pricing may always be considered as abusive of dominance and thus anti-competitive within the meaning of Article 40. Possible remedies include **non-enforcement** of the patent right at issue as well as the grant of a **compulsory license under facilitated procedures** (Article 31 (k), TRIPS Agreement).
- Where predatory pricing is practiced outside a licensing context, the TRIPS-compatibility of government measures to control such practice is tested against the terms of Article 8.2, TRIPS Agreement. Due to the anti-competitive nature of predatory pricing, **compulsory license under facilitated procedures** (Article 31 (k), TRIPS Agreement) may also be made available in this scenario, as an alternative to **patent non-enforcement**.

While the negative impact of predatory pricing on generic competition is obvious, its impact on access to medicines is less clear. Selling drugs below marginal costs may at first improve people's access to affordable medicines. In the medium and long term, however, access is likely to become more difficult, as generic competitors are driven out of the market.

As regards a definition of "predatory pricing" under national competition laws, there is a common understanding that this must involve sales below marginal cost. This being said, developing countries are not precluded from taking into account the fact that due to a lack of domestic know-how of generic producers, their domestic pharmaceutical markets often lack competitiveness to begin with, which facilitates a patent holder's efforts to drive existing competitors out of the market.

Overall, developing country policymakers should consider, in domestic legislation:

- A definition of what is "predatory" in pricing practices. Pre-existing weaknesses in the domestic competitive environment should be taken into account;
- Prohibitions of such practices should apply for the benefit not only of existing, but also of *potential* competitors, referring to the impact of lessening *or preventing* competition;
- What may be expected of an IPR holder to justify such pricing; and
- What forms of remedy apply after a price has been determined as predatory.<sup>532</sup>
  - The threat of compulsory licensing may be an efficient tool in this respect, as many patent holders prefer adjusting their prices to fair levels rather than seeing generic competitors (i.e. the compulsory licensee) enter the market. The TRIPS Agreement (Article 31) leaves members free to determine predatory prices as a substantive ground for compulsory licensing. Due to their anti-competitive character, predatory licensing practices may be addressed under **facilitated compulsory licensing procedures** (Article 31 (k), TRIPS Agreement).

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<sup>532</sup> Ibid, p. 190.

### 3.4.2.3 Refusals to license

#### Applicable TRIPS provisions

In the local pharmaceutical production context, one of the most important scenarios to be addressed by policymakers is the refusal by a patent right holder to grant a license to a potential generic manufacturer. The view has been expressed that Article 40, TRIPS Agreement, on restrictive licensing practices and conditions, applies under this scenario.<sup>533</sup> This provision defines some licensing practices and thus provides some guidance for implementation. This being said, measures addressing refusals to license must meet the requirements under Article 40, in particular show an anti-competitive character of the refusal to license. Alternatively, governments may have recourse to the more general provision under Article 8.2, TRIPS Agreement, which does not require anti-competitive conduct.

This being said, Article 40 does not specify under what circumstances the refusal by a patent (or other IPR) holder to grant a license may be considered as restraining competition and constituting abuse. Article 40.2 requires measures taken to address such abuse to be consistent with the other provisions of the TRIPS Agreement. Thus, the control of restrictive licensing practices may not be used to prevent the regular exercise and exploitation of IPRs, as they are assumed by the TRIPS Agreement standards. As observed above, some guidance in this respect may be provided by analyzing OECD country practice on refusals to license, bearing in mind that developing countries are free to apply alternative models.

#### Developed country case law

In OECD country practice, the refusal by the holder of an IPR to license his right to a third party may generally not be considered as abuse.<sup>534</sup> In the case of the United States, case law emphasizes the patentee's freedom to choose whether or not to license his patent.<sup>535</sup>

The European Court of Justice (ECJ) has several times reiterated its view that a dominant intellectual property holder is under no general obligation to grant a license to a third party.<sup>536</sup> However, the ECJ has also specified the exceptional circumstances under which the refusal to license could actually amount to an abuse of a dominant position (which always has an adverse effect on competition within the meaning of Article 40, paragraphs 1 and 2, TRIPS Agreement). According to the ECJ, abuse in this context depends on three cumulative criteria ("essential facilities doctrine"):<sup>537</sup>

- The party requesting the license intends to offer **new products or services** not offered by the right holder and for which there is a potential consumer demand on a "secondary market".
  - For example, generic producers may develop FDCs of ARV active ingredients

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<sup>533</sup> UNCTAD-ICTSD Resource Book, p. 556.

<sup>534</sup> See P. Roffe/C. Spennemann, "Control of Anti-competitive Practices in Contractual Licenses under the TRIPS Agreement", in Correa/Yusuf, pp. 293-329 (303).

<sup>535</sup> See "Competition Policy and the Exercise of Intellectual Property Rights", revised report by the UNCTAD secretariat, 19 April 2002, TD/B/COM.2/CLP/22/Rev.1.

<sup>536</sup> For instance in *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, case C-418/01 of 29 April 2004 [hereinafter ECJ, *IMS Health*]. This jurisprudence was followed by the European Court of First Instance in September 2007 in *Microsoft Corp. v. Commission of the European Communities*, case T-201/04 (available at: <http://curia.europa.eu/jurisp/cgi-bin/gettext.pl?lang=en&num=79929082T19040201&doc=T&ouvert=T&seance=ARRET>).

<sup>537</sup> ECJ, *IMS Health*.

to reduce patients' pill burden. These active ingredients have previously been patented in separate medical products. The generic producers would need a license from the patent holder(s) for all of these ingredients for production and sale of the new FDC. Due to facilitated treatment, the FDC would not constitute a mere duplication of the existing products but a new good not produced by the patent holder(s), for which there is a potential consumer demand on a "secondary market".<sup>538</sup>

- There are **no objective reasons** for the right holder to refuse to issue a license.
  - It is in the very nature of IPRs to exclude, for a limited period, competitors from the market. The owner of a patent on a pharmaceutical active ingredient may choose not to license the invention to any third party to remain the only supplier on the market for that active ingredient. However, where the potential licensee has no intention to duplicate the patented ingredient, but to use it for the development of a new product, which is not covered by the patent, the patent holder cannot invoke the exclusive character of its IP right to refuse a license. Using a patent in order to prevent the development of new and possibly superior products is contrary to one of the core objectives of IP protection (i.e. the promotion of innovation and technology dissemination) and therefore constitutes no objective reason for a refusal to issue a license.
  
- The refusal is to **exclude any competition on a secondary market**. The objective of this requirement is to prevent upstream IP rights from blocking the development of innovative downstream products. For this reason, ECJ jurisprudence does not insist on the existence of a genuine second *market*; it is sufficient to have two different *stages of production* that are interconnected.<sup>539</sup> This requirement becomes relevant in cases where activities under the upstream stage, which are covered by an IP right, are essential for the downstream activities. Without a license to carry out the upstream activities, a competitor has no possibility to develop the new downstream product. In other words, while the IP holder shall be entitled to fully exploit his rights, he shall not prevent the emergence of new products that are, as such, not covered by the original IP right, thereby eliminating competition:
  - For example, an FDC is the formulation of several active ingredients. Each ingredient is required for the formulation. There is a market for the ingredients, and a separate market for the FDC (or, in the terms of the ECJ, the separate ingredients are at the upstream stage of production, the FDC is at the downstream stage). To the extent that the ingredients are covered by one or several patents, a license from the patent holder(s) will be essential for any generic producer seeking to produce the FDC. The patents on the active ingredients do not cover the new FDC as such, but make its production impossible where no license is granted.
  - An example for a very particular application of the essential facilities doctrine is the 2005 decision by the Italian Competition Authority to order an interim measure on the multinational company Merck to grant licenses to domestic generic producers for the sole purpose of exporting the patented product to

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<sup>538</sup> Example from Berger, p. 192.

<sup>539</sup> See ECJ, IMS Health, para 45.



other EU members where the respective patent had already expired.<sup>540</sup> In this case, the envisaged exports did not concern a new, downstream product, as required by the ECJ, but a generic duplication. The Authority seems to have interpreted the secondary market requirement as covering not only new products but also the same product on a different geographical market. The apparent rationale is to prevent a patent holder from affecting competition outside the territorial scope of the patent. As the Italian generic producers had no intention of selling the generic copies within Italy, the patentee used its exclusive production right for the national market to influence sales (and thus competition) on foreign markets. While the ECJ in its essential facilities jurisprudence has focused on the promotion of product innovation through competition, the Italian Competition Authority seems to have put less emphasis on innovation and more weight on the promotion of competition as such, as a tool to lower drug prices. The Authority limited the patentee's exclusive right to produce the protected substance in Italy. But since the licensed generic production did not affect the Italian market, the core of the exclusive right (i.e. the right to exploit the patent within the national boundaries) seems to have been maintained.<sup>541</sup>

Developing countries may seriously consider adopting comparable approaches to restrictive licensing practices (even though this is by no means required under the TRIPS Agreement). The essential facilities doctrine as interpreted by the ECJ has been characterized as “a powerful tool to enforce effective competition for the benefit of consumers”.<sup>542</sup> Diligently applied, this doctrine strikes an appropriate balance between the legitimate interests of IP holders in effective protection and societal interests in innovative downstream product development.

#### ***3.4.2.4 Cross-licensing and patent pools***

Refusals to license (to be addressed either under Article 8.2 or Article 40, TRIPS Agreement) and other restrictive licensing practices under Article 40, TRIPS Agreement, may also occur in a context of cross-licensing or patent pooling. These are common strategies in developed countries to overcome the problems of blocking effects generated by exclusive rights and ensuing difficulties for follow-on innovation (e.g. through “patent thickets”). Normally, cross-licensing and patent pooling are traditional means in developed countries of opening up protected technology areas to enhanced competition.

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<sup>540</sup> See Press Release of 21 June 2005 (available at <http://www.cptech.org/ip/health/c/italy/>), concerning the patented active ingredient Imipenem Cilastatina; IP health newsletter of 30 June 2007 (available at <http://jiplp.oxfordjournals.org/cgi/content/short/2/7/452?rss=3D1>).

<sup>541</sup> The ECJ when addressing the interfaces between IPRs and competition and IPRs and trade, respectively, distinguishes between the **existence** of the exclusive right as such and its **exercise** through the right holder. While the EU rules on free trade and workable competition may not touch upon the existence of IP rights as such, they may well control their particular exercise by the rights holder. As to patent rights, their existence as such has the objective to enable the rights holder to **exclusively commercialize** the invention **within the substantive and geographical scope** of the patent. See M. Sucker/S. Guttuso/J. Gaster, “Fallgruppen zu Artikel 81 EG-Vertrag. VI. Immaterialgüterrechte” (commentary on the application of former Article 81 of the EC Treaty to IPRs), in EU/EC Commentary, Vol. 2, p. 475, para. 10; p. 478, paras. 19, 20, with references to ECJ case law (continuous jurisprudence since the 1960s).

<sup>542</sup> Brinker/Loest, p. 9.

Cross-licensing of patents occurs between two parties whose patents each cover subject matter needed by the other party. Rather than blocking each other, the parties may enter into an agreement to use each other's protected product or process. These agreements are often royalty-free. As they facilitate the mutual use of technology that would otherwise be blocked by an exclusive right, cross-licensing agreements are often regarded as being pro-competitive. On the other hand, cross-licensing will bring the involved technology under unified control. If the parties agree on exclusive licensing, access to new technologies will be refused to third parties (i.e. potential competitors) and thus prevent further competition.

The same applies to patent pools. These have the same objective as cross-licensing agreements (i.e. avoid the blocking of protected technology), but occur between two or more parties. The parties license a group of patents in a joint patent "pool" or "package". The pool may be held by the licensee, who may be a third party or an association of licensors, or an independent entity (as illustrated by the UNITAID example in box 11, below). For instance, the holders of different pharmaceutical patents may create among themselves a pool of those patents needed for the production of a new drug, or they may license the patent pool to a generic producer, who would be able to use all the protected materials against the payment of license fees. Depending on the way they are administered and their purpose, patent pools may have pro-competitive, but also anti-competitive effects. A pool is pro-competitive where the participating parties are able to use each other's technology for further competing product development, and where the pool is open to be used by third parties, against the payment of a fee. Box 11 provides an example of such an open patent pool created by UNITAID for accelerated treatment of HIV/AIDS. On the other hand, patent pools may also have serious anti-competitive effects where participating parties agree on joint use of the technology, establish uniform prices of the resulting products, and refuse licenses to outsiders. Such problems could be avoided where the pool participants are ready to license the involved technology to third parties on reasonable terms.<sup>543</sup> The threat of issuing a compulsory license under the "essential facilities doctrine" could convince patent pool owners or parties to a cross-licensing agreement to open the pool to competitors to allow follow-on innovation.

#### **Box 11: The Medicines Patent Pool**

The Medicines Patent Pool was created by UNITAID in December 2009 as a separate entity, with UNITAID funding for a period of five years.<sup>544</sup> UNITAID's mission is to "contribute to scaling up access to treatment for HIV/AIDS, malaria and tuberculosis, primarily for people in low-income countries, by leveraging price reductions for quality diagnostics and medicines and accelerating the pace at which these are made available."<sup>545</sup> UNITAID was established in September 2006 by the Governments of Brazil, Chile, France, Norway and the United Kingdom and has since then been joined by 29 additional countries and one foundation.<sup>546</sup> Funding is provided through regular budget contributions or airline ticket taxes.<sup>547</sup> In December 2009, the UNITAID Executive Board approved the establishment of a patent pool for AIDS medicines for low and middle income countries, which was launched in July of

<sup>543</sup> See "Competition policy and the exercise of intellectual property rights", P.M. Njoroge, Commissioner, Monopolies and Prices Commission, Kenya, presented at UNCTAD's Intergovernmental Group of Experts on Competition Law and Policy, Geneva, 17-19 July 2007. Note that Nobel laureate Joseph Stiglitz has proposed patent pools in the context of pharmaceutical R&D, see J. Stiglitz, "Patents, Profits, and People", in: *Making Globalization Work*. New York, W.W. Norton & Company, 2007, pp 103-132.

<sup>544</sup> See <http://www.medicinespatentpool.org/WHO-WE-ARE2/Background>.

<sup>545</sup> See UNITAID mission statement at <http://www.unitaid.eu/>.

<sup>546</sup> See UNITAID Donors.

<sup>547</sup> Ibid.

2010.<sup>548</sup> The objective of the Patent Pool is to create a common facility to which holders of patents on new ARV drugs and related technologies may license their rights, in exchange for the payment of licensing fees. To this end, UNITAID has committed up to \$4 million for one year. The Patent Pool may license substances and technologies received from patent holders to pharmaceutical producers to supply certain low and middle income developing countries (although licenses will be available without discrimination as to the geographical location of the producer). The rationale behind pooling patented technologies lies in the fact that until now, patents on the most recent drugs owned by different companies have blocked the development of more affordable generic versions of these drugs, as well as of fixed-dose combinations (FDCs) by generic or R&D-based producers. FDCs facilitate treatment, especially for children. The Patent Pool will facilitate the efforts by (R&D-based or generic) manufacturers to produce FDCs or create improved production processes for the drugs included in the pool, as well as efforts to develop effective generic versions of second line ARV drugs. The Patent Pool in early 2010 identified 19 products from nine companies for potential inclusion in the pool. Before the Pool can start making drugs and technologies available, it will have to negotiate the terms of the licenses with patent holder companies.<sup>549</sup> The first license was granted by the United States National Institutes of Health (NIH) in late September 2010. This license is royalty-free and authorizes the use of a series of patents related to the HIV medicine darunavir (for the treatment of drug-resistant HIV infections).<sup>550</sup> The idea of creating a patent pool was proposed to UNITAID by the civil society organizations Knowledge Ecology International (KEI) and Médecins Sans Frontières (MSF) in 2006.

#### 3.4.2.5 Summary of main policy options

In conclusion, developing countries may wish to address potential IP abuses in the local production context by providing in their domestic laws:

- **Definitions** of
  - The notion of “abuse” of an IPR;
  - The notion of “abuse of dominance” and “anti-competitive conduct” in IP-related practice;
  - The specific notion of “excessive pricing” (as a sub-category of abuse of dominance);
  - The specific notion of “predatory pricing” (as a sub-category of abuse of dominance); and
  - The conditions under which refusals to license (including in patent pools) constitute an abuse of a dominant position (which automatically has anti-competitive impact). In this context, the *essential facilities doctrine* as practiced by the European Court of Justice could provide some useful guidance.
- **Remedies** for the above cases, such as:
  - Non-enforcement of patent rights;
  - Compulsory licensing of patented inventions. To the extent that the practice at issue involves anti-competitive conduct (as defined in the domestic law),

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<sup>548</sup> On this and the following information, see “UNITAID Executive Board Approves Breakthrough Plan to Make AIDS Treatment More Widely Available at Lower Cost” as well as IP Watch, “First Patent Holder Grants Licences To UNITAID”, online publication, 1 October 2010 (<http://www.ip-watch.org/weblog/2010/10/01/first-patent-holder-grants-licences-to-unitaid/>).

<sup>549</sup> See statement by Ellen t’Hoen announcing the UNITAID Patent Pool

<sup>550</sup> See <http://www.medicinespatentpool.org/LICENSING>.

facilitated procedures for the granting of the license should be made available, as authorized under Article 31 (k), TRIPS Agreement.

- To the extent possible, remedies should take account of the particularities of each case:
  - Does the abusive/anti-competitive practice have beneficial effects in terms of improvements of domestic technological capacities, efficiency or enhanced long-term drugs availability?
  - Does this result outweigh the negative impact of the practice at issue (i.e. restraints on competition or/and obstacles for effective technology transfer and dissemination)?
  - Practices showing beneficial effects which outweigh their negative impact may be saved from the above remedies (“rule of reason” approach).

## **3.5 The protection of clinical test data**

### **3.5.1 Background**

#### **Introduction**

While a patent confers upon its owner the right to exclude third parties from a range of activities, it does not give the patent holder any positive right to market the protected product. According to most national laws, the marketing of both originator drugs and their generic copies needs to be approved by a national drug regulatory authority (DRA). The objective of the marketing approval process is to ensure the safety and efficacy of the respective products. The approval granted by a DRA is limited in its scope to the national territory.

The granting of a patent and the approval for the market of a pharmaceutical product (“regulatory approval”) are thus two separate processes that involve separate government agencies (i.e. the patent office and the DRA). An inventor who is granted a patent for a new and inventive drug may still be denied regulatory approval if clinical tests show potential negative effects of this drug on the human body.

Given the different objectives underlying the patent system and the granting of marketing approvals for pharmaceuticals, the regulatory approval process is usually addressed in laws that are separate from national IP laws. The originator of a drug thus has to file two separate applications, one with the DRA (for the regulatory approval) and another at the patent office (for the respective product and/or process patents). In order to meet the novelty requirement under the national patent law, the drug originator must file a patent application for the new product or substance as early as possible. The patent applicant also has to satisfy a number of technical and regulatory requirements before he can actually submit to the DRA a request for marketing approval, and both the clinical testing and related approval processes may require additional submissions and otherwise take considerable time. Consequently, the patent is often granted before the patent holder receives marketing approval for the patented pharmaceutical product. However, the term of patent protection (at least 20 years) is counted from the date of filing of the patent application (Article 33 of the TRIPS Agreement), irrespective of the date of marketing approval. The longer it takes to obtain marketing

approval, the shorter is the period during which the patent holder may effectively exploit his exclusive rights in the market.

WTO members in their domestic laws may condition the granting of regulatory approval on the applicant's submission of clinical trial data that prove the medical safety and pharmaceutical efficacy of a given drug. In case the originator of the data has already been granted marketing approval abroad, a country may decide to base domestic marketing approval on the recognition of the foreign approval. Alternatively, a country may also decide to require the data originator to carry out additional clinical trials, in case it considers the trials undertaken for the foreign approval as insufficient.

If marketing approval is sought by a generic producer, a country's DRA will not be prepared to recognize prior approvals granted to the data originator, who differs from the generic producer. Instead, it will at least require the generic producer to submit evidence of bioequivalence between the generic drug and the originator's product, i.e. to show that the copied product performs in the same manner as the originator's product (the safety and efficacy of which has already been proven).<sup>551</sup> By doing so, the generic producer does not make use of the originator's data, which remains undisclosed and unknown to him, in line with the TRIPS Agreement (see below for details). Rather, he has the DRA rely on the health and safety outcome resulting from the data submitted by the originator.<sup>552</sup> While the latter may still argue that approval of the generic products really stems from so called "free riding use" of the costly original test data, the TRIPS Agreement does not contain language that would prohibit any form of reliance by the DRA on the originator data (see below for details).

The approval of the generic drug by the DRA may subsequently be recognized by a foreign DRA with respect to the same generic producer, unless it considers the showing of bioequivalence submitted to the other DRA as insufficient.

In the course of bioequivalence evaluation, a DRA may also have to rely on the results of originator data submitted abroad by requesting a foreign DRA whether a certain substance has received regulatory approval. This situation may arise in cases where a foreign originator has not requested regulatory approval with the domestic DRA, because the originator company did not consider it worth filing a patent in that country, or because that country did not afford patent protection for pharmaceuticals at the time the product was discovered. In such a case,

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<sup>551</sup> "Bioequivalence" refers to the similarity of active ingredients in the originator and the generic drug. "Bioavailability" refers to the percentage of the active ingredient which reaches the patient's blood stream. See D. Dunlap-Hinkler, T.J. Hannigan, R. Mudambi, "Brazil Pharmaceutical Case", paper developed for UNCTAD's 2011 World Investment Report. Both bioequivalence and bioavailability are usually required for generic regulatory approval, because a combination of both will demonstrate that the generic has the same therapeutical effect as the originator drug. Generic producers obligated to demonstrate bioequivalence may do so by measuring "the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug." See Pugatch, p. 102, referring to FDA-CDER.

<sup>552</sup> As opposed to the examination of the original pharmaceutical product, the DRA when assessing a bioequivalent generic copy no longer analyzes the trials data *themselves*, but relies on the *outcome* of the clinical trials as indicated by these data, i.e. *on the prior judgment* that the drug (and, consequently, its bioequivalent), is safe and efficacious. See J.H. Reichman, "The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Good?" [hereinafter Reichman, *The International Legal Status*], in *Negotiating Health*, p. 142, referring to the *Bayer v. Canada* decision by the Canadian Federal Court of Appeal (1998) (referred to as "indirect" reliance on the test data, as opposed to "direct" reliance, where the DRA, when examining bioequivalence of a generic drug, analyzes the original data themselves).

the drug is in the public domain and the originator company cannot prevent any competitor from freely using it. However, in order for a competitor to be able to market a generic copy of the drug, the local DRA must still make a judgment about the efficacy and safety of the generic product, and this decision may require the authority to rely on the regulatory decisions made by a DRA in a country where the originator has actually been granted regulatory approval. Again, the originator company may argue that the generic producer free rides on the originator's efforts, even though the domestic DRA in these cases makes no direct use of the test data in question (rather, it uses the foreign decision that is based on such test data).

Responding to allegations of free riding use of originators' test data, it should be noted that the TRIPS Agreement in Article 39 does not contain language that would prohibit the reliance on the original test data.<sup>553</sup> A number of free trade agreements (FTAs) have instead attempted to give effect to the pharmaceutical companies' claims with results that vary from one FTA to the other, but which on the whole have grown more favourable to the pharmaceutical companies with each successive negotiating round. In general, it may be stated that as a result of these FTAs, the possibility for generic producers to seek marketing approval based on bioequivalence has been largely excluded. The FTAs basically prevent DRAs from relying, for a certain period of time, on data submitted by other parties (i.e. the data originator), based on the assumption that the generic competitor, by asking the DRA to rely on the original data or the resulting regulatory decision for the approval of his products, makes use of the clinical trial data generated by the data originator (see below for details). Thus, the generic competitor is required to repeat clinical trials for drugs that are proven to be bioequivalent to the originator's approved drugs. The detailed obligations that any given developing country or LDC will owe to the pharmaceutical companies in this regard will vary from country to country depending on the totality of the relevant agreements they have signed.

A further wrinkle arises from the Most-Favoured Nation (MFN) provision of the TRIPS Agreement, which was never previously applicable to IP law and which was adopted without some of the limiting safeguards, especially for regional trade agreements, which are found in the General Agreement on Tariffs and Trade's (GATT) version of the same doctrine.<sup>554</sup> As a result, a country that signs an FTA with country A, obliging it to protect clinical test data by means of an exclusive property right may find that it owes the same protection to all other WTO members.

Undertaking clinical trials means that the applicant for regulatory approval has to undertake a series of pre-clinical (i.e. using computers and animal testing methods) and clinical trials (i.e. three phases of tests on a growing number of human beings) to show the effect of the new compound on the human body, including its absorption, distribution, metabolism and excretion.<sup>555</sup> The costs for these trials have been subject to considerable controversy.<sup>556</sup> No matter what the actual figures are, generic producers can hardly be expected to bear such expenses, as they cannot recoup them through any exclusive rights under a patent.

Considering the magnitude of the costs incurred and the time needed for the submission of clinical test data, it is in the interest of pharmaceutical product originators to seek some form

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<sup>553</sup> While earlier drafts of the TRIPS Agreement contained language that would have made reliance on existing test data unfair commercial use, these provisions did not survive the modifications made in the Brussels Draft during the Uruguay Round Negotiations. See UNCTAD-ICTSD Resource Book, p. 525.

<sup>554</sup> See Article XXIV.5 of GATT, 1947.

<sup>555</sup> See Pugatch, p. 97.

<sup>556</sup> *Ibid*, p. 97/87.

of protection for their data. In fact, the case for expansive patents in the pharmaceutical sector typically relies on this argument, especially because a company needs to recoup both the costs of approved products and the costs of failed products, which outnumber the approved ones. This is known as the “risk premium”.<sup>557</sup> Whether beyond patent revenues, the originator companies should be entitled to even more compensation by other means for expenses related to the same product is an entirely different and controversial question. In any event, apart from the question of costs, it is in the interest of the product originator to keep the information relating to the product’s safety and efficacy secret to prevent competitors from using it and free-riding upon their investment. Secrecy may help the data originator maintain his lead time advantages, in particular by rendering more difficult any reverse engineering activities by competitors, which may be based, *inter alia*, on tacit knowledge or know-how not disclosed in the patent but revealed in the testing documents and the related data.

For these reasons, the TRIPS Agreement (see the next section for details), which in Article 39 introduces the protection of trade secrets into international law for the first time, provides for a separate type of protection of clinical test data, which has been characterized as an expression of trade secrets law.<sup>558</sup> As under patent law, it is essential to interpret the pertinent TRIPS provision in a way that strikes an appropriate balance between the above-mentioned interests of pharmaceutical product originators on the one hand and the need to ensure access to medicines and competition by product followers on the other hand, with due regard to the express language and the canons of interpretation applicable from international law, such as the Vienna Convention on the Law of Treaties and the principles of interpretation of the TRIPS Agreement as developed by the WTO Appellate Body.<sup>559</sup>

### **The TRIPS Agreement framework**

The TRIPS Agreement in its Article 39 (in particular paragraph 3) imposes certain obligations for those members that do not grant marketing approval based on the recognition of prior foreign approvals or on the basis of a mere showing of bioequivalence. Article 39.3, TRIPS Agreement, provides that:

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

The obligations incurred by members under Article 39.3 are toward the originators of pharmaceutical products, who defrayed the costs of the trials, irrespective of whether these products are patent-protected or not in the country where marketing approval is sought.<sup>560</sup>

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<sup>557</sup> See Reichman, *The International Legal Status*, p. 146, noting “the aggregate weight that clinical trial costs actually have on the pharmaceutical supply chain in the United States, and [...] the huge risk premium built into the pricing of medicines there, owing to the high costs of trials that result in denials of market approval.”

<sup>558</sup> See Pugatch, p. 98.

<sup>559</sup> On the latter, see UNCTAD-ICTSD Resource Book, Chapter 32 (Dispute Settlement), Annex 1 (Methods of Interpretation under the DSU), pp. 690 ff.

<sup>560</sup> Note that Article 39 is part of Section 7 of the TRIPS Agreement (“Protection of Undisclosed Information”), while provisions on patents are contained in Section 5.

According to Article 39.3, TRIPS Agreement, members have to provide protection against unfair commercial use and disclosure of, *inter alia*, pharmaceutical test data that were submitted to regulatory authorities for marketing approval purposes. The scope of Article 39.3 is limited to undisclosed data on pharmaceutical and agro-chemical products that utilize “new chemical entities”, provided that the process of originating the data entailed a “considerable effort”. The “considerable effort” requirement may be interpreted as encompassing not only economic factors but also technical and scientific considerations.<sup>561</sup>

In sum, Article 39.3 applies when:

- There is an obligation to submit test data for obtaining marketing authorization for pharmaceuticals and agrochemicals;
- The pertinent information is not publicly available;
- The origination of the data involves a considerable effort (in terms of financial, technical and scientific inputs); and
- The submission refers to a “new chemical entity”. Hence, there is no obligation with regard to new dosage forms and new uses or combinations of known chemical entities, even though the marketing of those may require another approval from the DRA.<sup>562</sup> In addition, the TRIPS Agreement does not specify what is meant by “new”. Members are free to apply the patent concept of novelty, according to which the obligation under Article 39.3, TRIPS Agreement, would not arise in cases where a chemical entity, even though not approved by the domestic drug regulator, has been approved abroad and is thus available to the public worldwide (under a worldwide approach to novelty, see above, Section 2.4.1.1). Alternatively, members are free to consider as “new” those chemical entities that have not received prior regulatory approval in the domestic territory, despite existing regulatory approvals of the same entity abroad.<sup>563</sup>

The above requirements will trigger a WTO member’s obligation to protect the relevant test data against:

**1. Disclosure** (Article 39.3, TRIPS Agreement, second sentence). This means that governments and their agencies (such as the DRA) should not disclose or reveal test data to outsiders, especially competitors of the originator pharmaceutical producer. This obligation, however, is not absolute. Disclosure of test data is permissible:

- **Where necessary to protect the public.** This proviso is important in the public health context. For example, public health authorities may need to warn consumers about the risks of toxic side effects in pharmaceutical products, as revealed in the clinical trials data, or they may wish their own scientific experts to independently evaluate the grounds for an approval decision abroad.
- Where steps are taken to ensure that the data is **protected against unfair commercial use** (see below).

**2. Unfair commercial use** (Article 39.3, TRIPS Agreement, first sentence). Unlike the obligation not to disclose relevant test data, the government’s obligation to protect test data

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<sup>561</sup> See UNCTAD-ICTSD Resource Book, p. 531.

<sup>562</sup> Ibid, p. 522.

<sup>563</sup> Ibid, p. 530. Note that a number of bilateral and regional FTAs make the latter approach mandatory. See, for instance, Article 15.10.1(c) of the United States - CAFTA FTA: “For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.” ([http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset\\_upload\\_file934\\_3935.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf)).



against unfair commercial use is expressed without any exceptions. While the TRIPS Agreement contains no definition of what constitutes “unfair commercial use”, the term is apparently based on the concept of “unfair competition” under Article 10*bis* of the Paris Convention, which is the foundation for incorporating Section VII into the TRIPS Agreement in the first place under Article 39.1.<sup>564</sup> However, Parties to the Convention have never been able to agree on the meaning of “unfair use”, because of:

- Different national legal traditions of unfair competition rules;
- Different moral standards in different countries as to what is “fair” in competitive relations; and
- Different levels of competition prevailing in different countries.<sup>565</sup>

These are important national differences, which necessarily bear on the interpretation of the obligation under Article 39.3 of the TRIPS Agreement to provide protection against “unfair commercial use”, all the more so because Article 10*bis* of the Paris Convention only interdicts acts of unfair competition in international trade.

The obligation to protect test data against unfair commercial use has been interpreted in different ways (see following sections). While it is not the purpose of this Guide to contribute to this academic discussion, the different interpretations of fairness in this context have fundamental implications for generic producers, including those from small developing countries and LDCs. Policy makers when implementing Article 39.3, TRIPS Agreement need to be aware of the implications of different policy options for local pharmaceutical producers and for access to medicines in their respective countries. For this reason, the following sections will discuss three different modes of implementing the unfair commercial use obligation, i.e. through:

- A misappropriation approach;
- A data exclusivity approach, including data exclusivity rules in free trade agreements;
- A compensatory liability or cost-sharing approach.<sup>566</sup>

All of these approaches have been developed in response to current national drug supply systems, which saddle pharmaceutical companies with the costs of providing data that may be considered a public good.<sup>567</sup> In recent years, proposals have been made to shift the responsibility for funding and oversight of clinical trials into the hands of public institutions.<sup>568</sup> Despite the importance of this issue for the future design of pharmaceutical R&D, an in-depth discussion would go beyond the scope and purpose of this Guide, which

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<sup>564</sup> Ibid, p. 523. Article 39.1 of the TRIPS Agreement states that:

“In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.”

<sup>565</sup> See S. Ladas, “Patents, Trademarks and Related Rights: National and International Protection”, Vol. 3, *Harvard University Press*, Cambridge, 1975.

<sup>566</sup> For a detailed overview, see R. Weissman, “Data Protection: Options for Implementation”, in *Negotiating Health*, p, pp. 151-178 [hereinafter Weissman].

<sup>567</sup> Reichman, *The International Legal Status*, p. 146.

<sup>568</sup> For the idea of a public prize fund see J. Love and T. Hubbard, “The Big Idea: Prizes to Stimulate R&D for New Medicines”. *KEI Research Paper* No. 1, March 2007; B. Krohmal, “Prominent Innovation Prizes and Reward Programs”. *KEI Research Note* 1, 2007; J. Love, “Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D”. *UC Davis Law Review*, Vol. 40, 2007, pp. 679-715. See also T.R. Lewis, J.H. Reichman and A.D. So, “The Case for Public Funding and Public Oversight of Clinical Trials”, *The Berkeley Electronic Press, Economist’s Voice*, Volume 4, Issue 1, 2007 (available at: <http://www.bepress.com/ev/vol4/iss1/art3/>).

aims to assist stakeholders in the use of TRIPS flexibilities under the existing drug development system.

### ***3.5.1.1 The misappropriation approach***

This approach is based on an interpretation of Article 39.3, TRIPS Agreement which seeks to facilitate, to the greatest possible extent, the early market entry of generic competitors. According to this interpretation, Article 39.3, TRIPS Agreement obligates members to protect test data in accordance with principles of unfair competition in international trade (i.e. Article 10*bis*, Paris Convention) that are expressly invoked in the chapeau clause of Article 39.1 of the TRIPS Agreement. This means that competitors of the data originator pharmaceutical producer must be prevented from obtaining the latter's data through unfair commercial means ("misappropriation"),<sup>569</sup> and of using it for unfair commercial advantage, such as to shorten the time and reduce the cost for reverse engineering. This leaves competitors free to either license existing data or to generate their own (such as through reverse engineering without unfair access to secret data), if the DRA so requires.

However, this obligation does not prevent the DRA from relying on the results of original test data from domestic or foreign approvals when assessing the safety and efficacy of generic competing products, based on claims of bioequivalence ("reliance"). In this connection, the generic producer is not obliged to submit to the DRA clinical data proving the safety and efficacy of his medicament, if he can show that the generic drug is bioequivalent to the originator product. The fact of reliance alone on a domestic or foreign approval and the results of the supporting test data would not of itself constitute unfair use under Article 39 of the TRIPS Agreement.<sup>570</sup>

The misappropriation approach is favourable to generic producers, in particular those in developing countries, as they usually cannot afford to develop their own clinical test data, for which they would have to repeat the same clinical and toxicological tests as already undertaken by the data originator. Such tests are time consuming and expensive, and often represent insurmountable barriers for the market entry of small producers of generic pharmaceutical products.<sup>571</sup>

From the generic producers' point of view, the misappropriation approach only facilitates the regulatory approval process of bioequivalent products, but does not concern existing patent rights that may cover the originator's product. As the generic product is a copy of the original one (more or less modified), the generic producer in order to submit its product to the regulatory authority (for purposes of demonstrating bioequivalence) will rely on lawful reverse-engineering of the patented drug in order to understand how it was formulated. It is at this juncture that the regulatory review (Bolar) exception becomes essential to authorize the

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<sup>569</sup> For examples of "misappropriation" see Reichman, *The International Legal Status*, p. 142, referring to cases where the DRA discloses the originator's data to a local competing firm or facilitates that firm's access to the data in order to provide the local producer with a competitive advantage; or where the government itself or one of its former staff exploit the commercial advantage of having access to clinical trials data.

<sup>570</sup> However, under certain FTAs, countries may assume tighter obligations that will prevent such reliance. See Box 12, below, for details.

<sup>571</sup> See Pugatch, p. 100.

use of the patented substance for regulatory purposes in order to ensure that marketing of the generic products may be commenced on the first day after patent expiry.<sup>572</sup>

Countries such as Argentina, Canada and Israel have, in varying degrees, implemented misappropriation regimes.<sup>573</sup> There is no WTO jurisprudence on the TRIPS-consistency of this approach.<sup>574</sup> But as observed above, members diverge considerably on what they regard as “unfair commercial use”. While some countries may consider it unfair to let second comers take advantage of the investments made by data originators (“free riding”), other countries may regard as unfair to impose on financially weak generic producers, in particular those in poor developing countries or LDCs, the same requirements as those set up for multinational pharmaceutical companies, especially where the latter may at the same time benefit from patent protection on the respective substance and may already have entirely recouped their R&D investment in OECD country markets. Where this is the case, data originators no longer need to recoup any remaining costs, and there is a risk of over-compensating the data originator at the expense of generic price competition. Finally, some societies may view as unethical the requirement to repeat clinical tests on substances the safety and efficacy of which has already been approved.<sup>575</sup>

The misappropriation approach, however, has been criticized for its alleged lack of consideration for the data originator’s substantial investments in terms of time and financial resources, and its desire to receive a fair return upon such investment.<sup>576</sup> As a matter of fact, even if the R&D expenses claimed by some studies were exaggerated and methodologically problematic,<sup>577</sup> they are still sufficiently high to prevent generic producers from undertaking their own clinical trials. Data originators may be deterred from investing in countries not providing any sort of protection to or compensation of their efforts.<sup>578</sup> On the other hand, these arguments lose considerable weight when considering that pharmaceutical companies normally recoup the bulk of their R&D costs in OECD countries, thus not depending on further rent extractions from developing country markets. This applies particularly in the context of small developing countries and LDCs, whose regimes of test data protection will have hardly any effect on investment choices by multinational enterprises.<sup>579</sup> Irrespective of such arguments, in practical terms the misappropriation approach as rooted in the express language of Article 39.3 of the TRIPS Agreement has not survived in recent bilateral or regional free trade agreements between developing and developed countries.<sup>580</sup> This is a considerable weakening of sovereign power, which developing country policy makers should be aware of.

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<sup>572</sup> For more details on this exception, see above, Section 3.1.3, and the discussion of the WTO panel report on *Canada - Patent Protection of Pharmaceutical Products*.

<sup>573</sup> See Weissman, p. 153.

<sup>574</sup> A WTO dispute initiated by the United States against Argentina for alleged breach of Article 39 of the TRIPS Agreement was settled at the stage of consultations. See C. Correa, “Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements”, in *Negotiating Health*, pp. 81-96 (85) [hereinafter Correa, Protecting Test Data].

<sup>575</sup> See Correa, Protecting Test Data, p. 93, who refers to unnecessary animal suffering or death as well as human health risks where placebo (i.e. no treatment, no cure) is used in comparative trials.

<sup>576</sup> For an overview of the most frequently advanced arguments, see Weissman, p. 154.

<sup>577</sup> See Pugatch, p. 98, referring to CPTech and Frank.

<sup>578</sup> According to Pharma-Israel, the interest group representing R&D-based pharmaceutical companies in Israel, at least 11 products for which a data exclusivity regime would be the primary means of protection have not been registered in Israel between 2000 and 2003, see Pugatch, p. 125.

<sup>579</sup> Weissman, p. 154.

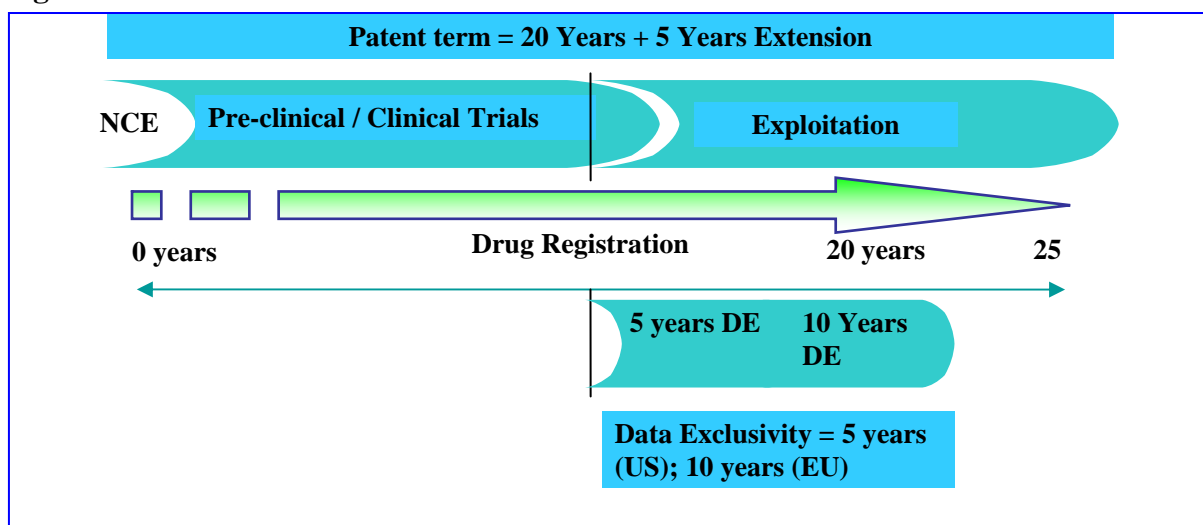
<sup>580</sup> Reichman, *The International Legal Status*, p. 146; Weissman, p. 155.

### 3.5.1.2 The data exclusivity approach

This approach accommodates, to the greatest possible extent, the interests of the product/data originators, making a market entry of generic competitors almost impossible before the lapse of a fixed period. According to this view, the terms “unfair commercial use” under Article 39.3, TRIPS Agreement, obligate WTO members to provide the originator company with exclusive rights in its test data for a fixed period starting from the date of approval of the pharmaceutical chemical entity by the DRA.<sup>581</sup> Many OECD countries follow the exclusive rights approach, preventing for a certain amount of time their drug regulatory authorities from relying on original test data when assessing the safety and efficacy of generic competing products, unless the data originator gives his consent.<sup>582</sup> It is important to reiterate that such TRIPS-plus regime applies also and particularly to drugs that are off-patent, thus creating a new category of exclusive rights parallel to those of the patent system.

In theory, even a regime of data exclusivity does not prevent competitors from coming up with their own data through their own efforts, either using the original drug where it is off-patent, or relying on an appropriate regulatory review (“Bolar”) exception, where the original drug is still patent-protected. As mentioned before, however, it is widely recognized that this obligation creates insurmountable barriers for generic producers in terms of financial resources and time. Where the protected data concern off-patent substances, a data exclusivity regime therefore erects an important new market access barrier for generic producers.

**Figure 2: Market exclusivity periods generated by patents and data exclusivity legislation**



Source: Pugatch, p. 119. The 5-year patent extension is provided under some OECD countries’ legislation to make up for delays in the granting of marketing approvals. This is not required under the TRIPS Agreement.

<sup>581</sup> For this view, see International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), “The Pharmaceutical Innovation Platform - Sustaining Better Health for Patients Worldwide”, Geneva, 2004, p. 40; J. Gorlin, “Encouragement of New Clinical Drug Development: The Role of Data Exclusivity”, IFPMA, Geneva, 2000. A similar proposal was bracketed in the pre-TRIPS Brussels Draft of December 1990 (see UNCTAD-ICTSD Resource Book, p. 525) and subsequently dropped from the crucial Dunkel Draft of the TRIPS Agreement (December 1991). Data exclusivity cannot therefore be considered an obligation under the TRIPS Agreement.

<sup>582</sup> For an overview of the pertinent Canadian, EU and United States legislation, see Pugatch, pp. 102 – 110.

But the impact of data exclusivity regimes on generic producers is not limited to cases of off-patent pharmaceutical products. Data exclusivity may also complicate generic producers' market entry where the respective product is in addition covered by a patent. Existing data exclusivity regimes provide terms of protection of between 5 and 10 years (sometimes 15 years for agrochemical products<sup>583</sup>), which usually end before a patent on the same product expires. Figure 2 may illustrate the parallel terms of patent and data protection in this context.

However, there are some cases where the term of protection for the test data actually reaches beyond the term of protection offered by the patent, in particular if the development process for a drug (i.e. the period of pre-clinical and clinical trials) is particularly long, and the term of patent protection remaining at the moment of drug registration (i.e. marketing approval) is shorter than the full span of data exclusivity.<sup>584</sup> Another important case where the term of exclusive data protection may extend beyond the term of patent protection may arise in the context of new uses of pharmaceutical products. As discussed above, WTO members may elect to exclude both product and process patents on new medical uses of known pharmaceutical products, thus preventing an extension of the patent term on the same substance. Discovering a new use may, however, require the granting of another marketing approval for the known pharmaceutical substance. The exclusive data rights generated by such new approval would be limited to the terms of the new approval, thus not hindering competitors from asking the DRA to rely on the original data for approving a generic product only for the first indicated use.<sup>585</sup> But where the new use is not protected by a (new) patent, the new term of exclusive data protection for the new use could effectively extend beyond the term of protection under the initial (and only) patent.<sup>586</sup> This possibility is in fact acknowledged and promoted by the United States-Morocco FTA, which expressly lays down the Parties' obligation to provide a three-year term of exclusive protection to "new clinical information", in addition to the five-year term of exclusivity for data regarding a "new pharmaceutical [...] product".<sup>587</sup> As to the relationship between the term of an existing patent and the additional three-year period of data protection, footnote 12 to Article 15.10(2) of this FTA states that:

"[...] In addition, when a product is subject to a system of marketing approval pursuant to paragraph 2 and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in Article 10.2."<sup>588</sup>

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<sup>583</sup> See Correa, *Protecting Test Data*, p. 89, referring to the United States – DR/CAFTA FTA.

<sup>584</sup> See Pugatch, p. 120.

<sup>585</sup> See R. Eisenberg, "The Role Of The FDA In Innovation Policy", *Michigan Telecommunications and Technology Law Review*, Vol. 13, 2007, pp. 345 ff [hereinafter Eisenberg]. In the context of the United States-Morocco FTA, it has been observed that such provisions could give rise to abuse by data originators, who could claim overlaps of usages between the generic products and their own, newly approved uses, even where the generics are only intended to cover old uses (which is possible after the expiry of the original 5-year period of exclusivity). Legal proceedings to dismiss such claims and to distinguish between old and new uses are likely to create further delay for market entry of generic competitors. See Abbott, *Contradictory Trend*, p. 11.

<sup>586</sup> See K. Timmermans, "Monopolizing Clinical Trial Data: Implications and Trends", *PLoS Medicine Journal*, 13 February 2007 [hereinafter Timmermans], available at <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0040002>.

<sup>587</sup> See Article 15.10(1) and (2) of the United States-Morocco FTA.

<sup>588</sup> Footnote 11 to Article 15.10(1) contains a comparable provision with respect to patents and the original, five-year term of data exclusivity.

Although it has been stated that data exclusivity rules will rarely extend beyond existing patent terms,<sup>589</sup> Table 5 below shows three examples of selected drugs where this was the case.

**Table 5: Patent and data exclusivity expiration periods in the United States for selected drugs**

<b>PRODUCT</b>	<b>Taxol (Paclitaxel)</b>	<b>Eprex (Epeotin Alpah)</b>	<b>Arava (Leflunomide)</b>
<b>PURPOSE</b>	Breast Cancer /Ovarian Cancer and others	Severe Anemia	Rheumatoid arthritis
<b>United States MARKET APPROVAL</b>	Discovered in 1962 Approved in 1994/1998	2000	1998
<b>United States Patent Expiry</b>	-----no patent available	2004	2001
<b>United States DE Expiry</b>	2004 (Orphan Drug)	2005	2003

Source: Pugatch, p. 120 (author's own calculations based on the database of the United States Food and Drug Administration - Center of Drug Evaluation and Research Electronic Orange Book, [www.fda.gov/cder/ob](http://www.fda.gov/cder/ob)).

Even if cases of the sort mentioned in the above table are rare, a major concern expressed with regard to the impact of data exclusivity on patented products relates to the effectiveness of compulsory licenses on a patented invention, when needed for public health purposes within the ambit of the Doha Declaration on the TRIPS Agreement and Public Health and the amended TRIPS provisions.<sup>590</sup> Production of a drug under a compulsory license will still require marketing approval from the DRA, which under data exclusivity regimes may not be granted without permission of the data originator (see also box 12, below, on data exclusivity under FTAs). A similar problem arises in the context of the regulatory review exception: while it allows generic producers to use the patented substance for submission of their application for regulatory approval, the DRA may not immediately respond by granting approval before the expiry of the exclusive rights in the original test data (see above, Section 3.1.3), except in the unlikely event that the generic producer is capable of producing her/his own test data.<sup>591</sup>

The data exclusivity approach has been justified as the only means to encourage R&D in new pharmaceutical products and to guarantee the data originator a fair return to compensate for the efforts made.<sup>592</sup> However, and as observed above, interpretations of what constitutes “unfair commercial use” vary considerably among WTO members and are possibly influenced by their national priorities. In the related area of pharmaceutical patents, many OECD countries until the 1970s considered the copying of pharmaceutical inventions as

<sup>589</sup> Pugatch, p. 120, referring to a 2001 study by IMS Health.

<sup>590</sup> See Abbott/Reichman, Section F.1.

<sup>591</sup> In the latter case, the regulatory review exception remains of crucial importance for generic producers of on-patent products, as test data may only be developed once the structure of the respective substance has been understood through reverse engineering of the patented product.

<sup>592</sup> See C. Priapantja, “Trade Secret: How does this apply to drug registration data?” Paper presented at ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, Department of Health and World Health Organization, May 2-4, 2000, p. 4.

entirely fair and beneficial to their industries.<sup>593</sup> Most importantly, proposals to expressly include in Article 39 of the TRIPS Agreement an obligation to provide for data exclusivity were rejected by other Parties during the Uruguay Round of multilateral trade negotiations.<sup>594</sup> This is a clear indication that there was no international agreement to read any requirement of data exclusivity into the terms of Article 39 of the TRIPS Agreement.<sup>595</sup> In addition, reliance by drug regulatory authorities on previously approved compounds for the purpose of generic approvals was a widely recognized practice in many countries prior to the negotiation of the North American Free Trade Agreement (NAFTA) of 1992, which for the first time introduced a rule on data exclusivity for pharmaceutical products on the international level.<sup>596</sup> In the literature, it has been observed that “it does not seem justified to suddenly label longstanding regulatory practices as ‘unfair’.”<sup>597</sup> Also, it is important to note that most of the approved drugs benefit from patent protection,<sup>598</sup> which already provides drug developers with an important means to recoup their investment into pharmaceutical R&D. In addition, early stage medical research is often publicly funded in OECD countries (see below, discussion on compensatory liability regimes).<sup>599</sup> From this perspective, it seems questionable whether reliance by a DRA on the test data of previously approved drugs may actually constitute “unfair commercial use” within the meaning of Article 39 of the TRIPS Agreement. Obligations to introduce data exclusivity rules for pharmaceutical test data, whether contained in FTAs or other instruments, may therefore be considered as “TRIPS-plus”.<sup>600</sup>

For policymakers, it is important to understand that even under data exclusivity regimes, there are ways to balance the interests of data originators with the need to promote the market entry of generic competitors. Examples will be provided under the section on policy options, below.

Before discussing the third option available for domestic implementation of Article 39.3 of the TRIPS Agreement, it is important to further highlight the impact of data exclusivity rules on public health policies in the context of bilateral and regional free trade agreement, in which developing countries are increasingly being involved (box 12).<sup>601</sup>

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<sup>593</sup> Many OECD countries did not introduce product patent protection for pharmaceuticals until the 1970s, see UNCTAD-ICTSD Policy Discussion Paper.

<sup>594</sup> For the text of this proposal, see UNCTAD-ICTSD Resource Book, pp. 525/526, referring to the negotiating history of Article 39 and the Brussels Draft of December 1990.

<sup>595</sup> According to Article 32 of the Vienna Convention on the Law of Treaties, preparatory work of a treaty and the circumstances of its conclusion may be used to determine the meaning of treaty language when other means of interpretation, such as the treaty’s express language, its object and purpose leave the meaning ambiguous. As discussed above, the declared purpose under Article 39.3 is the protection of certain test data, but this leaves open at least three different ways of implementing this obligation.

<sup>596</sup> See J.H. Reichman, “Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach”, *Marquette Intellectual Property Law Review*, Vol. 13, No. 1, 2009, pp. 1-68 [hereinafter Reichman, Rethinking the Role of Clinical Trial Data].

<sup>597</sup> See Timmermans, p. 2.

<sup>598</sup> Reichman, Rethinking the Role of Clinical Trial Data, p. 25, footnote 154, referring to Junod. According to that author, between 1998 and early 2004, only 27 out of 137 drugs approved by the United States Federal Drug Authority (FDA) were developed without “substantial patent protection”.

<sup>599</sup> Reichman, Rethinking the Role of Clinical Trial Data, p. 27, refers to “almost thirty billion dollars a year of federal funds that the NIH spends on upstream research in order to reduce the enormous risks inherent in early stage medical research” (citing Rai, Reichman, Uhlir, and Crosswell).

<sup>600</sup> According to other views, allowing generic competitors to rely on the originator’s data would grant such copiers a significant and substantial commercial advantage, as they did not have to invest the literally hundreds of millions of dollars and years of research effort that the originator did to generate that data in the first place. Allowing reliance on the data would constitute ‘unfair commercial use’. See IFPMA, “Data Exclusivity: Encouraging Development of New Medicines”, Geneva, 2007.

<sup>601</sup> For a general overview of the interface between FTAs and public health policies, see Part I, Section C of this Guide (Introduction).

### **Box 12: The protection of pharmaceutical test data in free trade agreements**

The issue of clinical test data protection is one of the most prominent areas of TRIPS-plus developments. Many FTAs concluded by the United States, the EU and EFTA contain obligations that go beyond the TRIPS minimum standards in the area of pharmaceutical test data protection. Examples are the United States FTAs concluded with Bahrain; the Dominican Republic-Central American Free Trade Agreement (DR-CAFTA); Chile; Jordan; and Morocco; the recent EU FTA with Colombia and Peru; and the EFTA–Chile FTA.<sup>602</sup> In particular, these FTAs contain express provisions on exclusive rights in clinical test data (data exclusivity) and (in the case of the United States FTAs, as opposed to the EU’s and EFTA’s FTAs) provide for a linkage between the drug regulatory procedures and the patent status of a drug. In May 2007, however, the expiry of the 2002 United States Trade Promotion Authority led to a bipartisan understanding between United States Congress and the Administration on the ratification of outstanding trade agreements, namely with Colombia, Panama and Peru. This understanding resulted in amendments to the latter FTAs with respect to provisions dealing with pharmaceutical products, reflecting concerns expressed in many quarters on the impact of those agreements on public health policies.<sup>603</sup> These amendments will be briefly outlined below, to the extent they concern the protection of clinical test data. Out of the three agreements mentioned, only the United States – Peru FTA has entered into force, as of October 2009.

#### **a) Minimum terms of protection**

Data exclusivity obligations under the United States FTAs apply to pharmaceutical and agrochemical test data. The term of protection is generally 5 years for pharmaceutical and 10 years for agrochemical test data, starting on the date of regulatory approval.<sup>604</sup> A similar 5-year term of protection for pharmaceutical test data is provided under the EU FTA with Colombia and Peru.<sup>605</sup> Under the amended United States FTAs with Colombia, Panama and Peru, Parties have the possibility to reduce the term of protection to less than five years where the test data originator has not involved considerable efforts and expenditures.<sup>606</sup>

For a DRA, data exclusivity means, in general terms, the obligation not to rely directly or indirectly on data submitted by a product originator (first comer) in the context of approval procedures initiated by a competitor (second comer), unless the first-comer gives his consent.

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<sup>602</sup> For the EU, the FTA with Colombia and Peru is the first agreement to contain express provisions on pharmaceutical test data exclusivity. For EFTA, the FTA with Chile does not represent a uniform approach. For instance, the EFTA – Egypt FTA broadly refers to Article 39, TRIPS Agreement, without further specification (Annex V, Article 3(e) of the EFTA – Egypt FTA); EFTA’s FTA with the Republic of Korea provides that protection of undisclosed information may be provided either through exclusivity or through a regime of compensatory liability; see Annex XIII (Article 3) to the EFTA-Republic of Korea FTA.

<sup>603</sup> See for example, GAO Report.

<sup>604</sup> For example, under the United States Trade Promotion Agreements concluded with Panama as well as Peru, exclusivity is mandated for a “reasonable period” that shall normally mean five years. This suggests that five years will be the norm but that it can be deviated from (see Article 15.10 (2) (b) United States-Panama FTA; Article 16.10 (2) (b) United States-Peru FTA). Older United States FTAs contain less flexible language on the term of protection.

<sup>605</sup> Article 224.2 of the FTA EU – Colombia/Peru.

<sup>606</sup> See e.g. Article 16.10.2 (b), United States – Peru FTA and the implementing legislation in Peru (Decreto Legislativo 1072, Article 5). (Full text available at: <http://www.ustr.gov/trade-agreements/free-trade-agreements/>) For more details, see P. Roffe and D. Vivas-Eugui, “A Shift in Intellectual Property Policy in United States FTAs?”, *Bridges Monthly Series*, Vol. 11, No. 5, August 2007 (available at <http://ictsd.net/news/bridges/>).



This means that a generic producer, after showing bioequivalence between his product and the data originator's product, no longer has the possibility to request the DRA to grant marketing approval either on the basis of the originator's data in themselves ("direct reliance" on the test data) or on the basis of the result of these data (i.e. the approval decision, "indirect reliance" on the test data).

While such data exclusivity is limited to the domestic context, some United States FTAs (Australia, Bahrain, DR-CAFTA, Morocco, and Singapore) also prevent a DRA from granting approval on the basis of test data submitted by the data originator in a foreign territory (direct reliance on the test data) or on the basis of the results in the foreign territory of such test data (reliance on the foreign approval decision for the originator's product).<sup>607</sup> Thus, in cases where the data originator has not patented and marketed his drug domestically (e.g. for lack of patent protection at the time the drug was discovered), a generic producer cannot request the domestic DRA to approve his drug based on a showing of bioequivalence plus reliance on the originator's test data submitted abroad.<sup>608</sup> FTA parties may require the data originator, in order to benefit from such protection, to seek marketing approval for his drug within 5 years after obtaining marketing approval in the other territory.<sup>609</sup> The combined terms of data protection in the other territory (i.e. 5 years) and, subsequently, in the domestic territory (i.e. another 5 years) may thus add up to a total term of 10 years of data exclusivity in the domestic territory. The new United States FTA with Peru, by contrast, provides for an option to avoid such addition of the terms of protection abroad and at home: according to this FTA, in cases where the Peruvian registration follows a United States registration, and occurs within six months from the United States registration, the term of exclusivity in Peru is shortened by six months.<sup>610</sup> This new mechanism provides the DRA with an incentive for rapid marketing approval in the country where the drug is approved subsequently (i.e. in general Peru), in exchange for a shorter period of effective protection in that country.

Despite this latter development, the FTAs, by conferring upon the data originator the right to prevent the marketing of generic products through reliance by the domestic DRA on his test data submitted at home or abroad, represent an important TRIPS-plus development *vis-à-vis*

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<sup>607</sup> Such foreign territory may be any third country, even those not being part of the above-mentioned FTAs.

<sup>608</sup> See, for example, Article 15.10.1(b) of the FTA United States - DR/CAFTA.

<sup>609</sup> *Ibid.*

<sup>610</sup> Peru FTA, Article 16.10.2(c).

<sup>611</sup> See, for instance, Article 15.10(1) and (2) of the United States - Morocco FTA.

<sup>612</sup> See Abbott, *Contradictory Trend*, p. 11.

<sup>613</sup> Abbott, *Contradictory Trend*, p. 8. See also P. Roffe, "Bilateral Agreements and a TRIPS-plus World: The Chile - United States Free Trade Agreement", *QUNO TRIPS Issue Papers* No. 4, Geneva 2004, p. 26, who observes that under the United States - Chile FTA, the link between marketing approval and the consent of the patent holder is less explicit and, unlike CAFTA, does not include references to marketing approvals in other countries.

<sup>614</sup> Abbott, *Contradictory Trend*, p. 8. Acknowledging these concerns, the linkage requirement was made optional under the more recent FTAs between the United States and Panama; as well as Peru.

<sup>615</sup> See UNCTAD-ICTSD Resource Book, Chapter 28, p. 537. On this particular issue, USTR has replied to Congress that the data protection provisions in FTAs would not stand in the way of compulsory licensing.

<sup>616</sup> See United States FTC Study and EU Pharmaceutical Sector Inquiry.

<sup>617</sup> See Article 16.10.2(d) and 16.10.4 of the United States - Peru FTA.

<sup>618</sup> See Article 4, *Decreto Legislativo* 1074 of 28 June 2008.

<sup>619</sup> See United States-Peru FTA, Article 16.10.3.

<sup>620</sup> According to the revised version of the FTA with Peru, a Party may comply with this clause by providing a period of marketing exclusivity for the first applicant to successfully challenge the validity or applicability of the patent (footnote 18 of chapter 16 of the FTA).

<sup>621</sup> In the case of the FTA with Peru, see Article 16.10.2.(e) and Article 16.13.2(a)(b).

the TRIPS minimum standard under Article 39.3.

On top of a 5-year term of exclusivity protection, some United States FTAs (Bahrain, Morocco) require another 3 years of exclusivity for new clinical information, i.e. *previously unapproved uses of approved products*.<sup>611</sup> For these new uses, there may be neither recognition of prior foreign approvals nor an independent bioequivalence examination by the DRA based on the original data, unless the data originator gives his consent. This provision may be seen as helping data originators “evergreen” their exclusive rights by preventing the market entry of generic competitors. Data originators might claim overlaps of usages between the generic products and their own, newly approved uses, even where the generics are only intended to cover old uses (which is possible after the expiry of the original 5-year period of exclusivity). Legal proceedings to dismiss such claims and to distinguish between old and new uses are likely to create further delay for market entry of generic competitors.<sup>612</sup>

### **b) Linkage between regulatory procedures and patent rights**

While the above observations particularly concern non-patented pharmaceutical and agrochemical products, most of the United States-sponsored FTAs also contain a provision that is likely to have an important impact with respect to patented pharmaceutical and agrochemical products. Many of these FTAs establish a link between the regulatory approval procedure and the patent right covering the respective product. For instance, Chapter 15, Article 15.10.2 of the DR-CAFTA provides:

“2. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party:

(a) shall implement measures in its marketing approval process **to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner;** and

(b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.” (emphasis added)

In other words, the decision by regulatory authorities to grant marketing approval is made dependent on the authorization of the patent holder (paragraph (a), as quoted above), thus linking the separate realms of drug regulation and patent law, as already discussed in the context of the regulatory review exception. Thereby, the term of data protection is effectively extended to the full term of a patent, which is not required under TRIPS.<sup>613</sup> In addition, the main burden of enforcing private patent rights is shifted away from the patent holder to the state, i.e. the regulatory authority, which often lacks any means and experience in evaluating the patent status of a drug.

As in the case of data exclusivity, “linkage” provisions like the one quoted above have been

interpreted as possibly precluding governments' possibilities to use compulsory licensing as a means of making available low-priced pharmaceutical products.<sup>614</sup> Since marketing approval is independent of patent law, the third party authorized to produce a patented product under compulsory license would arguably depend on the patentee's consent or acquiescence for the actual marketing of the product.<sup>615</sup> In addition, a linkage requirement as promoted under some FTAs deprives generic producers of the opportunity to challenge poor quality patents in patent infringement litigation. Such litigation is contingent upon receiving regulatory approval to market the generic copy of the patented product. Providing the possibility to challenge poor quality patents is an important means to ensure competitiveness and innovation in the pharmaceutical industry. As stated above, both the United States Federal Trade Commission and the European Commission have found that generic competitors prevail in a majority of patent litigation cases.<sup>616</sup>

The new United States FTAs with Peru, Colombia and Panama make linkage optional and in particular do not require that regulatory authorities withhold approval of a generic until they can certify that no patent would be violated if the generic were marketed.<sup>617</sup> Peru has taken advantage of this option in its implementing legislation.<sup>618</sup>

Instead, the revised FTAs require parties to provide procedures and remedies (judicial or administrative proceedings, including injunctions or equivalent effective provisional measures) for adjudicating expeditiously any disputes regarding patent infringement or validity that arise with respect to a product for which marketing approval is sought.<sup>619</sup> The revised texts also require greater transparency in these procedures, calling on parties to the FTA to make available: a) an expeditious procedure to challenge the validity or applicability of the patent (so as to break the 'link', where applicable) and b) effective rewards for a successful challenge to the validity or applicability of the patent.<sup>620</sup> In other words, the revised FTAs seek to balance the rights of patent holders with opportunities for generic producers to challenge patented products that might prevent competing products from entering the market. They shift the primary responsibility for patent enforcement back to the patent owner.

### **c) The "side letters" or "understandings" with respect to the TRIPS/Health solution**

Being aware of public concerns about the impact of FTAs on countries' abilities to promote enhanced access to medicines, the Parties to the United States FTAs with Bahrain, the DR-CAFTA countries and Morocco agreed on "side letters" or "understandings". According to these documents, the IP standards as contained in the respective FTAs do not affect the Parties' ability to protect public health.

Departing from the earlier United States FTAs, the amended texts of the Colombia, Panama and Peru agreements call on the parties, in the main text and not in side letters or understandings, to affirm their commitments to the Doha Declaration, particularly emphasizing that the provisions on data exclusivity should be subordinated to the right of a party to take measures to protect public health. The revised texts further oblige the parties to respect existing waivers granted by WTO members regarding provisions of the TRIPS Agreement.<sup>621</sup> These changes put both the Doha Declaration and existing waivers on the same level as other provisions in the FTAs, thus facilitating pro-public health interpretations of the provisions on regulated products, as well as other sections of the FTA.

### 3.5.1.3 The compensatory liability or cost-sharing approach

The “compensatory liability” or “cost-sharing” option seeks political acceptance on the part of OECD governments by offering fair compensation of the data originators’ efforts without the barriers to market entry and other anti-competitive effects occasioned by the data exclusivity approaches. It also promotes the immediate availability of pre-existing test data for the purpose of registering generic copies of the originator drug on the basis of bioequivalence and reliance upon the relevant medical literature (i.e. the outcome of the originator’s submission of clinical trials data).<sup>622</sup>

The compensatory liability option has particular relevance for those developing countries engaged in negotiating bilateral or regional free trade agreements with OECD countries, and it responds to developing country governments’ concerns about the public health impact of data exclusivity regimes. Some of the FTAs by EFTA, such as the agreements with the Republic of Korea and Lebanon, expressly provide for a compensatory liability regime as an alternative to the exclusive protection of test data.<sup>623</sup>

The compensatory liability or cost sharing option enables countries to address pressures from other governments by providing that reasonable compensation be paid to the data originators for a specified period of time by any generic producer who relies directly or indirectly upon the research outcomes those data establish. At the same time, any generic producer would have an automatic right to rely upon the originator’s test data for this purpose. Originator firms would have no exclusive rights in their data and could not block the granting of marketing approvals to generic competitors based on such data. Once the cost-sharing approach is taken seriously, there are at least three known approaches to implementing it.

#### Approach No 1: the FIFRA Model

One approach, put forward by *Weissman*, builds upon experience gained under the United States law known as the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which has long instituted an actual cost-sharing regime for test data results pertaining to pesticides

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<sup>622</sup> For details, see Weissman; and Reichman, *The International Legal Status*.

<sup>623</sup> See Annex XIII (Article 3) to the EFTA-Republic of Korea FTA. “The Parties shall protect undisclosed information in accordance with Article 39 of the TRIPS Agreement. The Parties shall prevent applicants for marketing approval for pharmaceutical and agricultural chemical products from relying on undisclosed test or other undisclosed data, the origination of which involves a considerable effort, submitted by the first applicant to the competent authority for marketing approval for pharmaceutical and agricultural chemical products, utilizing new chemical entities, for an adequate number of years from the date of approval, except where approval is sought for original products. **Any Party may instead allow in their national legislation applicants to rely on such data if the first applicant is adequately compensated.**” (Emphasis added.) However, it needs to be pointed out that under the United States–Republic of Korea FTA (Section 18.9.1), which was pending congressional approval as of early 2010, the same option is not available, data exclusivity being mandatory. According to the most-favoured nation clause of the TRIPS Agreement (Article 4), the Republic of Korea will have to extend the same level of protection of pharmaceutical test data to any other country, including the EFTA countries. For Lebanon, see Article 4 of Annex 5 to the EFTA-Lebanon FTA. “The Parties to this Agreement shall protect undisclosed information in accordance with Article 39 TRIPS. The Parties shall prevent applicants for marketing approval for pharmaceuticals and agricultural chemical products from relying on or referring to undisclosed test or other undisclosed data submitted by prior applicants to the competent approval authorities of the respective Parties for a period, from the date of approval, of at least six years, except where approval is sought for original products, **or unless the first applicant is adequately compensated.**” (Emphasis added.)

and certain other chemical products.<sup>624</sup> Weissman's approach takes account of the following elements:<sup>625</sup>

- The actual **cost of producing** the data (this obliges the data originator to disclose and document the actual costs of data generation).<sup>626</sup> The costs of developing a clinical test data file will normally arise in OECD markets, where the data originator normally seeks first marketing approval. In addition, originators may claim a *risk premium* to reflect possible failures in initial testing over time. Finally, the system may also provide an obligation by generic producers to pay compensation to the data originator for the *benefit of early market entry* (as compared to the amount of time needed in case of independent replication of clinical trials).
- The **proportionate global market share** allocated to the generic competitors: the cost share to be paid is apportioned to each national market, on the basis of market size and, preferably, relative ability to pay.<sup>627</sup>

In order to avoid over-compensation of data originators, limitations and caps have been suggested under this approach.<sup>628</sup> Much depends, however, on the theoretical justification for data exclusivity, which remains controversial and altogether lacking in consensus.<sup>629</sup>

On one theory, such a regime merely compensates for lost revenue, due to the fact that a patent was never granted in a specific territory, or if granted, was given only for a relatively short duration. On this principle, the existence of a patent in a given territory would free the government from any obligation to compensate the originator patentee for indirect reliance on his clinical test data because the returns guaranteed by the exclusive patent right would be deemed sufficient to compensate the inventor and data originator for all relevant costs of R&D. It is true that the development of a new chemical entity (NCE) and the related application for a patent precede activities related to the development of pre-clinical and clinical trials data related to the regulatory approval process (see above, Figure 2). Costs incurred to prepare the clinical test data file for the DRA may therefore differ from those costs incurred for the preparation of the patent application with the patent office.

However, as illustrated in figure 2, above, the term of the patent will usually expire after the data exclusivity term, especially where the patent has been extended to compensate for lengthy regulatory approval processes or the patent granting process. As the patent provides a powerful tool for the inventor to recoup both the investment for the invention and for the test data (especially when based on broad structural or functional claims),<sup>630</sup> several years of

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<sup>624</sup> See Weissman, pp. 156-159. The FIFRA provides for a cost-sharing system after a 10-year period of data exclusivity. This cost-sharing system has been efficiently administered through arbitration, independently of the preceding exclusivity period.

<sup>625</sup> Ibid, pp. 155-163.

<sup>626</sup> According to some stakeholders present at the UNCTAD peer review meeting, companies would be very reluctant to disclose any commercially sensitive information.

<sup>627</sup> The importance of the ability to pay has been emphasized by A.X. Fellmeth, "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement", *Harvard International Law Journal*, Vol. 45, 2004, pp. 442 ff. [hereinafter Fellmeth].

<sup>628</sup> Weissman, p. 155.

<sup>629</sup> Reichman, Rethinking the Role of Clinical Trial Data.

<sup>630</sup> See above, Section 2.5.1.3, referring to EPO jurisprudence, according to which product patent protection extends to all possible ways of manufacturing the product as well as to all possible ways of using the product, even uses that at the date of filing of the patent application were unknown to the inventor. Structural claims of similar width are available under German patent law, see Ensthaler, p. 120.

market exclusivity in addition to revenues generated by a patent in the pharmaceutical sector could yield far more than the costs actually incurred for pharmaceutical R&D.<sup>631</sup>

Other scholars have tried, however, to justify data exclusivity regimes on various theories, supporting the case for an independent reward over and above that provided by the patent system as such.<sup>632</sup> While these theories are extremely controversial and some remain skeptical of them,<sup>633</sup> they cannot be ignored. Hence, the proposed cap based on an existing patent may not satisfy FTA trade negotiators, for example, to alleviate other trade pressures.

In any event, Weissman's approach has been designed to incorporate two further limitations to the generic producers' obligation to compensate the data originator:<sup>634</sup>

- To the extent that the sales benefits made by the data originator reach a certain multiple (e.g. 20 times) of the costs required to generate the data, the data originator loses his rights to claim further compensation.
- The right to compensation expires after a certain amount of time (e.g. 5 years), counted from the date of marketing approval granted to the data originator.
- To this list we would add an additional limitation, namely that the reasonable royalty should not be based on market size alone, as in Weissman's model, but should also be adjusted for GDP *per capita* ability to pay.<sup>635</sup> Generic producers in poor countries cannot be subject to the same criteria as generic producers in OECD countries. Taking into account the fact that data originators obtain large returns from sales in OECD countries, the data originator would otherwise obtain preferential windfall gains accrued from sales in poor markets, at the expense of struggling generic producers based in developing countries.

#### Approach No 2: Various Royalty Models and Ability to Pay

Since *Weissman's* proposals in 2003, which may be seen as providing support to *Reichman's* advocacy of a cost-sharing alternative, another scholar, *Fellmeth*, has devised an elegant but still more complicated set of fairness formulas.<sup>636</sup> Drawing on the law and economics literature, *Fellmeth* analyzes several different models, including a "Simple Divisions Royalties Model" and a more sophisticated "Adjustable Royalties Model", which takes into account such factors as the initial costs of R&D, the time value of money, the number of participants in the scheme, and their ability to pay.<sup>637</sup>

#### Approach No 3: Standard Royalty and Ability to Pay

The difficulty with both of these approaches, however, is that determining the true costs of pharmaceutical R&D for any purpose, especially drug price negotiations, has proved a daunting task that has not been satisfactorily resolved to date. An illustration of these difficulties is provided by a noteworthy 2008 report by the OECD on pharmaceutical pricing policies.<sup>638</sup> *A fortiori*, developing countries' authorities would face major difficulties in determining the R&D costs occurring on the part of the data originator. In addition, it is

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<sup>631</sup> Weissman, p. 165; Reichman, *Rethinking the Role of Clinical Trial Data*, p. 41.

<sup>632</sup> See, for instance, Eisenberg, p. 345.

<sup>633</sup> Reichman, *Rethinking the Role of Clinical Trial Data*.

<sup>634</sup> See Weissman, p. 155.

<sup>635</sup> See *Fellmeth*, pp. 478-500.

<sup>636</sup> *Ibid.*

<sup>637</sup> *Ibid.*

<sup>638</sup> OECD, *Pharmaceutical Pricing Policies in a Global Market*, September 2008 (executive summary available at [www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)).

nearly impossible to determine how much of the expenses incurred by the data originator has been recouped in developed country markets.

For this reason, a simple approach may also be worth considering. On this approach, governments willing to adopt the cost-sharing model would simply take the cost of production of the generic producer as a proxy for determining the amount of compensation due to the data originator. They would obligate a generic producer to pay to the data originator a standard royalty above marginal costs of generic production for any period established to compensate for marketing approval based on the health authority's reliance on an originator's clinical test data results. Given that Canada used to impose a standard royalty of 4 per cent of the net selling price of the drug in final dosage form on a licensee of right to use patented pharmaceuticals until 1992,<sup>639</sup> and given that most data originators will recoup the bulk of their R&D expenses in developed countries anyway, a royalty comprising the generic producer's own marginal costs of production plus 1–3 per cent of these costs, depending upon GDP *per capita* ability to pay, would seem more than sufficient. While such an approach would give only an approximation of the real costs of the originator's R&D, it would avoid the transaction costs and possibly endless litigation that more complicated models might induce. Finally, it would also be limited in time, for instance to five years, during which the data originator would be entitled to claim compensation. Unless made impossible under the provisions of an FTA, cost-sharing models may also be limited in their scope to drugs that are off-patent, taking into account the fact that the patentee is likely to recoup all of his expenses on the basis of a patent.

### **3.5.2 Policy options**

Against the above background, developing countries seeking to implement a regime of test data protection may wish to consider the following issues:

- If the country is involved in the negotiation of a regional or bilateral free trade agreement with a developed country, counter-offering a cost-sharing approach would possibly represent a feasible option and, from a public health and local production point of view, a more balanced alternative to data exclusivity options. An example for this option is the EFTA–Republic of Korea FTA.
- If the country is not involved in such negotiations, it is important to define the national priorities in this context.
  - Certain advanced developing countries may be the home of successful generic companies that actively pursue medical R&D and bear corresponding costs, in particular for the generation of test data submitted to OECD-based DRAs. The introduction of a cost-sharing regime instead of a misappropriation approach would nevertheless not seem to be compelling, as developing country producers could recoup all of their costs in OECD markets, benefiting from expansive patent and test data exclusivity regimes in these jurisdictions. In the domestic context, a misappropriation approach would seem to be the most beneficial option to promote generic competition in these developing countries.
  - Poor developing countries and LDCs with producers that are unable to engage in much R&D but mainly copy and re-assemble existing drugs should avoid an obligation beyond that of Article 39.3, TRIPS Agreement (i.e. a

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<sup>639</sup> See Reichman/Hasenzahl, *Canadian Experience*, pp. 10, 37. This figure rose to 6 per cent in the early 1990s, see *ibid*, p. 37.

misappropriation regime). If bilateral pressure for TRIPS-plus approaches becomes irresistible, they may consider a cost-sharing regime, but it is likely that the burden on local producers would be too high.

- If a country has to go beyond the cost-sharing approach and adopts a regime of data exclusivity under constraint of an FTA or in response to overwhelming bargaining power, there are various ways to mitigate the potentially harmful effects of such a system on local generic producers and drugs availability:<sup>640</sup>
  - Exclusivity may be restricted to data on new chemical entities, excluding data on new indications, new methods of administering drugs, or new dosages. Chile and Egypt have followed this approach,<sup>641</sup> and Switzerland provides reduced terms of exclusivity for reformulated versions of existing drugs. Under certain FTAs, such as the one between the United States and Morocco, or the United States and Bahrain, such an approach is not possible, due to an obligation to provide exclusive protection to new clinical information (see box 12, above).
  - Countries may specify that the term of data protection shall not reach beyond the term of a parallel patent on the same substance. This possibility used to be expressly provided under European Community (EC) legislation and has been implemented by Greece, Portugal and Spain.<sup>642</sup> This approach is expressly prevented under certain FTAs.<sup>643</sup>
  - Exclusivity may be restricted to undisclosed information, as opposed to information publicly available.<sup>644</sup> This is also provided for under Article 39, TRIPS Agreement.
  - Exclusivity may be waived in case of compulsory licensing of patented pharmaceutical inventions. This is the approach taken by Chile under the FTA with the United States.<sup>645</sup> In this context, it should be noted that Chile's approach to the implementation of test data protection has been one of the main reasons for the January 2007 decision by the USTR to include Chile on the Priority Watch List of countries considered to show serious shortcomings in the protection or enforcement of IPRs.<sup>646</sup> On the other hand, the more recent United States – Peru FTA contains an understanding that the FTA obligations, such as the introduction of data exclusivity, should be interpreted in a manner supportive to promote access to medicines and should not stand in the way of

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<sup>640</sup> For details, see Weissman, pp. 165-177; and Timmermans.

<sup>641</sup> Timmermans, p. 3, referring to R. Weissman ("Public health-friendly options for protecting pharmaceutical registration data". *International Journal of Intellectual Property Management* 2006, No. 1, pp. 113–130); and to Government of Chile, Industrial Property Law No 19.039 modified by Law 19.996 of 2005.

<sup>642</sup> Timmermans, referring to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use. *Official Journal of the European Communities*; and to P. Ranson "Data protection in the pharmaceutical industry". *J Gen Med* 1, 2003, pp. 48–56.

<sup>643</sup> See United States – Morocco, footnote 12 to Article 15.10(2).

<sup>644</sup> Weissman, p. 168. Under some FTAs, even test data that has been publicly available may be subject to exclusive protection provided it concerns a chemical entity that has not been previously approved by the domestic DRA. See Article 15:10(1)(c) of the DR/CAFTA – United States FTA, and Abbott, *Contradictory Trend*, pp. 7/8. As opposed to Article 39.3, TRIPS Agreement, the decisive criterion for the novelty of the chemical entity is not whether it has been available to the public before, but whether it has been previously approved by the DRA.

<sup>645</sup> For details, see P. Roffe, "Intellectual Property Provisions in Bilateral and Regional Trade Agreements: the Challenges of Implementation", CIEL, Geneva, 2006 [hereinafter Roffe, 2006].

<sup>646</sup> See P. Roffe, "Chile and the Priority Watch List: Some Considerations", *Bridges Monthly Series*, no.11/2, Geneva, April 2007, p. 18 (available at: <http://www.iprsonline.org/ictsd/news/bridges11-2.pg18-19.pdf>). The legality of such challenges has been questioned, see Abbott/Reichman, pp. 980-981.



an effective utilization of the Paragraph 6 solution on compulsory licensing for exportation to countries lacking pharmaceutical manufacturing capacities (see also above, box 12).<sup>647</sup>

- In a related context, health authorities may waive data exclusivity when this is deemed in the interest of public health. The EU's domestic implementation of the WTO 30 August 2003 Decision/draft Article 31*bis* system provides for a waiver of data exclusivity in case of a compulsory license for the production for export of drugs to countries lacking domestic pharmaceutical manufacturing capacities.<sup>648</sup>
- A compulsory license on protected test data may be automatically issued whenever a third party seeks market authorization for a product equivalent to the originator's product. This would be comparable to the cost-sharing/use-and-pay approach, but would not be in line with those FTAs that require the Parties to introduce exclusive rights in test data.<sup>649</sup>
- Exclusivity may be waived in case the respective product is already covered by a patent. Again, such approach would not be compatible with those FTAs requiring exclusive test data protection, as such protection has to be granted to any product, irrespective of its patent status.<sup>650</sup>
- The term for data exclusivity may be shortened. See above for the example of Switzerland regarding limitations in protection to new chemical entities. Many of the FTAs requiring exclusive test data protection provide for a mandatory minimum period of protection of five years or more. An exception is, again, the recent United States – Peru FTA, which leaves Parties free to reduce the five-year term of protection in cases where the generation of the data has not required considerable efforts and expenditures (see box 12, above).
- Countries may condition the granting of data exclusivity on the quick domestic registration of the drug after the first marketing approval has been obtained abroad. Chile has issued regulations according to which failure to register a new drug within one year after obtaining the first global marketing approval will disqualify the drug from data exclusivity in Chile.<sup>651</sup>
- The start date of the exclusivity period may be referred to the first registration of the product *worldwide*. Some FTAs like CAFTA and United States – Peru, however, specify that the period of exclusive protection to be provided in a country must be counted from the date when marketing approval is granted in that country.<sup>652</sup>

While a number of the suggestions listed above are not necessarily in line with many of the older United States FTAs, more recent approaches to test data protection under the United States – Peru FTA and the EFTA – Republic of Korea FTA show considerably more flexibility to allow Parties a public health-oriented FTA implementation.

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<sup>647</sup> See Articles 16.10.2.(e) and 16.13.2(a)(b) of the United States – Peru FTA.

<sup>648</sup> Timmermans, referring to Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents relating to the Manufacturing of Pharmaceutical Products for Export to Countries with Public Health Problems. *Official Journal of the European Union*.

<sup>649</sup> See Weissman, p. 173.

<sup>650</sup> *Ibid*, p. 171.

<sup>651</sup> Roffe, 2006; Timmermans, referring to Government of Chile, Industrial Property Law No 19.039 modified by Law 19.996 of 2005.

<sup>652</sup> See Article 15.10.1(a) CAFTA; Article 16.10.2.(b) United States – Peru.

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