



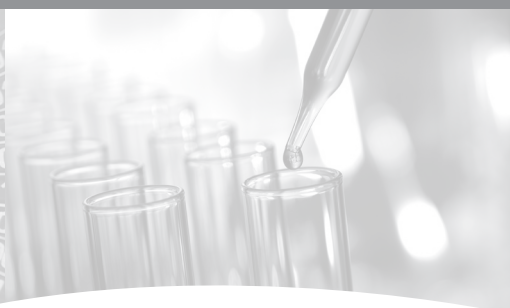
# Development Dimensions of Intellectual Property in Indonesia: Access to Medicines, Transfer of Technology and Competition





UNEDITED VERSION

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## **Foreword**

UNCTAD launched its first Development Dimensions of Intellectual Property (DDIP) report in 2010, in Entebbe, Uganda. Work on a second DDIP report is currently being undertaken in Cambodia. This latest publication in the series of DDIP reports, the third, examines the patent regime in Indonesia and suggests possible amendments to better ensure that the system established under their Patent Law better supports the specific development objectives of greater access to medicines, transfer of technology and competition.

The objective of these reports is founded upon several ideas that UNCTAD has reiterated over the years in the context of its programme on intellectual property and development – first, that intellectual property is not an end in itself, but a means to an end; second, that the intellectual property regime shapes not only the contours of the right to exclude others based on the fruits of intellectual and creative endeavour, but also the shape of the public domain; and third, that intellectual property regimes need to be tailored to the level of development and to specific development objectives, within the permitted scope under the international obligations to which a country has committed itself. This means that IP regimes cannot simply be transplanted from one country to another, as the situation and context of each country making a request for a DDIP report will necessarily differ from one to another. The starting point is therefore the development goals of the country in question.

The situation of Indonesia is in many respects quite unique. It is a large country of many islands, with a sizeable population. While classified as a developing country, its economy is growing rapidly. It has and continues to be a recipient of technology transfer in some of its key industries, including for example, pharmaceuticals and food products. And, at the same time, it is home to some of the richest biodiversity in the world. Its increasing capacity in the sciences means that there is a certain amount of local innovation, and local universities are increasingly encouraged to apply for IP protection over the fruits of their research.

The development perspective necessitates taking into account the diverse set of circumstances in Indonesia, and then examining how existing patent legislation can best be amended. In order to ensure that the DDIP report for Indonesia addresses the unique situation of the country, the report has adopted a methodology that is bottom-up, with consultations with a wide range of domestic stakeholders. We sincerely hope that policy makers in Indonesia will find useful the analysis and recommendations contained in this report.



Supachai Pantichpakdi  
Secretary-General of UNCTAD



## **Acknowledgments**

This publication was prepared by Kiyoshi Adachi, Chief of UNCTAD's Intellectual Property Unit, Investment Capacity-Building Branch of the Division on Investment and Enterprise, under the supervision of Nazha Benabbes Taarji, Head, Investment Capacity-Building Branch and the guidance of James Zhan, Director of the Division on Investment and Enterprise. UNCTAD gratefully acknowledges extensive comments on versions of this guide by Pedro Roffe, Christoph Spennemann, Ahmed Abdel Latif, Padmashree Gehl Sampath, and Ermias Biadgleng. Monica Adjivon and Greg Hudson provided assistance in the finalization of this document.

## **Table of Abbreviations**

<b>ABS</b>	Access and benefit sharing
<b>AIDS</b>	Acquired immunodeficiency syndrome
<b>API</b>	Active Pharmaceutical Ingredient
<b>ARV</b>	Antiretroviral Drug
<b>ASEAN</b>	Association of South East Asian Nations
<b>BI</b>	Boehringer Ingelheim
<b>BKPM</b>	Investment Coordinating Board of Indonesia
<b>BMZ</b>	Germany's Federal Ministry for Economic Cooperation and Development
<b>CAFTA</b>	United States-Dominican Republic-Central America Free Trade Agreement
<b>CBD</b>	Convention on Biological Diversity
<b>CL</b>	Compulsory License
<b>DDIP</b>	Development Dimensions of Intellectual Property
<b>DGIPR</b>	Indonesia's Directorate General of Intellectual Property Rights
<b>DRA</b>	Drug Regulatory Authority
<b>EU</b>	European Union
<b>FDI</b>	Foreign Direct Investment
<b>FTA</b>	Free Trade Agreement
<b>GSK</b>	Glaxosmithkline
<b>HIV</b>	Human immunodeficiency virus
<b>ICA</b>	Italian Competition Authority
<b>ICTSD</b>	International Centre for Trade and Sustainable Development
<b>IP</b>	Intellectual Property
<b>IPR</b>	Intellectual Property Rights
<b>KPPU</b>	Commission for the Supervision of Business Competition
<b>LDC</b>	Least Developed Country
<b>LIPI</b>	Indonesian Institute of Sciences
<b>NADFC</b>	National Agency for Drug and Food Control
<b>NCE</b>	New chemical entity
<b>NGO</b>	Nongovernmental Organization
<b>NRTI</b>	Nucleoside analogue reverse transcriptase inhibitors
<b>PCT</b>	Patent Co-operation Treaty
<b>PIC</b>	Prior informed consent
<b>R&amp;D</b>	Research and Development
<b>RISTEK</b>	State Ministry of Research and Technology
<b>SMTA</b>	Standard material transfer agreement
<b>SOE</b>	State Owned Enterprise
<b>TK</b>	Traditional knowledge
<b>TNC</b>	Transnational Corporation
<b>TRIPS Agreement</b>	World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property
<b>UN</b>	United Nations
<b>UNCTAD</b>	United Nations Conference on Trade and Development
<b>US</b>	United States
<b>WHA</b>	World Health Assembly
<b>WHO</b>	World Health Organization
<b>WTO</b>	World Trade Organization

## **Background: the Terms of Reference, the Process and the Orientation of the Report**

This Report was prepared in response to a request for technical assistance submitted to UNCTAD in July 2010 by Indonesia's Directorate General of Intellectual Property Rights (DGIPR). This request asked UNCTAD to examine the current Indonesian Patent Law and to recommend possible amendments to better align it with the following specific development objectives:

1. Access to medicines;
2. Transfer of technology; and
3. Competition

UNCTAD responded positively to this request in August 2010. Financing for this exercise was provided with the generous support of Germany's Federal Ministry for Economic Cooperation and Development (BMZ).

In carrying out this work, UNCTAD put considerable emphasis on the need to tailor a country's intellectual property (IP) laws to its technological and economic stage of development, as well as to its specific development objectives. The preparation of this report was further guided by the intent to make recommendations that respond to the prevailing situation in the country. For this reason, the Report is prepared based not only on deskwork, but also on a series of interviews and consultations conducted with domestic stakeholders in Jakarta in November 2010, as arranged by DGIPR. The final report takes account of comments received from domestic stakeholders in April-May 2011, as well as during a peer review meeting in Jakarta on 21 July 2011, organized by DGIPR.

The interviews conducted in Indonesia were largely based on questions developed by Professor Ruth Okediji of the University of Minnesota's School of Law for the UNCTAD-International Centre for Trade and Sustainable Development (ICTSD) project on IPRs and sustainable development. These questions are designed to provide a framework for analyses conducted by UNCTAD's fact-finding missions to (i) help developing countries in identifying critical policy issues relevant to the use of IP to effectively leverage development prospects within regulatory frameworks reflective of specific socio-economic and cultural conditions; and (ii) help developing countries in the formulation of medium- to long-term recommendations on how developing countries could make their IP frameworks more coherent and transparent, and consistent with the countries' identified economic and human development goals.

In collaboration with the DGIPR, UNCTAD established a list of interview partners from government offices, the private sector, academia and civil society, covering all three areas of interest indicated in the request for technical assistance. The interviews were conducted from 11-15 November 2010 by the Legal Officer and Chief of UNCTAD's Intellectual Property Unit. Interview partners and other stakeholders consulted for this study are mentioned throughout the report, and include the DGIPR, the Center for Innovation at the Indonesian Institute of Sciences (LIPI), the Business Innovation Center, the National Agency for Drug and Food Control (NADFC), the Commission for the Supervision of Business Competition (KPPU), the Investment Coordinating Board of

Indonesia (BKPM), the Indonesian Inventor Association, staff of the pharmaceutical firms Dexa Medica and Kimia Farma, and staff of the Suryomurcito & Co. law firm. The study also made use of earlier interviews conducted in March 2010 with a number of pharmaceutical firms and stakeholders for a separate project in Indonesia, which included representatives of Japanese pharmaceutical companies with subsidiaries in the country, local pharmaceutical manufacturers and distributors and, from civil society, local staff at Hilfswerk Austria International. UNCTAD thanks the DGIPR for arranging the interviews and consultations required for this exercise.

The recommendations contained in this DDIP report are based on an analysis of an official English translation of the current Patent Law. It is recognized that the controlling version of the Patent Law in the event there is a question of interpretation, is the official version of the Law in Bahasa, as passed by the Indonesian parliament and signed into law by the President.

This report is organized in three chapters, featuring the interface of the Patent Law with the issues of access to medicines, technology transfer and competition, respectively. Each chapter, after describing the factual background in Indonesia and the pertinent institutional set-up, provides a detailed analysis of the Patent Law in relation to these objectives, and makes recommendations for legislative amendments where appropriate.

The main orientation of this report is on how to utilize the flexibilities and obligations in international agreements on IP (with particular emphasis on the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement)) to support the respective development objectives outlined above, stressing in the case of Indonesia both areas where maintaining a robust public domain would be in the country's interest and also where certain IP rights could be of strategic interest to Indonesia.

The TRIPS Agreement established minimum standards for WTO Members on patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuits and undisclosed information, incorporating various elements of earlier IP conventions on these topics. All WTO Members must therefore have TRIPS-compliant IP legislation, which includes patent legislation. The TRIPS Agreement, however, is as much a political document as it is a legal document, and its wording leaves countries certain flexibility in national implementation. Developing countries have often sought to leverage these flexibilities in order to ensure that their IP regime supports (and does not undermine) important development objectives. Indonesia, as a WTO Member, is no exception and must have TRIPS-compliant patent legislation.

As a country that is rapidly developing, Indonesia presents a very unique and different set of issues compared with, for example, small island states or the Least Developed Countries (LDCs). Economically, Indonesia's economic growth has had strong growth over the past few years. Its geography is comprised of over 17,000 islands which lie between the Indian and Pacific Oceans. It is the fourth largest country in the world by population (over 240 million people) with an area of 1.9 million square km and its length from West to East spanning around 5,000 km, and from North to South around 1,700 km. It is home to a rich array of biodiversity, with a tropical climate (high humidity and temperatures). Indonesia already has a number of successful industries, including chemicals, pharmaceuticals, electronics manufacturing and food products. The most recent UNDP Human Development Index ranks Indonesia at 108 among 169 countries,

and falls in the medium human development range.<sup>1</sup> The World Bank classified Indonesia as a “middle income country”.<sup>2</sup>

Major development challenges remain in Indonesia, however, in the three areas identified for this study. A key question with respect to public health and access to medicines is how the Patent Law can support better the country’s aspirations to have universal health care. Technology transfer is needed to upgrade the country’s capacity to innovate. A working relationship between competition and intellectual property laws needs to be established, among others. The research and analysis contained in this report will examine each of these issues in turn.

This study forms part of the series of Development Dimensions of Intellectual Property (DDIP) reports, and shall be available in printed media, as well as online at <http://www.unctad.org/ddip>.

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<sup>1</sup> UNDP Human Development Index, 2010.

<sup>2</sup> World Bank World Development Indicators, 2010.



## **Executive Summary**

In line with the terms of reference for this study as set out in Indonesia's request for technical assistance in July 2010, UNCTAD undertook in November 2010 a field mission to Indonesia to discuss possible revisions to the current Patent Law in order to better harmonize the Law with its development objectives of ensuring greater access to medicines, supporting technology transfer and seeking better synergies with Indonesia's Competition Law.

The following recommendations address the issue of how the current Patent Law could be amended to better support the country's objective of universal access to health care and greater access to medicines.

***Recommendation 1:** Product and process patents should be disallowed for new uses of known substances, unless there is a change in the underlying chemical structure. This could be specified in a new Article 7(e). The possibility to obtain a simple patent (utility model) for minor changes in chemical structure or new methods of delivery could be maintained in the Patent Law provided the applicable criteria are met, as a means to incentivize research and product development in areas of strength for Indonesia such as biodiversity and TK-based medicines. Article 6 would need to be revised to permit simple patents on chemical compounds in this case.*

***Recommendation 2:** The current version of Article 7(d) would appear to not exclude the possibility of granting patents on biodiversity-based products on a case-by-case basis. It should, however, be made clearer that some change or process would need to alter the substance found in nature that causes it to exhibit different properties. The definition of a non-biological process would also need to be clarified. Article 7(d)(i) should be re-drafted to read "all living creatures, except micro-organisms, unless some change or process has altered the living creature causing it to exhibit different properties". It is suggested to add an Article 7(d)(iv) stating that genome and germplasm, as well as mere extraction/isolation, are precluded from patent protection.*

***Recommendation 3:** A Bolar exception that provides a safe harbour from **both** civil and criminal liability, **without limitation of time**, should be made explicit in the Patent Law. Article 135(b) should be removed and replaced by a corresponding exception in Article 16. The following is suggested text for a new Article 16(4):*

*"Exempted from civil and criminal liability under the Patent Law is the production and use of a pharmaceutical product protected by a patent in Indonesia before the termination of its term, with the purpose to obtain authorization to market a generic version of that product after the termination of patent protection."*

**Recommendation 4:** *While Indonesia's pharmaceutical production policies clearly favor developing national capacity to produce the full range of medicaments domestically, parallel importation is still practiced in the local food industry. As parallel importation is permitted under the TRIPS Agreement flexibilities, Indonesia may wish to consider providing 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. This could be added as a new sub-section under Article 16(1).*

**Recommendation 5:** *The current Patent Law provides only a safe harbour from criminal liability for would-be parallel importers. This should be expanded, and could be done by deleting Article 135(a) and introducing a more general exception to patent rights as a sub-paragraph in Article 16.*

**Recommendation 6:** *With respect to the provisions on compulsory licenses (CL), Indonesia may wish to consider expanding the grounds for issuing a CL beyond non-working to at least encompass national emergencies (which could include pandemics). This would require a revision of Article 75(2) of the Patent Law.*

**Recommendation 7:** *Consideration should be given to incorporate into the Patent Law the notification mechanisms under the 30 August 2003 Decision in the event that its local pharmaceutical industry is requested to act as a regional exporter for medicaments under the so-called Paragraph 6 system.*

**Recommendation 8:** *The Government should convene a meeting of stakeholders to examine the question of how an adequate remuneration rate should be set in the event of a non-voluntary use of a patent (CL or government-use license).*

Developing countries generally seek greater technology transfer. The provisions of the Patent Law can be structured to either support or hinder this objective. This report suggests the following changes to the Patent Law in order to support efforts to build up local innovative capacity and increase technology transfer.

**Recommendation 9:** *The provision in the Patent Law concerning the authority of the DGIPR to regulate licensing in order to further the objective of transfer of technology could be better aligned with the text of the TRIPS Agreement. Article 71 should be amended to read that “[a] licensing agreement shall not contain any provisions that may directly or indirectly damage the Indonesian economy, or contain restrictions which obstruct the international transfer of technology and limits the ability of the Indonesian people to master and develop technology in general and with the Patented Invention in particular.”*

**Recommendation 10:** *Given that the majority of patent applications filed in Indonesia are by foreigners, technology transfer and dissemination could be facilitated by requiring patent applicants to disclose the best means for implementing the invention in question. Indonesia should consider including a best mode disclosure obligation in patent applications. This could be included in Article 24(2)(i).*

**Recommendation 11:** *Indonesia should include a mandatory disclosure of origin requirement in their patent law for applications utilizing genetic resources and*



*traditional knowledge. The sample texts from India and Switzerland should provide some guidance as to appropriate text to be included in Article 24 of the Patent Law. At this point in time, it is not recommended for the DGIPR to be given responsibilities to assess PIC and equitable ABS, though this should be discussed between the DGIPR and the Ministry of the Environment as Indonesia's competent authority under the CBD. The consequence of a failure to disclose should include suspension of the consideration of the patent as an incomplete application, the non-granting of a patent application, or for patents already granted, the revocation of a patent by the DGIPR. This remedy should be included in the DGIPR's revocation powers under Article 88 of the Patent Act.*

***Recommendation 12:*** *Indonesia may wish to expand the research exception to cover all research and experimentation in connection with scientific or technological studies, and eliminate any distinction between commercial and non-commercial research. The text of a revised Article 16(3) would read:*

*“Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said Patent is for the sake of education, research, experiments and analysis in connection with scientific or technological studies.”*

***Recommendation 13:*** *Indonesia should consider whether it is appropriate to remove industrial applicability and establish a separate standard for utility for the grant of simple patents. If so, Article 105(5) should be amended to read that standards for novelty and utility for simple patents shall be defined by Government Regulation, and the rules concerning simple patents should be amended accordingly.*

***Recommendation 14:*** *There is no reason why a compulsory license should not be available for simple patents. Article 107, which excludes the possibility to issue a compulsory license for a simple patent, should be removed.*

The relationship between competition and intellectual property is complex. At one level, competition law is designed to act as a check on the abuse of the exclusive rights conferred through intellectual property law. More broadly, it is in the interest of society to ensure that first, only those inventions worthy of the grant of exclusive rights receive protection, and second, that the exclusive rights granted through IP rights are no longer than the minimum needed, and that competitive forces are able to lower prices for inventions and creations, making them more accessible to a greater proportion of the population. The following recommendations discuss how competition policy and the Patent Law should interface given these objectives, and suggest possible changes to the current Laws.

***Recommendation 15:*** *The DGIPR should enter into discussions with the Commission for the Supervision of Business Competition to discuss a possible amendment to the Competition Law, namely the removal of Article 50(b). This would open up the possibility for the Commission to hear cases related to, for example, excessive pricing or refusals to license based on a dominant position in the market and anti-competitive terms and conditions of contractual licensing*

*agreements. A compulsory or a government-use license could be issued by the DGIPR in cases where the Commission finds abuse.*

***Recommendation 16:*** *Provided that the DGIPR can secure a revision of Article 50 of the Competition Law, a subparagraph (4) should be introduced in Article 75 of the Patent Law that tracks the language of Article 31(k) of the TRIPS Agreement. A subparagraph should be introduced in Article 99 along similar lines, which would allow the possibility of issuing a government-use license upon a finding of anti-competitive behaviour.*

***Recommendation 17:*** *As in the recommendation regarding remedies for anti-competitive behaviour, the DGIPR and the Commission for the Supervision of Business Competition should discuss the removal of the restriction in Article 50(b) of the Competition Law preventing the national competition authority from determining abusive licensing practices involving IP. This would pave the way for discussion between these bodies on a set of guidelines on prohibited licensing practices, and any possible exceptions. The DGIPR and the Commission may wish to issue separate guidelines for competition and technology transfer issues or they may wish to combine all licensing guidelines into one document.*

***Recommendation 18:*** *The local working requirement in the Patent Law can likely be maintained on the grounds that the TRIPS negotiators have left this issue ambiguous. Where the Patent Law does not already specify a time limit, such as in the case of the right to prevent imports of products that are made using patented processes, consideration should be given to introducing a time element whereby a patent holder would be given a sufficient amount of time to begin working the underlying patent or expose him/herself to the loss of rights. While there is no reason why different time periods in which a patent holder needs to work his or her patent could be adopted before s/he risks a compulsory license or a right to import a product that is made using a process-patent, such time periods should generally be uniform across patent categories.*

***Recommendation 19:*** *Opposition systems that allow for patents to be challenged either before or after a patent has been granted, are important checks on the issuance of bad quality patents. No change in the pre-grant and post-grant opposition systems in the Patent Law should be made until the DGIPR has assessed the extent to which mistakenly granted patents are a problem in Indonesia.*

## **Chapter 1 – The Patent Law and Access to Medicines**

The Doha Declaration on TRIPS and Public Health (2001) recognized the relationship between patent law and access to medicines. The WHO's Report of the Commission on Intellectual Property Rights, Innovation and Public Health (2006), and later the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008), pointed to the complexity of this relationship as it ranges from the impact of patents as incentives for drug discovery to the effect of patents on the market for generic medicines. Simply put, the way in which the patent regime is structured can either promote or hinder greater access to medicines, which is why care should be taken in ensuring that patent legislation in countries that seek to maximize access objectives. This chapter first examines Indonesia's public health system and the role that access to medicines plays in this system; then the chapter will analyze specific provisions in the current Patent Law and suggest possible amendments given the development objective of public health and greater access to medicines.

### ***1.1 Indonesia's Public Health System and its Objectives***

Indonesia's Ministry of Health is responsible for the implementation of relevant laws and regulations concerning public health. The regulation of medicines and clinical trials falls under the jurisdiction of one of the Ministry's independent agencies, namely the National Agency for Drug and Food Control (NADFC). The portfolio of NADFC includes, *inter alia*, the approval of medicines for distribution within Indonesia as well as for export, and the inspection of pharmaceutical manufacturing facilities for compliance with safety and quality standards.

Key government policies on access to medicines are driven by the Government's goal of universal health care. Universal access to health care has long been an aspiration of Indonesia, and is underpinned by the 2004 Social Security Law<sup>3</sup>, which stipulates that four state-owned companies shall administer social insurance, which includes health insurance. A decentralized public medical insurance programme is available for the poorest that live on less than 1 USD a day. Despite the 2004 Law, many people still lack health insurance to pay for treatments and medicines, however, and ongoing efforts exist to ensure that the wider population in Indonesia has access to public health insurance with the current consideration by the parliament of a bill on comprehensive social security insurance. When passed, the new law would mark a significant step toward the realization of universal access.

Aside from social health insurance, efforts also exist to try to contain costs so as to make medicines and vaccines more widely available to the population. The medicines market in Indonesia is a mixed one with local industry now controlling over 70% of the market and foreign firms accounting for the remainder.<sup>4</sup> This domestic market can be segmented between a branded generic market and a low-cost non-branded generic market. Prices of medicines are generally not regulated as such, but reference prices are established for a handful of essential medicines, and are required to be included on the packaging labels

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<sup>3</sup> The bill on comprehensive social security insurance is designed to implement the 2004 Social Security Law.

<sup>4</sup> UNCTAD Indonesia Case Study (2011, forthcoming).

for pharmaceuticals. Indonesia has four state-owned companies involved in the manufacture of medical products, i.e., Kimia Farma, Indofarma, Bio Farma and Phapros. These firms are run as profit seeking enterprises, but can also be deployed as instruments of government policy when necessary. Plans for a merger between Kimia Farma and Indofarma were delayed in 2010.

While never clearly articulated as a public policy statement, the Indonesian health authorities have often stressed the need for self-reliance to meet pressing public health and related technology transfer needs in the area of medicines. Three recent examples of this are its government-use licenses, its policy of encouraging firms to set up local pharmaceutical factories and its efforts at developing local vaccine production capacity. These actions are described in turn below as they relate to this study.

On 5 October 2004, the Government issued Presidential Decree No. 83, issuing a government-use license permitting the state-owned enterprise Kimia Farma to manufacture generic versions of two ARVs for the treatment of HIV and AIDS, namely Nevirapine (for which Boehringer Ingelheim holds the patent) and Lamivudine (for which GlaxoSmithKline holds the patent). A later government-use license was issued over Efavirenz in 2007 (for which Merck holds the patent). A government-use license essentially functions as a compulsory license, giving Kimia Farma the right to produce and distribute generic versions of these drugs without the permission of the patent holder. In issuing the decree, the Government cited the price differential between the patented drug and the cost of producing a generic equivalent as the rationale for issuing the government-use license. Compensation to the patent holders was established under the Decree at 0.5% of the generic net sales value. Kimia Farma manufactured generic medicines under this Decree and distributed the output through government hospitals, but later discontinued manufacture of the ARVs due principally to the high cost of importing active pharmaceutical ingredients. (APIs). The government-use license was issued specifically for local production, rather than for the importation of the ARVs.

Even before the government-use licenses, though, the Indonesian government had set up policies to encourage the local production of pharmaceuticals and related technology transfer. Local laws and regulations require that only those firms with a factory in the country are able to obtain a license from the NADFC to distribute medicaments. This policy was expanded in late 2008 with the promulgation by the Minister for Health of Decree No. 1010. This Decree requires that all drugs that can be locally manufactured must be manufactured in Indonesia in order to be eligible for marketing authorization, subject to certain limited exceptions (Decree No. 1010, Articles 2 and 6). Importation is permitted for drugs destined for public health programmes, new drugs and drugs that cannot be manufactured locally, with the proviso that a foreign manufacturer must sign a written consent to transfer technology to permit the local manufacture of that drug within 5 years time (Decree No. 1010, Articles 9 and 10) otherwise the marketing authorization would be withdrawn. Local pharmaceutical firms are given the right to submit an application for marketing authorization over the generic version of a patented product up to two years before the expiration of patent protection in Indonesia (Decree No. 1010, Article 13). This policy remains controversial, particularly with foreign manufacturers, although the NADFC has stated in interviews with the fact-finding mission that it would be flexible in the implementation of Decree No. 1010 so as to not deny needed medicines to be imported into the country.

Finally, the Government of Indonesia's efforts at vaccine production can also be cited as an example of supporting self-reliance on public health matters. The state-owned enterprise Bio Farma is a collaborating partner of WHO's Global Pandemic Influenza Action Plan. Through this collaboration as well as other bilateral collaborations with Japan, India and other countries, Bio Farma engages in research and development, as well as the manufacture/distribution of vaccines. In 2007, the Government of Indonesia received a great deal of press coverage for its decision to withhold H5N1 (bird flu) virus samples from the World Health Organization (WHO) and its collaborating research centres. This decision was triggered when the WHO collaborating centres had apparently shared Indonesia virus samples with third party firms in developed countries to develop vaccines, without the knowledge of the country.<sup>5</sup> The country's efforts in part led to the adoption of a resolution at the World Health Assembly (WHA) to begin negotiations among WHO Member States on a standard material transfer agreement (SMTA) designed to ensure better benefit sharing for developing countries that provide samples.<sup>6</sup>

The impetus in Indonesia to encourage and develop local productive capacity in the medicines and vaccines sector is strong, as well as its desire to see local productive capacity help in ensuring greater access to quality medicines at reasonable cost. These objectives are reflected in policy actions such as those above, a number of which have received much publicity in the local and international media. Given the clear goal of the country to support this local productive capacity in the pharmaceutical and vaccines sectors, the remainder of this chapter shall examine Indonesia's Patent Law and how it could be amended to better support this objective. The analysis and recommendations are discussed by subject matter.

## **1.2 New Uses of Known Substances**

The TRIPS Agreement gives WTO Members substantial leeway in determining the scope of the respective three conditions for the granting of a patent (i.e., novelty, inventive step and industrial application). In the area of pharmaceuticals, there are differences in the practices of countries with respect to how they treat the patentability of new medical uses of known substances. As a known substance, it is arguable that many such patent applications could fail for lack of novelty, a position that is supported by expert commentary.<sup>7</sup>

This is not necessarily the end of the story, however. While US patent law denies product patent protection on new medical uses of known substances, it allows process claims, for example.<sup>8</sup> The current version of the European Patent Convention that came into effect in December 2007 provides that pharmaceutical product and process patents are available not only for first, but equally for second and subsequent medical uses. New use patents

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<sup>5</sup> See, for instance, Walsh at <http://www.time.com/time/health/article/0,8599,1619229,00.html>.

<sup>6</sup> Negotiations were concluded and SMTAs were endorsed by the World Health Assembly in May 2011 (see WHA Resolution 64.5).

<sup>7</sup> 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." See UNCTAD-ICTSD Resource Book, 387 (italics supplied) (citing Domeij at footnote 641).

<sup>8</sup> Such patent is permitted in the US provided that the new use is not anticipated in the composition or structure of the known substance (inventive step) or the new claim does not rely on the the process already declared in the previous patent claim (obviousness). See, USPTO, *Manual of Patent Examining Procedure (MPEP)*, Eighth Edition, August 2001, Latest Revision July 2010, Chapter 2100 Patentability, 2113, available at [http://www.uspto.gov/web/offices/pac/mpep/mpep\\_e8r6\\_2100.pdf](http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r6_2100.pdf).

are permitted under Chinese law through a drafting convention that allows applicants to apply for a new pharmaceutical method of use. Chinese patent authorities have not hesitated striking down claims to broadly drafted new uses, however (a second use patent on Viagra was invalidated by the State Intellectual Property Office of China in 2004).<sup>9</sup> The Andean Community patent law explicitly stipulates that both products and processes already patented and included in the state of the art may not be the subject of a new patent on the sole ground of having been put to a use different from the originally contemplated by the initial patent.<sup>10</sup>

One of the most written about, and certainly controversial, versions of the exception from patentability of new uses is Section 3(d) of the Indian Patent Act, as amended in 2005. This provision provides that 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 new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, are excluded from patentability. This provision became the subject of litigation in India when Novartis challenged a ruling by Indian patent authorities that its leukemia drug Glivec was only a slightly modified form of an existing treatment. A High Court ruling that the Patent Office was justified in its exclusion of a patent application for Glivec on the grounds of Section 3(d) has been appealed to the Supreme Court of India, and is pending the conclusion of final arguments as of the time of this writing. The outcome of this litigation will likely have implications on the limits of the new uses exception worldwide, as it is taking place in the world's largest generic pharmaceutical manufacturer.

There has to date been no case at the WTO Dispute Settlement bodies testing whether there is or is not an obligation to permit the granting of patents on new uses of known substances, or on the scope of any such obligation.

The situation in Indonesia is rather unique, and calls for some consideration of where it wishes to draw the line with respect to the patentability of new uses of known substances. On one hand, Indonesia has a robust generic medicines industry which caters mainly to domestic demand, providing the market with a wide variety of both unbranded and branded off-patent medicaments. Countries that have such a generic industry are usually interested in preventing the so-called "evergreening" of patents<sup>11</sup>, which would be made easier by permitting the granting of a patent on a known existing product for a newly discovered use, either directly on that product or through a process patent.

At the same time, several stakeholder interviews, including with some of the larger generic medicines manufacturers in Indonesia, indicated that they have commenced research on the development of biodiversity-based and traditional knowledge-based medicines, and are targeting this field as a strategic growth opportunity. This development is timely in light of the successful conclusion of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biodiversity (the Nagoya Protocol) in October

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<sup>9</sup> See Castellano (2006), "Patent Law for New Medical Uses of Known Chemical Compounds and Pfizer's Viagra Patent", *The Intellectual Property Law Review*, Vol. 46, No. 2.

<sup>10</sup> Andean community, Decision 486, Article 21, Sept 14, 2000.

<sup>11</sup> 'Evergreening' is a term popularly used to describe patenting strategies that are intended to extend the patent term on the same compound. WHO (2006).

2010.<sup>12</sup> Given the vast biodiversity resources in the country, the potential exists for local firms active in this field to benefit from the incentive to receive exclusive rights and to recoup some of the costs associated with R&D efforts needed to make commercially viable biodiversity-based pharmaceutical products.

This is not an easy task, however. For example, Eisai Co., Ltd., a Japanese R&D-based pharmaceutical manufacturer, established an R&D facility in Indonesia for the purpose of developing biodiversity products in the early 2000s, but closed the center in 2006 owing to difficulties in commercializing products from the samples collected.<sup>13</sup> There is thus a case to be made that new use patents could help to incentivize the R&D on biodiversity-based medicaments and support the development of this niche market, but the success of such ventures is by no means certain.

Indonesia's current Patent Law does not state directly whether new uses of known substances can qualify for patent protection. Article 7(b) of the Patent Law does exclude from the definition of invention "any method of examination, treatment, medication, and/or surgery applied to humans and/or animals". A strict interpretation of this clause would have the effect of denying process patent protection on new medical uses of a known product, in line with Article 27.3(a) of the TRIPS Agreement, while product patent protection could potentially also be denied on novelty grounds.

Given the local pharmaceutical industry's aspirations to develop biodiversity and related TK-based pharmaceutical products, and as there appears to be some local capacity to undertake R&D to develop biodiversity and related TK-based medicaments, it may make sense to preserve some type of incentive in the Patent Law to encourage the development of such medicines. This could be accomplished as follows: product patents for new uses of known products could be strictly excluded on grounds of lack of novelty and process patents for new uses, which are generally methods of treatment, could be excluded from patent protection either as discoveries or as an exception to patent rights. This would go some ways in addressing the potential problem of ever-greening existing patents. The Patent Law could, however, leave open the possibility of obtaining a simple patent for instances where the underlying chemical structure has been changed slightly, or where a new method of delivery is embodied in a single product (combined pills, a new liquid form of a chemical entity, a new topical ointments, etc.). This would provide an incentive to develop, for example, less invasive or more efficient ways of administering a pharmaceutical substance. Under the Patent Law, applicants must choose whether to apply for a regular or simple patent when filing an application; thus, the incentive would be for would-be applicants to carefully consider the merits of their claims before putting forth claims for new uses. In this case, the subject matter restrictions for simple patents would need to have revised, as Article 6 of the Patent Law is interpreted to exclude the granting of simple patents on chemical compounds.

Note, however, that the DGIPR would still need to assess patent applications for pharmaceutical derivatives of existing medical products under the three criteria for patentability. In such cases, the question will be whether, in assessing the inventive step criteria, slightly different chemical structures are truly non-obvious to a person with the level of ordinary skill.

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<sup>12</sup> This treaty sets up the global system of rules for access and benefit sharing for genetic resources and related traditional-knowledge.

<sup>13</sup> Interview with PT Eisai Indonesia, 8 March 2010.

*Recommendation: Product and process patents should be disallowed for new uses of known substances, unless there is a change in the underlying chemical structure. This could be specified in a new Article 7(e). The possibility to obtain a simple patent (utility model) for minor changes in chemical structure or new methods of delivery could be maintained in the Patent Law provided the applicable criteria are met, as a means to incentivize research and product development in areas of strength for Indonesia such as biodiversity and TK-based medicines. Article 6 would need to be revised to permit simple patents on chemical compounds in this case.*

### **1.3 Substances Found in Nature**

The interest of local pharmaceutical firms in biodiversity-based pharmaceutical products is also relevant to the question of whether substances found in nature are patentable. A number of patent laws worldwide treat such substances as non-patentable discoveries, rather than as an invention. At the same time, a case can be made that substances that have been extracted from their natural environment and, due to such extraction or subsequent refinement, behave differently from their original form, could potentially be eligible for patent protection provided the patentability criteria are otherwise met.

The current Indonesian Patent Law does not state the extent to which medicaments that are derived from substances found in nature are patentable. Article 7(d) of the Patent Law excludes from the definition of invention “all living creatures, except micro-organisms” and “any biological process which is essential in producing a plant or animal, except non-biological processes or micro-biological processes”. It is not clear what is meant by a biological process, as this is not defined. With respect to plants, there is certainly no obligation under the TRIPS Agreement to grant patent protection over plant varieties so long as the Member has a *sui generis* system of plant variety protection in place (see TRIPS Agreement, Article 27.3(b)).

One should, however, not carry these exclusions from the definition of invention too far – many medicines are indeed plant-based, including some on the essential medicines list such as morphine. Few would argue that a genuinely new plant-based medicine is not eligible for patent protection, provided the other criteria for patentability are satisfied.

In fact, most countries draw the line between what is patentable and non-patentable based on the extent to which some type of extraction and/or refinement has taken place that has caused the plant or animal to exhibit different properties. 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 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>14</sup>

Brazil's Patent Law establishes that:

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<sup>14</sup> Law 24.481, as amended by Law 24.572, consolidated text approved by Decree 260/96, of March 20/96.



"all or part of natural living beings and biological materials found in nature, even if isolated therefrom, 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>15</sup>

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>16</sup>

Note that Argentina, Brazil and the Andean Community all specifically exclude the genetic material of living things. Argentina's law goes further by also specifically excluding genetic cloning processes for human beings and processes for modifying the germ line genetic identity of human beings. Brazil's and the Andean Community's law excludes mere separation/isolation.

In Asia, Section 3(c) of the Indian Patent Act states that the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature is excluded from patentable subject matter. Live products are not wholly excluded from patentability in India, however, and patents are available for micro-organisms that otherwise meet patentability criteria under Section 3(j) of the Patent Act, as revised in 2002. Under Article 25(1) of the Chinese Patent Law, material that is a mere discovery of nature is not patentable, but may be given patent protection in isolated or purified from its natural environment if it has distinct characteristics.<sup>17</sup>

The classification of substances found in nature as outside the scope of invention has the effect of a blanket exclusion from patentability, and removes the possibility of a case-by-case analysis of patent applications. It is for this reason that it is important to define what constitutes a substance found in nature clearly. As with the case of new uses of known products discussed above, an overly broad exclusion of substances found in nature would likely not help support the R&D efforts by local firms to develop biodiversity-based products. In this regard, Indonesia may wish to consider the exclusion from patentability of all natural living things, including its genome or germplasm, as well as its extraction or isolation. Allowing patents on simple extraction or isolation would perhaps end up discouraging R&D by tying up the basic building blocks of research. It is, however, suggested to leave open the possibility to obtain a patent on products that may be derived from the living thing, to be considered on a case-by-case basis against the patentability criteria.

*Recommendation: The current version of Article 7(d) would appear to not exclude the possibility of granting patents on biodiversity-based products on a case-by-case basis. It should, however, be made clearer that some change or process would need to alter the substance found in nature that causes it to exhibit different properties.*

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<sup>15</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>16</sup> Ibid.

<sup>17</sup> See Lui at [http://www.nature.com/nbt/journal/v19/n1/full/nbt0101\\_83.html](http://www.nature.com/nbt/journal/v19/n1/full/nbt0101_83.html).

*The definition of a non-biological process would also need to be clarified. Article 7(d)(i) should be re-drafted to read “all living creatures, except micro-organisms, unless some change or process has altered the living creature causing it to exhibit different properties”. It is suggested to add an Article 7(d)(iv) stating that genome and germplasm, as well as mere extraction/isolation, are precluded from patent protection.*

#### **1.4 Protection of Clinical Test Data**

According to Article 39.3 of the 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. Indonesia at present has no specific law on test data protection, but does protect clinical test data under its Law Concerning Prohibition of Monopolistic Practices and Unfair Business Competition.<sup>18</sup> As the TRIPS Agreement only requires protection of clinical test data on new chemical entities against unfair competition, and does not require data exclusivity as such, the protection granted under the above Law would appear to meet TRIPS standards. In this regard, it should be noted that Indonesia is currently not a party to any bilateral or regional treaty that would foreclose any of its flexibility on test data protection.

Indonesia may well benefit from elaborating on the flexibilities provided to Indonesia's generic manufacturers in utilizing existing clinical test data for bioequivalence and subsequent marketing approval. For example, the NADFC should not, even as a matter of standard operating procedures, have to look into the patent status of a generic equivalent being submitted for marketing approval. If the marketing approval is used prior to the expiry of the patent, it is the holder of the patent right, and not the Drug Regulatory Authority (DRA), who should exercise his or her right in civil proceedings as a private right. This report will not, however, go into such issues in detail since it is beyond the scope of this study, which deals with potential amendments to the Patent Law, except as it relates to the regulatory review exception. This is discussed in Section 1.5 below.

#### **1.5 Regulatory Review Exception**

One specific exception to patent rights that is of particular relevance to countries that have a generic pharmaceutical industry is the regulatory review exception, which is also relevant in the context of how clinical test data is protected in the country. The former is usually a question of patent law, while the latter is a question of drug regulation. In line with the terms of reference for this study, this paper will focus on the former.

A patent confers upon its holder the right to exclude others from making, using or selling the protected product or process. It, however, does not authorize the right holder to put the patented product on the market. With respect to pharmaceutical products, such marketing authorization is obtained from a specialized government body, typically the country's DRA, which in the case of Indonesia is the NADFC.

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<sup>18</sup> Law Concerning Prohibition of Monopolistic Practices and Unfair Business Competition, Law No. 5 of 1999.

Obtaining approval from a DRA for the marketing of a drug often takes a good deal of time, sometimes up to several years.<sup>19</sup> Generic producers, in order to obtain marketing approval, often depend on the use of essentially the same active pharmaceutical ingredients and excipients as those used in a patented drug for which the originator has already received marketing approval, and for which the originator has already submitted 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>20</sup> From the point of view of a generic competitor, regulatory approval processes take a considerable amount of time, effort and money invested in reverse-engineering the patented compound, as well as formulating an equivalent product, and they may require substantial amounts of test production to demonstrate reliable manufacturing.<sup>21</sup>

If a patent holder uses his or her exclusive right to prevent generic producers from using the patented substance to conduct these experiments, a generic producer could only begin the process of experimentation and tests to obtain marketing approval after the patent has expired. Considering the time required for the approval process, marketing of the generic drug would be delayed to well after the expiry of the patent, thus extending, *de facto*, the right holder's period of exclusivity. From a public health and access to medicines perspective, delayed market entry of generic competitors is likely to delay the possible decrease of drug prices.

WTO case law has recognized the existence of an exception that is designed to address the question of acts undertaken by generic manufacturers related to seeking the marketing approval of generic equivalents of patented medicaments before the expiry of a patent, in order to enable generic competition to start as early as possible after the end of the patent term. In 2000, the WTO Dispute Panel in *Canada - Patent Protection of Pharmaceutical Products* ruled that a regulatory review exception falls within the exceptions envisioned under Article 30 of the TRIPS Agreement.<sup>22</sup> 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>23</sup>

Having been firmly grounded in WTO law, this exception, commonly also known as a Bolar exception<sup>24</sup>, has been maintained by many countries in their patent legislation. For example, Article 43 of the Brazilian patent law exempts acts "regarding patented inventions, which aim exclusively [at] the production of information, data and test results directed to procure commerce registration, in Brazil or any other country, to allow the exploitation and commercialization of the patented product, after the termination of the

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<sup>19</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.

<sup>20</sup> For more details on these different marketing approval procedures, see Section 3.5.

<sup>21</sup> *Canada - Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000, para. 7.45.

<sup>22</sup> Article 30 of the TRIPS Agreement permits exceptions to patent rights where it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

<sup>23</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>24</sup> The name of the exception takes its name from a party to a US case, namely *Roche Products Inc. v. Bolar Pharmaceutical Co.* (733 F. 2d. 858, Fed.Cir., cert.denied 469 US 856, 1984).

terms” of the patent.<sup>25</sup> The Egyptian patent law also contains a provision that exempts from patent infringement acts “where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that the marketing starts after the expiry of such a protection period”.<sup>26</sup> India, which is the world’s largest supplier of generic medicines, also maintains a Bolar exception in Section 107 of its Patent Act. It should be noted that the European Union, which previously opposed a regulatory review exception, has now adopted a version of its own.<sup>27</sup>

When formulating such a provision, WTO Members may decide whether to allow such an exception 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>28</sup> authorized the broader option (i.e., for both pre-clinical and clinical research). The Canadian Bolar exception, which was the subject of the WTO case mentioned above, goes even further, allowing activity designed to obtain regulatory approval in foreign countries.<sup>29</sup>

It should be noted that this exception has been the subject of Free Trade Agreements (FTAs) from time to time. Musungu and Oh note, for instance, that US FTAs with Bahrain, CAFTA (United States-Dominican Republic-Central America Free Trade Agreement), Chile and Morocco each includes language stating that export by a generic manufacturer of a product which is otherwise covered under the Bolar exception is only permissible for purposes of registration in the country from which the export emanates.<sup>30</sup>

In this context, laws excessively limiting the use of clinical test data (both in the developed country context and as spread among developing nations through bilateral and regional FTAs) can interfere with the generic producer's ability to reap the full benefits of an existing regulatory review exception. While the Bolar exception authorizes a generic producer to use a patented substance for purposes reasonably related to the granting of marketing approval, 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 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>31</sup> Undertaking their own clinical trials is too costly and time consuming for many generic producers, who will in that case await the expiry of the period of test data exclusivity. Some civil society organizations have also pointed out that having to repeat a clinical trial on the same substance is unethical. This wait will cause a considerable delay in the granting of regulatory approval for the generic drugs, and *de facto* extend the exclusive position of

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<sup>25</sup> Article 43 of Brazil’s Law No. 9279/96, as amended.

<sup>26</sup> Article 10(2) of Egypt’s Law on the Protection of Intellectual Property Rights (2002).

<sup>27</sup> See Directive 2001/83/EC, as amended by Directive 2004/27/EC.

<sup>28</sup> *Merck v. Integra Lifesciences*, 125 S. Ct. 2372 of 13 June 2005.

<sup>29</sup> Garrison, C. 2006. *Exceptions to Patent Rights in Developing Countries*. Issue Paper 17, UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 58.

<sup>30</sup> Musungu, S. and C. Oh. 2005. *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* Study 4C. Geneva, Switzerland: CIPIH (Commission on Intellectual Property Rights, Innovation and Public Health). <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>.

<sup>31</sup> For more details, see the discussion on test data protection, Section 3.5, below.

the original product beyond the patent term, contrary to the purpose of the regulatory review exception.

In addition, even in cases where the generic producer could effectively produce his or her own trial data, provisions in certain FTAs such as the Dominican Republic-CAFTA Agreement obligate the DRA to refrain from granting marketing approvals on generic drugs without the consent of the patent holder as long as the original version is protected under a domestic patent (the so-called “linkage” of patent law and drug regulation). Rather than leaving the task of patent enforcement up to the patentee, these laws effectively turn the DRA into a quasi-patent enforcement authority, despite the fact that many of these authorities do not have the expertise to verify the patent status of a drug.<sup>32</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. Such “linkage” provisions sometimes also 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>33</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>34</sup>

The regulatory review exception in Indonesia’s Patent Law is contained in Article 135(b). This provision states that “the production of a pharmaceutical product protected by a patent in Indonesia in a period of 2 (two) years before the termination of the patent protection with the purpose to process the permit and to do marketing after the termination of the patent protection” is exempted from the criminal provisions of the Law. According to both the NADFC and the DGIPR, this Bolar exception is in practice interpreted as a shield from both civil and criminal liability under the Patent Law, notwithstanding language in the basic patent legislation that appears to carve an exception only from criminal liability. Article 135(b) also appears to place emphasis on the manufacture of the product than on research and clinical trials on the product covered by the patent for filing a marketing authorization request. In this regard it is noted that the Ministry of Health’s Ministerial Decree No. 1010 of 2008 also permits local firms to apply for marketing authorization of a generic version of a patented drug up to two years before the expiry of patent protection (Article 13, Decree No. 1010).<sup>35</sup>

From discussions with stakeholders, however, the exception does not appear to be widely used by the local generic industry. Reasons for this appear to stem from not only a poor understanding of the exception by many in the local pharmaceutical industry, but also as a result of the propensity of the local firms to avoid civil litigation (i.e., having to respond to cease and desist letters by foreign patent owners and defending against their suits in a court of law). A change in the text of the law to shield generic manufacturers is urgently

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<sup>32</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.

<sup>33</sup> In this context, it should again be noted that as of June 2002, 73% of patent invalidation claims initiated by generic producers in the United States had been successful, see US FTC Study, p. 16. Between 2000 and 2007, generic competitors prevailed in 62% 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 (available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)).

<sup>34</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>35</sup> For a discussion of Decree No. 1010, see Section 1.1 above.

needed as the stated position of government authorities is insufficient to provide the assurance sought by local generic pharmaceutical producers to take full advantage of the available regulatory review exception.

Additionally, there appears to be no convincing rationale for the Bolar exception under the Patent Law to be limited to a period of two years before the termination of the patent. In some cases, reverse engineering and experimentation will take longer than two years. Moreover, other countries with a robust generic industry, such as Brazil and India, have no particular time limitations on the Bolar exception in their patent legislation.

A Bolar exception will become increasingly important as the Indonesian generic pharmaceutical industry becomes more and more adept at reverse engineering and able to take advantage of disclosure in patent applications to commence manufacturing of generic equivalents as soon as possible. For this reason, the full range of the exception should be explicitly codified in the Patent Law.

*Recommendation: A Bolar exception that provides a safe harbour from **both** civil and criminal liability, **without limitation of time**, should be made explicit in the Patent Law. Article 135(b) should be removed and replaced by a corresponding exception in Article 16. The following is suggested text for a new Article 16(4):*

*“Exempted from civil and criminal liability under the Patent Law is the production and use of a pharmaceutical product protected by a patent in Indonesia before the termination of its term, with the purpose to obtain authorization to market a generic version of that product after the termination of patent protection.”*

## **1.6 Parallel Imports**

Pharmaceutical companies often sell their products at different prices in different countries, depending to a large extent on what the market will bear and in the light of applicable price controls on medicaments. Parallel importers take advantage of the price difference between countries. They purchase certain IPR-protected products at a low price in a low-price country and import them into high price countries, undercutting the local price set by the right holder. The low-priced products are then imported in parallel to the official channels of distribution established by the right holder.

It is important to underline that parallel imports are not counterfeits; they are original products of the patent holder sold by 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>36</sup>

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<sup>36</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 already 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

Exhaustion can be international, regional or national (where international exhaustion means any sale anywhere in the world will cause the patent holder to lose the right to control the further distribution and resale of a product, and national exhaustion means that only domestic sales will cause such a loss of right).

In the context of pharmaceuticals, considering the pressure of parallel imports to reduce drug prices or the prices of APIs imported for local manufacturing of pharmaceuticals, the London-based, independent Commission on Intellectual Property Rights in 2002 recommended that developing countries seeking to promote access to medicines "should aim to facilitate parallel imports in their legislation."<sup>37</sup> A similar recommendation with respect to the treatment of parallel imports in developed and developing countries was subsequently adopted in the World Health Organization's 2006 Report of the Commission on Intellectual Property Rights, Public Health and Innovation.<sup>38</sup>

More generally, under Article 6 of the TRIPS Agreement and paragraph 5(d) of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Members are free to admit or to prohibit parallel imports in their domestic legislation, subject to non-discriminatory treatment. Despite its potential to lower the price of available medicines, few countries have to date effectively used parallel importation as a tool for greater access to medicines, however, with South Africa being the notable exception.

In Indonesia, there is a strong policy to encourage local production of pharmaceuticals, as evidenced by the December 2008 Decree No. 1010 issued by the Ministry of Health. This Decree requires every company to manufacture every one of its pharmaceutical products in Indonesia, subject to limited exceptions; imports are permitted subject to a technology transfer requirement that enables local production to commence within 5 years of the start of importation. One may question whether given such a policy, it would make any sense to provide for the possibility of parallel importation at all in the Patent Law at all, except for certain patented APIs.

In practice, however, Indonesia may find that it may not be practical, from a business, economic or health perspective, to try to manufacture certain medicaments domestically, particularly those that are complex, expensive and needed, relative to other medicaments, in smaller quantities. The NADFC has stated that it will approach the question of enforcing Decree No. 1010 flexibly to accommodate access needs in the country.<sup>39</sup> To the extent that virtually no country in the world can manufacture all of its requirements of medicines, Indonesia will still need to import, and it would thus make sense to have a patent law that permits parallel importation. Furthermore, in an interview with the NADFC, it was revealed that other industries, and in particular companies engaged in the Indonesian foods and food processing industry, engages in parallel importation as a standard business practice.<sup>40</sup>

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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>37</sup> Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy", London, 2002, p. 42.

<sup>38</sup> WHO, *Report of the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health*, Geneva, April 2006, p. 124, paragraph 4.19.

<sup>39</sup> Interview with A. Retno Tyas Utami, Director for Control of Production of Therapeutic Products and Household Products, National Agency of Drug and Food Control, Indonesia, 10 March 2010.

<sup>40</sup> Interview with National Agency of Drug and Food Control, Indonesia, 12 November 2010.

According to the DGIPR, parallel importation of patented products and products made under a patented process are permitted in Indonesia. While this may be the interpretation of public officials and the current practice, the Indonesian Patent Law presently does not provide support for this interpretation.

With respect to import of patented products that have been first sold outside Indonesia, Article 135(a) carves out an exception to patent rights. This provision permits the importation of a pharmaceutical product protected by a patent in Indonesia that has been marketed in a country by the patent holder. The problem, however, is that this clause expressly provides only a shield to the importer from criminal liability, and not from civil liability. Notwithstanding how this provision may be interpreted by the Indonesian authorities, Article 135(a) would seem only to encourage patent right holders in Indonesia to seek a private cause of action against would-be parallel importers.

Finally, the Patent Law is silent as to whether Indonesia applies a doctrine of international, regional or national exhaustion. From a simple drafting point of view, the Patent Law should be clear with respect to the regime of exhaustion employed. In this regard, it is generally understood that an international exhaustion regime facilitates parallel importation the greatest, while national exhaustion would make parallel importation more difficult.

*Recommendation: While Indonesia's pharmaceutical production policies clearly favor developing national capacity to produce the full range of medicaments domestically, parallel importation is still practiced in the local food industry. As parallel importation is permitted under the TRIPS Agreement flexibilities, Indonesia may wish to consider providing 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. This could be added as a new sub-section under Article 16(1).*

*Recommendation: The current Patent Law provides only a safe harbour from criminal liability for would-be parallel importers. This should be expanded, and could be done by deleting Article 135(a) and introducing a more general exception to patent rights as a sub-paragraph in Article 16.*

## **1.7 Compulsory and Government Use Licenses**

A compulsory license (CL) is an authorization granted by a government to a party other than the holder of a patent to use a patented invention without the consent of the patent holder.<sup>41</sup> A government-use license is a compulsory license that is granted in favour of a government entity. These tools often become the subject of great controversy when developing countries have issued them on certain medicaments, as was the case of Thailand's government-use licenses on ARVs, a blood thinner and a number of medicines used in the treatment of cancer in 2006, 2007 and 2008, respectively.

This section deals with the issue of CLs and government-use licenses from the perspective of public health and access to medicines. A number of recommendations on CLs and government-use licenses are, however, contained in other parts of this report, such as in the respective sections on competition remedies, working requirements and

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<sup>41</sup> UNCTAD-ICTSD Resource Book, p. 461.



simple patents. The recommendations contained in these respective sections should also be taken into consideration when examining possible revisions to the Patent Law.

The provisions concerning CLs are contained in Articles 74 through 87 of the current Indonesian Patent Law. The provisions on government-use licenses are contained in Articles 99 through 103. As a Member of the WTO, these provisions must respect the procedural requirements for CLs and government-use licenses contained in Article 31 of the TRIPS Agreement.<sup>42</sup> In this regard, there does not appear to be anything in the Patent Law articles on CLs and government-use licenses that contravenes the TRIPS Agreement. This report makes, however, a number of suggestions that are designed to enable Indonesia to better leverage existing TRIPS flexibilities in the use of CLs and government-use licenses, given its current access to medicines policies.

The first point is that the current provisions on CLs limit the possibility of a CL to situations where the patent has not been worked in Indonesia, under Article 75(2) of the Patent Law. It can be surmised that this is one of the reasons why Indonesia opted to issue government-use licenses over three ARVs, i.e., Lamivudine, Nevirapine (both in 2004) and Efavirenz (in 2007), rather than CLs. As noted earlier in this chapter, the licenses were granted in favour of Kimia Farma, a state-owned enterprise. Government-use licenses are not limited to cases of non-working under the current Patent Law.

There are certain advantages of government-use licenses over CLs procedurally under the TRIPS Agreement, the most notable of which is the ability to proceed with the issuance of the government-use license in the absence of failed prior negotiations with the patent holder, and is thus easier to issue in the face of a medical emergency, for example. At the same time, a government-use license would limit the choice of firms who could import or produce using that license to government ministries and state-owned enterprises, of which there are currently only four, which includes one for biologics/vaccines (Bio Farma), as well as government contractors. Moreover, Kimia Farma produced ARVs under the government-use licenses for a short period of time despite being granted a 7-8 year license, due to the inability to import raw materials cost effectively. By contrast, with a robust private generic industry in Indonesia, some consideration should be given to expanding the situations where a CL may be issued, at least to certain national emergencies. This would enable a wider range of firms to respond to crises such as pandemics, albeit the issuance of the CLs could possibly take longer than government-use licenses due to the requirement of prior negotiations with the patent holder.

*Recommendation: With respect to the provisions on compulsory licenses (CL), Indonesia may wish to consider expanding the grounds for issuing a CL beyond non-working to at least encompass national emergencies (which could include pandemics). This would require a revision of Article 75(2) of the Patent Law.*

The second point is that the Patent Law does not appear to have incorporated the system of notifications for CLs contained in the 30 August 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. While the amendment is still awaiting enough signatories to be made part of the TRIPS Agreement (the future Article 31*bis*), this Decision institutes an elaborate system whereby CLs are encouraged as a means for providing medicines to countries with little

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<sup>42</sup> Further regulations on government-use licenses were issued in Government Regulation No. 27 of 2004, which requires a Presidential Decree to issue a government-use license.

or no manufacturing capacity, provided the CLs of the manufacturing/exporting and the importing country are notified to the WTO.

Indonesia is certainly not a country with an absence of any manufacturing capacity. With a strong local generic industry, however, it can potentially serve as a candidate exporting country. Furthermore, Indonesia's rapid economic growth into a middle income country has meant that R&D-based pharmaceutical companies from the developed countries are increasingly seeking patent protection on new chemical entities (NCEs) in the country. Given the importance Indonesia places on regional cooperation (being the seat of the Association of South East Asian Nations (ASEAN) where three members are LDCs (and assumed not to have manufacturing capacity in pharmaceuticals under the Decision)) and its geographic position close to many Pacific islands nations where many countries lack any manufacturing capacity in pharmaceuticals, it would appear important for the provisions of the so-called Paragraph 6 system to be fully incorporated into the Patent Law.

*Recommendation: Consideration should be given to incorporate into the Patent Law the notification mechanisms under the 30 August 2003 Decision in the event that its local pharmaceutical industry is requested to act as a regional exporter for medicaments under the so-called Paragraph 6 system.*

The final point is with respect to remuneration rates on non-voluntary licenses. Article 78 of the Indonesian Patent Law stipulates that the "implementation of a Compulsory License shall be accompanied by the payment of royalties by the compulsory licensee to the Patent Holder" and Article 101(2) provides that the "exploitation of a Patent by the Government shall be carried out with the provision of reasonable compensation to the Patent Holder." The DGIPR sets the royalty rate in the case of a compulsory license (Article 78(2)), while the remuneration rate can be set elsewhere in the case of a government-use license. The royalty rate can be challenged at the Commercial Court if the patent owner feels that the offered compensation is insufficient (Article 102). No specific remuneration rates are specified in the Patent Law, but in practice, they are announced with the issuance of the CL or the government-use license.<sup>43</sup>

Remuneration rates are typically not specified in a patent law. They can be the subject of regulations or guidelines issued by the national IP office, or announced on an ad hoc basis, as in the case of Indonesia's government-use license over ARVs. Still other countries, such as the Philippines, set a maximum royalty rate for CLs (3% of the net wholesale price of the patented commodity).<sup>44</sup>

The TRIPS standard for remuneration in the case of pharmaceuticals is governed under Article 31(h) of the TRIPS Agreement and the 30 August 2003 Decision noted above, which states that remuneration should be "adequate", taking into account the economic value of the authorization in the importing country. In this regard, the Indonesian Patent Law is in line with, and arguably exceeds, international law and no particular amendment would appear to be required.

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<sup>43</sup> See, for instance, the 5 October 2004 Decree of the President of the Republic of Indonesia No. 83 of 2004, regarding exploitation of patent by the Government on ARVs.

<sup>44</sup> Section 35-B(3), the Philippine Republic Act no. 165 of 1947, as amended by Presidential Decree 1263 in 1977.

The more difficult question is that of whether the specific remuneration royalty rate cited in the Indonesian government-use licenses of 2004 and 2007 (i.e., 0.5% of the net sales value of the ARVs) could be considered “adequate” or “reasonable”. Unfortunately, there is no real precedent on this issue. Royalty rates have differed widely in relation to non-voluntary licenses, from as low as 0.01% (in the United States) to as high as 45% (United Kingdom) of net sales.<sup>45</sup> Theoretically, therefore, a 0.5% royalty rate may actually be an adequate rate of remuneration (and then again, it may not). The more important issue is whether Indonesia would be able to adequately explain how they arrived at the 0.5% remuneration rate and to be able to defend its adequacy, in the event that the country were challenged on this issue by the patent holder (or the government of the patent holder). In this regard, it would appear to be important to stress that Kimia Farma is an SOE that produces non-branded generics at razor thin margins. As Kimia Farma no longer produces the ARVs, this may not be an issue any more for the ARVs over which Indonesia issued government-use licenses. This is, however, a problem that should be given some thought in so far as the Government has not ruled out the possibility of issuing CLs or government-use licenses in the future. There are also regional implications of how Indonesia addresses this issue, as the 0.5% rate appears to have been used as a benchmark when the Thai government issued their government-use licenses on certain pharmaceuticals between 2006 and 2008.

*Recommendation: The Government should convene a meeting of stakeholders to examine the question of how an adequate remuneration rate should be set in the event of a non-voluntary use of a patent (CL or government-use license).*

## **1.8 Enforcement of IPRs**

In the context of medicines and patents, it should be recalled that patent rights are first and foremost private rights. Patent owners are principally expected to initiate civil proceedings against those who infringe upon their exclusive rights or who violate the terms of their license, without help from law enforcement authorities.

Patent infringement needs to be distinguished from the issue of counterfeit medicines, however, which attempts to pass off often sub-standard medicines as originally manufactured medicines.<sup>46</sup> Such attempts are not only legitimately the concern of law enforcement and criminal sanctions, but also actionable under civil law as well using trademark law or under unfair competition law. It is acknowledged that Indonesia does have a problem in regulating a grey market for second hand pharmaceuticals, and interviewed officials confirm that counterfeit medicines is a widespread problem due in part to the prevailing practice of self-medication in the country and the lack of prescription controls at many pharmacies. As this report deals with possible reforms to the Patent Law, however, no specific recommendations are made with respect to issues that fall under other laws. Indonesia’s health, law enforcement and patent authorities need nonetheless to be clear that the legitimate manufacture of generic, off-patent medicines should in no way be confused with the issue of counterfeit medicines.

With respect to patent law enforcement issues, other sections discuss a recurrent problem in the current Indonesian Patent Law, that is, exceptions to patent rights which shield

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<sup>45</sup> James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* (2005), World Health Organization and UNDP Health, Economics and Drugs TCM Series No. 18, p. 42.

<sup>46</sup> See IMPACT, *The Handbook* (2011).

individuals from only criminal liability without shielding those individuals from civil liability. This problem occurs with the research and experimentation exception (discussed in the next chapter), parallel importation and the regulatory review exception (both discussed earlier in this chapter). Relevant recommendations are contained in the respective discussions of these topics above, and will not be repeated here.

From the November 2010 fact-finding mission, it appeared that the court system in the country did not have many cases before it alleging patent infringement. In the medium term, increased training of judges in hearing patent cases will probably be necessary as patents on NCEs filed by foreign firms increase. Also, a separation of powers currently excludes the possibility of the Commission for the Supervision of Business Competition to hear cases to check possible abuses of IPRs. This paper considers this to be a problem, and relevant analysis and recommendations are contained in the chapter on competition below.



## **Chapter 2 – The Patent Law and Technology Transfer**

Developing countries seek to encourage greater technology transfer<sup>47</sup> to support the development of key industries alongside efforts to upgrade their domestic capacity to innovate. They see it also as part of the bargain in which they have agreed to minimum standards of protection using intellectual property rights under the TRIPS Agreement.<sup>48</sup> The relationship between patents and technology transfer is by no means straightforward or automatic, however. Most people would agree that there is a relationship between the two. But different aspects of patent law have very different effects on technology transfer. For example, licensing has always been one means by which technology covered by intellectual property rights can be transferred to a licensee. The dynamics of licensing start to become more complex, however, when taking into consideration the added element that technologically advanced countries, which are the home to licensors, typically have greater bargaining power over determining the terms and conditions of licenses compared to those countries that have less technological capabilities (i.e., the licensees). In this regard, the present report treats Indonesia as a developing country that is a net importer of technology. In addition to licensing, patent applications serve the important function of disclosure. Certain exceptions in patent law also can facilitate technology transfer and innovation. After reviewing the overall framework for technology transfer in the country, this chapter examines how different topics addressed under the current Patent Law in Indonesia either help or hinder technology transfer, and suggests a number of changes.

### **2.1 *Indonesia's Framework for Technology Transfer***

Indonesia has no overarching policy framework for encouraging technology transfer as such. A number of policies pursued by Indonesia's various government ministries (such as agriculture, industry or health) call for increased technology transfer, but are not necessarily coordinated with each other. Nor is technology transfer mentioned as an explicit objective in the current Patent Law.

With respect to technological development and innovation, the Government promulgated a law in 2002 to establish a national system for research, development and application of science and technology. This Science and Technology Law established a National Research Council to provide strategic direction on developing the country's scientific research capacities. A National Development Strategic Policy for Science and Technology was promulgated shortly after this law was enacted, and emphasizes the importance of R&D as a driver for Indonesia's future economic development. This policy is incorporated into Indonesia's National Mid-Term Development Plans (2004-09 and 2010-14 respectively), and focuses on improving domestic science and technology capacities in the areas of food security, new and renewable energy resources, transportation, information communication technologies, defense and health/medicines.<sup>49</sup>

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<sup>47</sup> It should be noted that there is no uniformly accepted definition of what constitutes technology transfer. Relatively broad definitions have been put forth under the Draft Code of Conduct on Technology Transfer, as well as by WIPO (2009). We will not review the debates over the definition of technology transfer here, as it is not the intent of this report to enter into a debate on the semantics of technology transfer.

<sup>48</sup> See [http://www.wto.org/english/tratop\\_e/trips\\_e/techtransfer\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm).

<sup>49</sup> Taufik (2007).

At present, scientific research and development policy in Indonesia is coordinated by the State Ministry of Research and Technology (RISTEK). RISTEK, *inter alia*, provides grants for research, including to individuals, non-profit organizations, government research institutions and university research projects. Government funding provides much of the support for R&D in Indonesia. The largest government-affiliated non-departmental research institution to which RISTEK provides grants is the Indonesian Institute of Science (LIPI), which in turn disburses grants to individual basic and applied science projects in various sectors. The ability of local institutions to undertake R&D is, however, limited, underlining the need to build capacity to better access and absorb technology from abroad, both formally and informally. In general, technology transfer agreements with foreign institutions are negotiated in Indonesia by the local institution undertaking R&D.

The predominant proportion of inbound technology transfer takes place in private sector transactions. Individual firms negotiate with potential partners for technology transfer, for example as part of establishing a joint venture or in-licensing technology. Not surprisingly, technology transfer activity in Indonesia is robust in certain key industries identified by the National Mid-Term Development Plans, such as biotechnology, medicines and vaccines, energy, information communication technology and aerospace. As noted in chapter 1 for example, in the area of medicines and vaccines, local pharmaceutical firms have to date been recipients of substantial amounts of technology in the context of establishing local factories to manufacture medicaments.<sup>50</sup>

There has been a longstanding debate about the extent to which developing countries have bargaining power when negotiating technology transfer agreements, where it is generally assumed that developed country licensors would have the greater ability to dictate favourable terms. In order to address this situation, one interesting recent development in Indonesia is that domestic universities are increasingly being encouraged by the Government to apply for intellectual property protection over the fruits of their research. Many of the re-known universities in the country have now established offices to coordinate the filing of IP applications.<sup>51</sup> The hope is that taking out IP rights, whether in the form of patents or simple patents, would give local institutions greater bargaining power in negotiations to receive technology transfer on more favourable terms, that this would serve as an incentive to encourage more local innovation, and that this would help bridge the gap between upstream research efforts and efforts to commercialize the developed technology downstream. Using patents to protect upstream research by universities has been controversial in other countries, though, as it has been argued that granting the right to exclude others on upstream technology could potentially tie up important technologies and prevent the technology from being widely disseminated.<sup>52</sup> This report reverts to this issue in the section on licensing below.

The stakeholders interviewed during the UNCTAD field mission in November 2010 indicated clearly that Indonesia's leading industrial sectors have benefited from technology transfer, and that technology transfer from developed countries has been indispensable for its development. In industries of strategic importance from a

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<sup>50</sup> Domestic pharmaceutical firms originally obtained much of their technology from Japanese and US firms. More recently, the state-owned enterprise Bio Farma is a recipient of technology to develop vaccines locally. See also Wie (2001).

<sup>51</sup> Interview with LIPI, 12 November 2010.

<sup>52</sup> The US Bayh-Dole Act generated much discussion on this issue. More recently, there are similar efforts to encourage universities to patent in India. See Sampat (2009).

development perspective such as energy, electronics and pharmaceuticals, TNCs have been instrumental in providing the basic technology on which Indonesian manufacturers rely today. Despite efforts of the Government, local innovation capacities remain limited. Other studies point to a number of weaknesses in the overall science, technology and innovation system of the country, including a lack of coordination among the stakeholder agencies and actors.<sup>53</sup>

Of course, changes in the Patent Law alone would not be sufficient to address all of the shortcomings of the current regime on technology transfer or the limitations of the country's innovation capacities. There are a number of areas which deserve analysis and which could benefit from amendments to support the country's efforts to enable Indonesia to obtain technology from abroad on more favourable terms, and support their development objectives. These issues are addressed in turn.

## **2.2 Licensing and Transfer of Technology**

A license is a contract under which written authorization is granted by the owner of intellectual property to another person empowering the latter to make, sell or otherwise use the subject matter for a limited period in a limited territory.<sup>54</sup> Technology which is proprietary can be transferred through licenses. That technology may be covered by a patent, or it could comprise unpatented know-how. Licenses can be limited to technologies used to make products, or could be part of more elaborate transactions as in the establishment of a joint venture. Normally, technology is licensed in return for the payment of royalties or fees.

Licenses are governed under the Indonesian Patent Law in Articles 69 through 73. Article 69 sets out the basic freedom of patent holders to license out technologies patented in Indonesia. In order to receive protection under the Indonesian Patent Law and to be able to enforce the terms of the license, a license agreement must be registered with the DGIPR (Article 72). The Law does not cover licenses over technologies patented elsewhere but not in Indonesia. The law governing licenses of foreign patents not protected in Indonesia is thus governed by either general contract law or under the Trade Secret Law.

An interesting feature of the provisions on licensing is Article 71 of the Patent Law, which stipulates that “[a] licensing agreement shall not contain any provisions that may directly or indirectly damage the Indonesian economy, or contain restrictions which obstruct the ability of the Indonesian people to master and develop technology in general and in connection with the Patented Invention in particular.” The DGIPR is empowered to refuse the registration of any licensing agreement on an Indonesian patent that contravenes Article 71, but this presumably has no effect on licensing agreements under general contract law that cover patents granted elsewhere but not in Indonesia, or for licensing contracts covering know-how and trade secrets.<sup>55</sup> It is not clear whether the DGIPR has previously used this provision to refuse the registration of a license agreement on grounds of an obstruction of the ability to master and develop technology.

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<sup>53</sup> See Taufik (2007).

<sup>54</sup> Adapted from the definition of license in Black's Law Dictionary.

<sup>55</sup> A similar provision exists under the Trade Secret Law which stipulates that licensing agreements shall not contain any provisions that may directly or indirectly damage the Indonesian economy or any provisions that can create an unfair competition as regulated in the prevailing laws and regulations (Article 9). This is enforced by a similar provision giving DGIPR the power to refuse registration of a licensing agreement over a trade secret (Article 8(2)).



The choice of language in Article 71 of the Patent Law appears to place the emphasis on the absorption of technology contained in a license, and the ability of Indonesians to innovate, without specification as to whether the license is between a foreign person and an Indonesian or between Indonesians. The text of the Article thus underpins the aspirations of Indonesia to ensure that license agreements contribute to the technological development of the country.

Usually, however, provisions that invalidate licenses or portions thereof in patent legislation are based on concerns about anti-competitive behaviour or restraints on trade, and therefore a discussion with respect to the effects on licensing on competition is discussed separately in Chapter 3 below. The text of Article 71 makes no reference to anti-competitive behaviour or restraints on trade as such, instead giving the DGIPR wider authority in determining what constitutes a restriction which obstructs “the ability of the Indonesian people to master and develop technology”.

The flexibility provided in the TRIPS Agreement to prohibit licenses is contained in Articles 8(2) and 40 of the TRIPS Agreement. The former Article provides that:

“Appropriate measures, provided they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

The latter article, *inter alia*, enumerates some examples of particular cases that may constitute an abuse of IP rights. These provisions are thought to have their origins in proposals by industrialized countries at the negotiations hosted by UNCTAD on a draft international code of conduct for the transfer of technology, to introduce competition law as a test in order to address the problem of when a restrictive clause should be declared void,<sup>56</sup> and may explain in part the reference in Article 8(2) to “the international transfer of technology”. Nowhere is it explicitly stated in the TRIPS Agreement, though, that practices that adversely affect the international transfer of technology should be restricted to competition-based claims. Nor is the “international transfer of technology” ever defined in the TRIPS Agreement.

The current text of Article 71 still leaves open the question, though, of whether refusing to register a license agreement on grounds of obstructing the ability of Indonesians to master and develop technology falls under the ambit of Article 8(2) of the TRIPS Agreement, which is limited to practices that adversely affect the international transfer of technology. It is therefore suggested that the text of this Article be amended. This could be done by including a specific reference to international transfer of technology, in order to better align the text of Article 71 of the Patent Law with the TRIPS Agreement.

*Recommendation: The provision in the Patent Law concerning the authority of the DGIPR to regulate licensing in order to further the objective of transfer of technology could be better aligned with the text of the TRIPS Agreement. Article 71 should be amended to read that “[a] licensing agreement shall not contain any provisions that may directly or indirectly damage the Indonesian economy, or contain restrictions which obstruct the international transfer of technology and*

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<sup>56</sup> See South Centre (2000).

*limits the ability of the Indonesian people to master and develop technology in general and with the Patented Invention in particular.”*

## **2.3 Disclosure Requirements**

### **A. Generally**

Disclosure is required as part of a patent application in order to substantiate that the inventor has effectively made a patentable invention and to make new technical information available to the public so that others are able to both recreate the invention and to improve upon it.<sup>57</sup> Full disclosure is therefore part of the social contract underlying the grant of an exclusive patent right. The ability of Indonesians to learn from the patent applications, the majority of which are currently filed by foreigners<sup>58</sup>, thus depends on a system of disclosure that allows local inventors to take and absorb the information contained therein. In this manner, patent disclosure is an important tool to facilitate technology transfer.

It is rarely in the commercial interest of a patent applicant to provide complete and effective disclosure – an inventor risks that others may take commercial advantage of the investment made in developing a new invention in the event the inventor fails to obtain a patent. A research exception permits others to experiment and potentially make a product or process that renders the technology of the patent applicant obsolete (see section 2.4 on the research and experimentation exception below). The incentive for the patent applicant is therefore to provide minimally sufficient disclosure to secure the exclusive patent right. For this reason, patent laws often stipulate the level of disclosure required in patent applications, and insufficient disclosure is considered grounds not to grant a patent.

Article 24 of the current Indonesian Patent Law stipulates what must be contained in the patent application. Article 24(2)(i) states that the application form must contain a written description of the invention which contains complete information on the ways of implementing the invention. Beyond this, the Patent Law does not stipulate what or how an invention must be disclosed. In practice, discussions take place between patent examiners at the DGIPR and patent applicants in order to determine whether an inventor has met the criteria for patentability. Few patent applications appear to have been rejected to date, however, on grounds of incomplete disclosure.

The TRIPS Agreement provides flexibility to countries to set a standard for disclosure appropriate for each Member country. Article 29.1 of the TRIPS Agreement states:

“Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the **best mode** for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.” (emphasis added)

This “best mode” requirement, when included in a patent law, requires applicants to reveal the best known way of carrying out the invention. The United States, for example,

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<sup>57</sup> UNCTAD-ICTSD (2005). *Resource Book on TRIPS and Development*. Cambridge, Cambridge University Press, p. 448.

<sup>58</sup> DGIPR (2010).

requires the inventor to indicate the best mode of making or practicing the invention.<sup>59</sup> The US requirement is relatively unique in patent law from a comparative perspective. The European Patent Convention, for example, only requires that applicants must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art,<sup>60</sup> without incorporating a “best mode” requirement. Japan similarly has no “best mode” disclosure requirement.<sup>61</sup>

A “best mode” disclosure requirement would be one way to create a pro-competitive environment for technology development in Indonesia and to facilitate technology transfer and follow-on innovation. This is especially so given that the large majority of patent applications filed in Indonesia are by foreign owners of technology, primarily under the Patent Cooperation Treaty (PCT).<sup>62</sup>

*Recommendation: Given that the majority of patent applications filed in Indonesia are by foreigners, technology transfer and dissemination could be facilitated by requiring patent applicants to disclose the best means for implementing the invention in question. Indonesia should consider including a best mode disclosure obligation in patent applications. This could be included in Article 24(2)(i).*

## **B. Disclosure in the Context of the Convention on Biological Diversity**

Indonesia has rich biological diversity. With a wide array of flora and fauna spread out over 17,000 islands between the Indian and Pacific Oceans, the diversity of nature found in the country has provided the basis for the livelihoods of many indigenous and other local communities, and has become a major tourist attraction for the country. This same biodiversity has also become attractive as a potential new source of products, whether they are cosmetics, medicines or foods, just to name a few. As noted in the case of biodiversity-based medicines in Chapter 1, local pharmaceutical firms (the large generic manufacturers in Indonesia) are interested in biodiversity-based products just as much as foreign firms (Eisai had earlier established an R&D laboratory in Indonesia to explore the possibility of developing and commercializing biodiversity-based medicaments). While the global trade in products developed from biodiversity resources is still relatively nascent, many developing countries with abundant flora and fauna are looking to the sustainable development of biodiversity-based products as an area which could contribute to economic growth.

Trade in biodiversity resources is regulated, *inter alia*, by the Convention on Biological Diversity (CBD) at the international level. A number of provisions in the CBD are designed to help prevent so-called biopiracy and the misappropriation of commercial benefits that are improperly obtained as a consequence of applying for, owning or transferring intellectual property. Biopiracy undermines equitable access and benefit sharing (ABS) between the country of origin of the biodiversity (genetic) resource or traditional knowledge and the recipient of those resources under the CBD. The relevant provisions are articulated in Article 15.5 of the CBD, which provides for access to genetic

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<sup>59</sup> See 35 U.S.C. 112.

<sup>60</sup> See Article 83, European Patent Convention.

<sup>61</sup> A detailed description of the invention must be adequately and thoroughly described so that a person skilled in the relevant field could conduct the invention. See Japan Patent Act sect. 36.4.1.

<sup>62</sup> DGIPR Annual Report 2009, p. 12.

resources subject to the prior informed consent (PIC) of the Party providing those resources. Other relevant provisions in the CBD include Article 15.4 and 15.7, which state that any granted access to genetic resources must be on mutually agreed terms (MAT), and that measures need to be taken to ensure that the benefits that derive from the commercialization of any research and development are shared fairly and equitably. Article 8(j) of the CBD further encourages the preservation of traditional knowledge (TK) and calls for the equitable sharing of benefits that derive from the use of TK relevant for the conservation and sustainable use of biodiversity. Beyond these general principles, more detailed rules on ABS were recently adopted by the Tenth Conference of the Parties to the Convention on Biological Diversity in Nagoya, Japan (i.e., the Nagoya Protocol) in October 2010. The Nagoya Protocol opened for signature in February 2011.

Patent disclosure has long been suggested as a tool to help support efforts to ensure that these and other CBD provisions are implemented, and that the IP system is not used to commit misappropriation and biopiracy.<sup>63</sup> A disclosure obligation would require patent applicants to disclose the source and/or origin of any genetic material and/or any related traditional knowledge use in a claimed invention. It may also include a requirement to provide for evidence of PIC from the competent authority of the country of origin and evidence of fair and equitable benefit sharing.<sup>64</sup>

While the Nagoya Protocol ultimately did not adopt a mandatory disclosure requirement, countries are free to adopt such a requirement and in a number of cases have done so. These countries include the Andean Community countries,<sup>65</sup> Belgium,<sup>66</sup> Bolivia,<sup>67</sup> Brazil,<sup>68</sup> China,<sup>69</sup> Colombia,<sup>70</sup> Costa Rica,<sup>71</sup> Denmark,<sup>72</sup> Ecuador,<sup>73</sup> Egypt,<sup>74</sup> the European Community (EC),<sup>75</sup> Germany,<sup>76</sup> India,<sup>77</sup> the Kyrgyz Republic,<sup>78</sup> New Zealand,<sup>79</sup> Norway,<sup>80</sup> Panama,<sup>81</sup> Peru,<sup>82</sup> the Philippines, Portugal, Romania,<sup>83</sup> South Africa,<sup>84</sup>

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<sup>63</sup> Correa, C. and Sarnoff, J.D. (UNCTAD, 2006). *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*. New York and Geneva, United Nations, p. 5. See also TRIPS Council Meeting, 14 June 2005, Agenda Items C-E, Statement by India (TRIPS Council India Statement), p. 2; WTO, IP/C/W/447, p. 2, available at: [http://www.wto.org/english/tratop\\_e/tripos\\_/art27\\_3b\\_e.htm](http://www.wto.org/english/tratop_e/tripos_/art27_3b_e.htm); Correa, C.M. (2003); and UNEP/CBD/COP/6/20, CBD COP Decision VI-24.C, paras. 1 and 2.

<sup>64</sup> Medaglia, J. and Rukundo, O. (2010) *Monitoring Compliance: Disclosure Requirements and the International Certificate*. ICTSD BioRes Review, Vol. 4, Issue 3, p. 10.

<sup>65</sup> Andean Community: Decision 486 ("Common Intellectual Property Regime") December 2000, Article 26 (h); Andean Community decision 391.

<sup>66</sup> Belgium: Patent Law; Project : Law No. 2005-04-28/33: Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention, en ce qui concerne la brevetabilité des inventions biotechnologiques.

<sup>67</sup> Bolivia: Supreme Decree No. 24676, Article 2, Final Provisions VII - Seventh.

<sup>68</sup> Brazil: Provisional Measure No. 2.186-16 (August 23, 2001).

<sup>69</sup> China: Patent Law Amendment (2008), Article 5(2), 26(5).

<sup>70</sup> Colombia: Executive Decree 720.

<sup>71</sup> Biodiversity Law 7788, Article 80; Rules on Access (2003) Art. 25; amendments made in 2009.

<sup>72</sup> Act 412, 31 May 2000 amending Danish Patent Act, paragraph 3; Danish order on Patents and Supplementary Protection Certificates, Order No. 93, Danish Penal Code 163.

<sup>73</sup> Political Constitution of Bolivia (2008), Art. 381, 382.

<sup>74</sup> Egyptian Law No. 82 of 2002 on the Protection of Intellectual Property Rights, Art. 13.

<sup>75</sup> EC Directive 98/44, Recital 27.

<sup>76</sup> Germany: Patent Act § 34a PatG.

<sup>77</sup> India: Patent Law Amendment (2002) Section 10, 25.

<sup>78</sup> Kyrgyz Republic: On Protection of Traditional Knowledge (June 26, 2007), Art. 8.

<sup>79</sup> New Zealand: Patent Bill 2009 and Section 17 Patent Act (1953).

<sup>80</sup> Norway: Patent Law Amendment 2004, Section 8b.

<sup>81</sup> Executive Decree No. 25 (April 28, 2009) Art. 19.

<sup>82</sup> Biodiversity Law (August 10, 2002) Art. 4c, as amended.

<sup>83</sup> Romania: Patent Law 64/1991, rule 14.1.c) source shall be indicated.

<sup>84</sup> Patent Law Amendment (December 7, 2005).

Sweden<sup>85</sup>, Switzerland,<sup>86</sup> Thailand,<sup>87</sup> Venezuela,<sup>88</sup> and in other countries.<sup>89</sup> Countries differ, however, in whether disclosure is voluntary or mandatory, whether the disclosure requires additional proof of having met CBD requirements of PIC and equitable ABS, and whether failure to comply with CBD requirements is sanctioned within or outside of the governing patent law. Not all of these countries have implemented the disclosure requirement through their patent legislation.

There has been an ongoing debate regarding the relationship between the CBD and the TRIPS Agreement. Developing countries, including Indonesia<sup>90</sup>, have argued that the TRIPS Agreement should be amended to require mandatory disclosure. Some developed countries have argued the contrary, saying that a mandatory disclosure requirement is not needed, and that the TRIPS Agreement is not the appropriate instrument to regulate ABS.<sup>91</sup> At the heart of this debate is the question of the effect of disclosure on a patent application, i.e., whether a WTO Member can deny or invalidate patents obtained in violation of CBD ABS principles when patentability criteria are otherwise met. As of the writing of this advisory report, this issue remains unresolved at both the CBD and TRIPS forums, and may remain so for the foreseeable future. It also remains to be seen whether the absence of a consensus agreement on disclosure in the Nagoya Protocol will give impetus to negotiations at the TRIPS Council on this issue. The issue of mandatory disclosure is also a key negotiating point in WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

The potential role of disclosure in helping to prevent biopiracy and misappropriation is clear. A country with rich biodiversity resources and related TK such as Indonesia stands to benefit from such a requirement. Indonesia has a clear interest to ensure benefit sharing for genetic resources and TK that originate in the country, both commercially and from any advances in technology that might arise therefrom. Indonesia's Patent Law presently contains no such disclosure of origin requirement.

In the absence of global consensus on the need to revise the TRIPS Agreement, its relationship to the CBD/Nagoya Protocol or on the full legal effect of disclosure, this report suggests that a mandatory disclosure of origin requirement be introduced into the Patent Law, but to ensure that its effect is consistent with the assessment by IP authorities for determining the substantive conditions for entitlement (that is, in the case of patents, novelty, inventive step and industrial applicability). This approach is fully consistent with Indonesia's obligations under the TRIPS Agreement. According to Correa and Sarnoff:

“Article 29.1 of the TRIPS Agreement specifies mandatory and facultative patent application disclosure requirements. But that Article does not preclude countries from imposing additional disclosure requirements for national applications, particularly when effectuating substantive conditions of entitlement.”<sup>92 93</sup>

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<sup>85</sup> Swedish Patent Decree, Section 5a.

<sup>86</sup> Amendment of Patent Law of June 22, 2007, RO 2008 2551, Art. 49 a.

<sup>87</sup> Act on Protection and Promotion of Traditional Thai Medicinal Intelligence B.E. 2542.

<sup>88</sup> Biodiversity Law 2009.

<sup>89</sup> Some countries are operating by practical measures equivalent to disclosure by ensuring close cooperation of the relevant authorities in biodiversity and ABS and notification to the relevant IP office and other practical measures; see African Model Law, Art. 65.

<sup>90</sup> See World Trade Organization, document TN/C/W/59 of 19 April 2011.

<sup>91</sup> *Ibid.*

<sup>92</sup> Sarnoff, J.D. (2004), pp. 40-41, Compatibility with Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of

Under a mandatory disclosure regime, patent applications would need to be examined by the DGIPR in light of both novelty and inventive step, given disclosure of TK or the use of a genetic resource that has its origins in Indonesia. Patent examiners would have to assess, for instance, whether a medicine that uses a plant extract from a certain tree found only in Sumatra is sufficiently novel or has been changed sufficiently to meet the inventive step test, given a certain indigenous community's use of that plant in traditional medicine.

With respect to the effect of non-disclosure in the post-grant period, one drawback of the current Patent Law is that patents that have been granted can generally only be revoked by a commercial court upon complaint by a third party (Article 91). The DGIPR may revoke a patent only under two specific circumstances: first by application of the Patent Owner, who may apply to the DGIPR to revoke his or her own patent (Article 90), and second, as a result of the failure by the patent holder to pay annual fees to maintain the patent (Article 88). Adding to the Patent Law a disclosure of origin requirement should leave open the possibility for the DGIPR to revoke a patent for failure to disclose relevant information concerning the invention.

In the absence of international agreement, it is not recommended at this stage for IP offices to check on whether there has been prior informed consent under the CBD and examination of underlying benefit-sharing agreements, although the Nagoya Protocol leaves open the possibility of designating the patent office as such a "checkpoint". Under the Protocol, each country is obliged to designate at least one checkpoint. While this CBD requirement is certainly important, the capacity to undertake a comprehensive review of PIC and agreements for equitable ABS may not exist at present at the DGIPR. These agreements may be better examined by the formal national competent authority for Indonesia under the CBD, namely the Ministry of Environment.

From a drafting perspective, the examples from India and Switzerland are illustrative, and are contained in the Box below.

**Box 1: Examples of Disclosure Requirements in Patent Laws –  
India and Switzerland**

**India**

**Section 10:** "Every complete specification shall... disclose the source and geographical origin of the biological material in the specification, when used in an invention."

*Two new grounds for revocation:*

**Section 25:** "The complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention."

"The invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."

Legal Access and Benefit Sharing, Memorandum for Public Interest Intellectual Property Advisors (PIIPA), Washington: PIIPA.

<sup>93</sup> Correa and Sarnoff, p. 24.

## **Switzerland**

**Article 49a:** “For inventions based on genetic resources or traditional knowledge the patent application must contain information concerning the source:

- a) of the genetic resource to which the inventor or the applicant had access, when the invention is based directly on that resource;
- b) of the traditional knowledge of indigenous or local communities related to the genetic resources to which the inventor or applicant had access, when the invention is based directly on that knowledge.

If the source is not known to either the inventor or the applicant, the applicant must confirm this in writing.”

**Article 59(2):** [...] “If the patent application does not meet the other requirements of this Act or the Ordinance, the Institute shall set a time limit for the patent applicant by which the defects must be corrected.”

**Article 59a (3b):** “The Institute shall reject the patent application if [...] The defects mentioned in Article 59 paragraph 2 are not corrected”.

**Article 81a (Wrongful declaration of the source):** “Whoever wilfully makes a wrongful declaration as referred to in Art. 49a, shall be liable to a fine up to 100’000 Swiss Francs. The judge may order the publication of the ruling.”

**Source:** 2002 Patents (Amendments) Act of India and Amendment of the Swiss Patent Law of 22 June 2007, RO 2008 2551

Finally, it should be noted that adding a disclosure of origin requirement in Indonesia’s Patent Law will not have any direct effect on patent applications filed by would-be biopirates in other countries. While this means that the effect of a disclosure of origin requirement may not be to stop all incidence of biopiracy, the disclosure in Indonesia will still make public the information about the genetic resource or traditional knowledge upon which an invention is based. Other jurisdictions may take this into consideration, and may very well look into whether Indonesia had granted a patent or not. The disclosed information may also find its way into databases of genetic resources and related TK worldwide, which will help authorities in other countries make a determination as to the patentability of a claimed invention that is based on such resources.

*Recommendation: Indonesia should include a mandatory disclosure of origin requirement in their patent law for applications utilizing genetic resources and traditional knowledge. The sample texts from India and Switzerland in Section 2.3 should provide some guidance as to appropriate text to be included in Article 24 of the Patent Law. At this point in time, it is not recommended for the DGIPR to be given responsibilities to assess PIC and equitable ABS, though this should be discussed between the DGIPR and the Ministry of the Environment as Indonesia’s competent authority under the CBD. The consequence of a failure to disclose should include suspension of the consideration of the patent as an incomplete*

*application, the non-granting of a patent application, or for patents already granted, the revocation of a patent by the DGIPR. This remedy should be included in the DGIPR's revocation powers under Article 88 of the Patent Act.*

#### **2.4 The Research and Experimentation Exception**

Research and experimentation exceptions are a common form of exception to patent rights worldwide. While the existence of an exception for research and experimentation has not to date been challenged under WTO Dispute Resolution procedures, such an exception has traditionally been recognized by statute and courts to enable scientists and other researchers to use patent disclosure to support the advance of science and technology, and allowing inventors the freedom to experiment to come up with better products or processes. The exception is generally premised on the idea that it is often not in the interest of the holder of a patent to voluntarily allow research that could potentially undermine the economic value of the patented invention. The exception has an impact on the ability of Indonesians to build on scientific research undertaken both at home and abroad, and therefore is relevant to the question of supporting technology transfer.

A research and experimentation exception is provided under Article 16(3) of the current Patent Law. This provision grants an exemption to third parties for the purpose of education, research, experiment or analysis, as long as it does not harm the “normal interest of the Patent holder”. Under commentaries of domestic IP law, the “normal interest of the Patent holder” is construed to mean commercial interest, thereby exempting only research of a non-commercial nature.

A number of developing countries, such as, for example, Kenya and Lebanon, have an exception like Indonesia's that exempts only research and experimentation of a non-commercial nature. In practice, however, it is becoming increasingly difficult to delineate between commercial and non-commercial research and experimentation. A number of factors have blurred the line between research that advances legitimate business (commercial) and research that is purely academic or non-commercial. One factor is the way in which research is conducted, since applied commercial research often relies on basic research done in universities and other research institutions. Other factors include legal developments such as the US Bayh-Dole Act<sup>94</sup> and similar acts in other countries that encourage academia to apply for patents on their research as a means to support the commercialization of innovation.<sup>95</sup>

This blurring has led to a narrowing of the research exception in some of these countries. For example, until recently the research exception in the United Kingdom, developed through common law and implementation of the European Patent Convention, tended to be interpreted quite narrowly.<sup>96</sup> The research exemption did not arise when acts in question are considered in relation to private and non-commercial interests.<sup>97</sup> The recent UK case of *CoreValve Inc v Edwards Lifesciences AG & Anor* appears to have broadened the exception somewhat.<sup>98</sup> In this case, the court ruled that it is when the preponderant

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<sup>94</sup> 35 U.S.C. §200-212.

<sup>95</sup> See, for example, in India, The Protection and Utilization of Publicly Funded Intellectual Property Bill (2008).

<sup>96</sup> *SF&F v Evans* [1989] FSR 513 and *McDonald v. Graham* [1994] RPC 515 (CA).

<sup>97</sup> The Court of Appeal in *SF&F v Evans* interpreted the phrase “relating to the subject matter of the invention” narrowly to mean “in the sense of having a real and direct connection with that subject matter”.

<sup>98</sup> High Court of England and Wales (patent Court), *CoreValve Inc v Edwards Lifesciences AG & Anor* [2009] EWHC 6 (Pat) 9 January 2009.



purpose of the research is to generate revenue, that a claim of infringement cannot be avoided. Research is permitted until the point that the research starts to generate revenues, for example, by selling samples of the product for purposes beyond generating information about the product. In the United States, the 2002 *Madey v. Duke* ruling found that experimental research, using a patented product without the consent of the patent holder, constitutes patent infringement where used to further “the infringer’s legitimate business” interests. This ruling is widely seen as having curtailed the argument that universities, whose charters committed their institutions to pursue a nonprofit objective, enjoyed a wide research exception defense against claims of patent infringement.<sup>99</sup>

In the light of the blurring of what constitutes commercial and non-commercial research, Indonesia may wish to consider whether it wishes to maintain a research and experimentation exception based on this distinction.

In this regard, other countries have generally opted for two alternate approaches to the research and experimentation exception. The first approach is to carve out a wide exception for all research and experimentation. Examples where this approach has been taken include in Brazil, which exempts acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or research<sup>100</sup> and Article 8(1) of the Bangui Agreement establishing the Africa Industrial Property Organization (OAPI), which provides that “the rights deriving from the patent shall not extend . . . to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research.”<sup>101</sup> Absent any further qualification, these texts would provide a safe harbor against infringement for practically all scientific and technological research activities.

The other approach is to try to distinguish between research and experimentation “on” the patented product/process, and research and experimentation “with” the patented product/process. Continental European research exceptions are generally intended to cover only research “on”, but not research “with”, the patented product/process.

In an interesting variation of these two alternate formulations of the exception, Swiss law now exempts research done for both commercial and non-commercial purposes, as long as the objective of the research is to generate new knowledge about the patented invention. The Swiss Patents Act exempts research done “on” the patented product/process while ensuring access to patented research tools (research “with”), through a right to claim a non-exclusive license to use the invention.<sup>102</sup>

If Indonesia seeks to maximize benefits from the increasing numbers of patent applications that have been filed in the country by foreign patent owners, it may wish to provide for a broad research and experimentation exception, much like the ones contained in the Brazilian patent legislation or in the Bangui Agreement. This would provide local researchers with the opportunity to research using a patented product or process to come up with local adaptations and improvements. In many respects, such an exception would make the disclosure in patent applications themselves a form of technology transfer. If universities in Indonesia are being encouraged to take out patents on the fruits of their

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<sup>99</sup> *Madey v. Duke University*, 307 F.3d 1351 (Fed.Cir. 2002), cert. denied 539 U.S. 958, 123 S.Ct. 2639, 156 L.Ed.2d 656 (2003).

<sup>100</sup> Article 43(II) of Brazil’s Law No. 9279/96, as amended.

<sup>101</sup> Article 8(1)(c), Annex I of the Agreement Revising the Bangui Agreement of 2 March 1977, on the Creation of an African Intellectual Property Organization (1999).

<sup>102</sup> See Articles 9 and 40(b) of the Swiss Patents Act, entered into force on 1 July 2008.

research, an accompanying research and experimentation exception would seem like an important companion policy that should be advocated alongside, so as not to stifle innovation.

It is unlikely that exempting research and experimentation broadly would run afoul of the TRIPS Agreement. Article 30 of the TRIPS Agreement requires that the exception does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. It would seem to defeat the purpose of disclosure if a patent owner were free to pick and choose who would be able to conduct research with the patented product or process. Moreover, technology transfer and dissemination is an explicit objective of the TRIPS Agreement, as articulated in its Article 7. It could be argued that the rights of the patent owner are fully protected in so far as if an improvement or adaptation is commercialized, a patent owner could still claim a right over the original technology contained therein. Aside from these arguments, one may take some comfort that the exception has not been challenged to date at the WTO.

*Recommendation: Indonesia may wish to expand the research exception to cover all research and experimentation in connection with scientific or technological studies, and eliminate any distinction between commercial and non-commercial research. The text of a revised Article 16(3) would read:*

*“Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said Patent is for the sake of education, research, experiments and analysis in connection with scientific or technological studies.”*

## **2.5 Simple Patents**

Utility models may be a good way of encouraging incremental innovation. Utility models are often used to protect inventions that do not meet the strict “inventive step” test under patent law, but that nevertheless contribute a new and useful product or process to society. The current Indonesian Patent Law provides for the granting of a utility model, i.e., the so-called “simple patent”, in Chapter VIII, and follows this pattern. Simple patents are available for ten (10) years from the date of filing.

Detailed provisions for the granting of simple patents are set out in separate government regulations (Article 108) and are, in principle, outside the scope of this study. There are, however, a number of provisions within the Patent Law that govern simple patents which have an impact on local innovative capacities and technology transfer. In particular, Article 105(5) requires that both the novelty standard and the industrial applicability standard for patents apply to simple patents as well.

It should be borne in mind that utility model systems are thought to act as an incentive for inventors whose predominant inventions are incremental or adaptive, and are generally seen as one means to provide inventors in developing countries with a financial reward for incremental innovation. In Indonesia, in fact, an application for a simple patent accounted for 6% of total filings in 2009, and the 6% figure breaks down to local

applicants 5% and foreign applicants only 1 %.<sup>103</sup> The goal, for a domestic innovation standpoint, would be to encourage the greater use of simple patents by local inventors by giving them a limited commercial right that is tailored to the type of innovation in which they engage, and which in turn would give local innovators a tool in negotiating with potential partners for technologies that will enable them to move up the value chain. In this regard, utility models are not covered under the TRIPS Agreement, allowing signatory countries a wide degree of flexibility in the shaping of an appropriate utility model regime. The system of simple patents can therefore be tailored to encourage local inventors to make better use of the Patent Law, and to compensate them for the effort they have put into their innovations.

The novelty standard under Article 3 of the Patent Law is a global one, which is met if there has been no prior technological disclosure either in or outside Indonesia. The alternative to a global novelty standard is a relative one, where novelty means that the invention in question is new to the country in question. It is questionable whether many domestic small-scale inventors, who are expected to benefit most from utility model protection, can meet a strict standard of novelty.<sup>104</sup>

The same could be said about the standard for industrial applicability (Article 5). Using the same industrial applicability standard for patentable inventions with simple patents may defeat the purpose of having a utility model system if the bar for industrial applicability is set too high. According to Article 5 of the Patent Law, an invention is considered as susceptible of industrial application if it can be implemented in industry as described in the patent application.

That having been said, it is also questionable whether it would make sense to set patentability standards too low either. Indonesia has firms in a number of industries in which inventors could meet a global novelty standard when applying for simple patents and the argument could be made that the IP system should try to encourage these firms to innovate and seek to obtain rewards for the fruits of their innovation. Furthermore, in a world where patent searches can be done on the Internet, tying novelty to prior technological disclosure only in Indonesia may result in some foreign technologies becoming subject to exclusive rights when they might otherwise fall in the public domain.

As Indonesia, like Malaysia<sup>105</sup>, has dispensed with the inventive step requirement for simple patents, the only other possible area where patentability criteria could be relaxed to accommodate the system of simple patents is industrial applicability. In this regard, the United States, for example, has adopted a broad standard of utility as the third criteria for utility model protection, instead of industrial applicability. There are different standards of ‘utility’ enunciated by various courts in the US, but at its broadest interpretation, utility simply means that the invention is not “frivolous, injurious to the well-being, good policy or sound morals of the society”.<sup>106</sup> A broad utility standard for simple patents in Indonesia would make it relatively easier for applicants to obtain the rewards for their inventions, provided such criteria were met.

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<sup>103</sup> DGIPR Annual Report 2009, p. 12.

<sup>104</sup> See Suthersanen, U. 2006. *Utility Models and Innovation in Developing Countries*. Issue Paper 13, UNCTAD-ICTSD Project on IPRs and Sustainable Development.

<sup>105</sup> *Ibid.*, p. 21.

<sup>106</sup> See *Lowell v. Davis 15 F. Cas. 1018 (D. Mass 1817) at q019*.

As utility models are not governed under the TRIPS Agreement, countries are free to set the standards for their granting without restrictions, provided they have not signed any other treaties to the contrary. Indonesia may wish to consider whether a broader standard of utility may make more sense for simple patents than the same criteria of industrial applicability as is currently applied for patents.

*Recommendation: Indonesia should consider whether it is appropriate to remove industrial applicability and establish a separate standard for utility for the grant of simple patents. If so, Article 105(5) should be amended to read that standards for novelty and utility for simple patents shall be defined by Government Regulation, and the rules concerning simple patents should be amended accordingly.*

Under Article 107 of the Patent Law, it is not possible to issue a compulsory license on a simple patent (but it appears possible to issue a government use license on a simple patent, by virtue of Article 104). The rationale for the issuance of a compulsory license, however, remains the same regardless of whether the technology involved is a patent or a simple patent/utility model. As currently formulated, Part Three of the Patent Law provides that compulsory licenses may be granted for non-working of the patent in Indonesia and in the public interest. There would appear no reason to tie up technologies that are not worked in Indonesia, irrespective of whether they are protected for twenty (20) or ten (10) years from the date of filing. This would seem to be unsupportive of technology transfer.

*Recommendation: There is no reason why a compulsory license should not be available for simple patents. Article 107, which excludes the possibility to issue a compulsory license for a simple patent, should be removed.*

An additional recommendation on simple patents is contained in section 1.2 of this advisory report concerning the new uses of known substances, and is not repeated here.

## **Chapter 3 – Patent Law and Competition**

The set of policies that deal with competition at the national level can generally be divided into two categories: first, antimonopoly laws and regulations; and second, unfair competition prevention laws and regulations. The former is concerned with the question of abuse of dominant market power while the latter addresses unfair trade practices. The relationship of intellectual property rights (including patents) to these respective sets of laws differs. Antimonopoly laws interface with patent law when the exclusive rights granted through a patent are exercised in a manner that constitutes an abuse of market power, usually through demonstrating first that the underlying patent confers a dominant market position to its holder, and then showing how that market power was exercised in an abusive manner. In this way, competition law can act as a check on the abuse of IPRs. Unfair competition laws, according to Article 10*bis* of the Paris Convention, exist to prevent certain commercial practices that mislead the public as to the nature of a competitor's product. This also encompasses the protection of pharmaceutical test data.

Apart from the two legal concepts above associated with the term “competition”, this term can also be understood to include competition from a broader socio-economic perspective. In this regard, competition is important when it comes to the question of how patent law can facilitate, for example, the timely entry of generic competition into the marketplace for medicaments.

The following sections first examine Indonesia's framework for competition, and then analyzes areas of the Indonesian Patent Law that have an impact on competition, from both the two legal perspectives and the broader socio-economic perspective, and suggests areas where the Government of Indonesia may wish to consider amending the current legislation.

### ***3.1 Indonesia's Framework for Competition***

Indonesia's competition policies are set by the Commission for the Supervision of Business Competition (KPPU). The Commission is guided by the Law Concerning Prohibition of Monopolistic Practices and Unfair Business Competition (Law Number 5 of 1999). KPPU is a state commission which has the authority to, *inter alia*, conduct investigations on any party alleged to have violated the Law, to make determinations based on those investigation and issue directives to remedy the situation according to their findings. Indonesian Law No. 5/1999 is structured so that both antimonopoly issues and unfair competition issues are addressed in the same piece of legislation.

The mandate of the competition authority is, however, limited. Article 50(b) of the Law excludes the consideration of cases arising from “agreements related to intellectual property rights, such as licenses, patents, trademarks, copyright, industrial product design, integrated electronic circuits, and trade secrets as well as agreements related to franchise”. No case based on abuse of IP rights has therefore been investigated by the KPPU to date, whether based on an antimonopoly claim or on an unfair competition claim.

### ***3.2 Competition Remedies in the Patent Law***

Article 31 of the TRIPS Agreement provides for use of the subject matter of a patent without the authorization of the right holder (i.e., a compulsory or government use license) as a remedy for certain anti-competitive behavior. Specifically, Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) of Article 31 (those dealing with prior negotiations, notice and limiting the license to predominant supply of the domestic market) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

A number of countries have used a compulsory license as a means to remedy anti-competitive acts. The two examples of Italy and South Africa, which are both cases in the pharmaceutical sector, are presented below. For the reasons stated in section 3.1 above, there does not appear to be any competition law cases to date that have invoked a compulsory license as a remedy in Indonesia.

**Italy.** In March 2007, the Italian Competition Authority (ICA) came out with its decision finalizing an earlier ICA *ad interim* order for multinational pharmaceutical company Merck to grant a license to an Italian pharmaceutical manufacturer, Dobfar, to produce an active ingredient for antibiotics used in the treatment of certain infectious diseases.<sup>107</sup> Merck held the patent on Imipenem/Cilastatina, which had expired in most countries but was still protected in Italy under an extension certificate that effectively prolonged the life of the patent beyond the patent term. In 2002, Dobfar, with the assistance of the Italian Ministry of Industry as mediators, unsuccessfully sought a voluntary license from Merck for manufacturing the product in question.<sup>108</sup> Dobfar had requested the license to manufacture Imipenem/Cialstatina for export to generic manufacturers of antibiotics elsewhere in the EU. As required under Italian law, the case was sent to the ICA for consideration upon failure of the Ministry-mediated negotiations.

When considering *ad interim* measures, the ICA applying EU law (i.e. Article 82 of the Treaty establishing the European Economic Community), analyzed the question of whether Merck was dominant in the relevant market. Here, it considered the fact that Imipenem/Cialstatina was an active ingredient needed for the production of certain antibiotics, rather than on just the market for the ingredient itself, and concluded that Merck was indeed dominant in numerous national markets of EU countries. Once the ICA had established Merck as dominant, it considered the question of whether Merck abused its dominant position by refusing to issue Dobfar a voluntary license to manufacture the active ingredient for export to non-EU generic manufacturers of antibiotics. The ICA then provided an analysis of why Merck's refusal should be considered abusive, including the following aspects:

- 1) The active ingredient is essential for the production of generics by Merck's competitors, and Dobfar is an indispensable supplier for the competitors; by refusing to license to Dobfar, Merck was impeding competition in national markets where the active ingredient was no longer protected (either by patent or extension certificate).

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<sup>107</sup> Provvedimento 16597. A364 Merck - Principi Attivi in Boll. 11/2007, available at <http://www.agcm.it>.

<sup>108</sup> The mediation procedure is provided for under Italian law (Law 112/2002 and Ministerial Decree of 17 October 2002).

2) There was an unjustified refusal to license by Merck, in order to exclude competition by generics using the essential facility; and

3) “The refusal to deal by Merck has been used not to preserve the economic exploitation of the IP right, but to maintain, in fact, the exclusive rights on the active ingredient in countries in which the undertaking no longer has any exclusive right of exploitation.”<sup>109</sup> This was so because Dobfar had no real possibility of delocalizing production abroad, where the patent had already expired.

While it is not entirely clear whether the decision relies more on a variation of the “essential facilities doctrine”<sup>110</sup> or a “refusal to deal” analysis in determining abuse by Merck, some academics note that this decision is noteworthy because the ICA made its decision taking into consideration a refusal affecting markets outside the territory of exclusivity (Italy).<sup>111</sup> Favorable consideration was given to the fact that there was a need to protect competition by potential manufacturers in export markets where there was no IP protection over the active ingredient, which was considered to be an essential facility, and particularly those markets of other EU countries where Imipenem/Cialstatina was already off-patent.

It should be noted that the ICA intervened on the question of abuse only after the failure of an agreement to voluntarily license, as prescribed by Italian law, and only after dominance had been established. The *Merck* case is, however, unique in that it involved EU issues, and could also be seen as testing the level of protection conferred by an Italian extension certificate, which extends the period of exclusivity beyond the term of the patent.<sup>112</sup> In any event, it appears that the ICA took pains to ensure that their decision was consistent with existing EU antitrust cases<sup>113</sup> and relevant competition laws, without being seen as overreaching.

**South Africa.** Perhaps the world’s best known case involving the interface between pharmaceutical patents and competition law is *Hazel Tau and others v. Glaxosmithkline, et. al.*, a case that was heard before the South African Competition Commission.<sup>114</sup> In this case, an HIV-positive woman, along with several other HIV-positive complainants, local health care providers and NGOs,

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<sup>109</sup> English translation of par. 137 of decision Provimento 14388 A364, As contained in Coco, R. and Nebbia, P., 2007, “Compulsory licensing and interim measures in Merck: a case for Italy or for antitrust law?”, *Journal of Intellectual Property Law & Practice*, 2(7): 454.

<sup>110</sup> The essential facilities doctrine originates from US antitrust case law, and has been applied in many countries. The essential facilities doctrine has put a limit to the former general rule, that a firm has no obligation to deal with its competitors. There are strict requirements to the doctrine, i.e. an abuse is likely, if the following apply: 1) control of the essential facility by a monopolist; 2) competitors’ reasonable inability to duplicate the essential facility; 3) a refusal to grant the use of the facility to the competitor; and 4) the feasibility of providing the facility in the absence of any justifications for denying access. *United States v. Terminal Railroad Association*. [1912] 224 US 383. See also the analysis in Chapter 3 for how the essential facilities doctrine is applied in the area of copyright.

<sup>111</sup> Coco and Nebbia, p. 455.

<sup>112</sup> *Ibid.*

<sup>113</sup> The ICA distinguished existing ECJ precedents on the interface between IP and competition on the grounds that the refusal affected markets outside the zone of exclusivity. These precedents appear to require, inter alia, that the refusal to license the product in question impedes the appearance of a new product for which potential demand exists. See C-241 and 242/91 *Radio Telefis Eireann & others v. Commission* [1995] ECR I 743; C-148/01 *IMS Health GmbH v. NDC Health GmbH* [2004] ECR I 5039, among others. ECJ case law confirms, however, that when considering the relationship between IP and competition, the essential function and the specific subject matter of the IP rights at issue must be considered. See 15/74 *Centrafarm BV v. Sterling Drug Inc.* [1974] ECR 1147.

<sup>114</sup> *Hazel Tau & Others v. GlaxoSmithKline and Boehringer Ingelheim*, Competition Commission of South Africa (2002). The text of the opinion of the Commission is not publicly available.

filed an action with the Competition Commission in 2002 alleging that the global pharmaceutical firms of Glaxosmithkline (GSK) and Boehringer Ingelheim (BI), and their related subsidiaries, violated section 8(a) of the South African Competition Act<sup>115</sup>, engaging in excessive pricing of five ARVs used in the treatment of HIV/AIDS, on which these firms held patents. The complaint was filed after these two firms rejected requests by South African generic manufacturers for licences to produce these ARVs. The complainants plead that these firms were dominant, as contemplated by section 7 of the Competition Act, and that they reached the threshold of the required annual turnover in section 6 of the Competition Act. In fall 2003, the Competition Commission issued three preliminary findings: first, that the defendants denied a competitor access to an essential facility; second, that the defendants engaged in excessive pricing; and finally, that the defendants engaged in an exclusionary act that had an anti-competitive effect that outweighs technological, efficiency or other pro-competitive gain.<sup>116</sup>

In examining the case, the Competition Commission accepted the argument made by the complainants that in general, ARVs cannot be considered substitutable for each other, and that the defendants were dominant within the meaning of section 7 of the Competition Act. The complainants argued that the treatment regime is sequenced, involving the commencement of three ARVs simultaneously, with alternative ARVs being prescribed in the event of treatment failure and side effects. The complaint then continued:

“[e]ach ARV constitutes its own market both in respect of manufacturers and marketers. Coupled with patent protection, the relevant international respondent companies (as manufacturers and suppliers to South Africa) are dominant in respect of the South African market for each particular ARV that is the subject of this complaint. In this case, therefore, dominance exists regardless of each firm’s share of the market for a particular therapeutic class of ARVs.”<sup>117</sup>

The complainants further developed an alternate line of establishing dominance, citing sales of the therapeutic class of ARVs, indicating that both firms named in the action had sales of nucleoside analogue reverse transcriptase inhibitors (NRTIs, i.e., the class of medicines to which the five ARVs belonged) that exceeded the annual turnover requirements under section 6 of the Competition Act. Having agreed with the complainants that GSK and BI were dominant in the South African market, either for these five ARVs or for the therapeutic class to which they belong, the Competition Commission concluded that these ARVs were “essential facilities”, without which it would be impossible, *inter alia*, to manufacture fixed dose combinations in South Africa.

Excessive pricing was established by the complainants using comparative charts, which showed the price charged and the estimated economic value of the formulations in question, with one column showing the price charged by the companies for the patented product, the price of the WHO pre-qualified generic alternative and the estimated economic value of the formulation. These charts were

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<sup>115</sup> The Competition Act of South Africa, Law No. 89 (1998).

<sup>116</sup> Media release from the South Africa Competition Commission, dated 13 October 2003.

<sup>117</sup> Petitioners’ complaint (2002), para. 56.



then used to argue that the prices charged by the two firms were “grossly disproportionate to the economic value of the goods even when taking into account the cost of production, research and development (R&D) costs and an appropriate rate of profit.”<sup>118</sup> It should be noted that such cost-comparisons are, in many jurisdictions, critical for establishing excessive pricing in competition cases.

The Commission then concluded that the act of refusing to license amounted to a prohibited exclusionary act. According to the Commissioner of the Competition Commission, “promoting development, providing consumers with competitive prices and product choices, advancing social and economic welfare and correcting structural imbalances – have been made difficult in this context by the refusal of the respondents to license patents.”<sup>119</sup>

Both these cases point to the fact that the compulsory license remains an important remedy for anti-competitive behavior even though it is not always a simple matter to substantiate a claim of anti-competitive behavior to the standards required under competition law. In this regard, perhaps one of the most important points from an analysis of the South African case, is that a finding of violation of the South African Competition Act by the Competition Commission, without progressing to further hearings on administrative penalties or on the issuing of compulsory licenses, paved the way for settlement agreements with both GSK and BI<sup>120</sup>, resulting in licenses at lower cost of the subject ARVs to a South African generic manufacturer.<sup>121</sup> There appears to be a preference by pharmaceutical patent holders to agree to private licenses with generic manufacturers over the potential issuance of a compulsory/government-use license even at a significant discount.

The provisions for compulsory license and government-use licenses are set out in the current Indonesian Patent Law respectively in Articles 74 to 87 and Articles 99 to 103 (see also section 1.7 of this report). The substantive grounds for the granting of a compulsory license is non-working or insufficient working (Article 75(2)), or if “the relevant Patent has been implemented by the Patent Holder or the licensee in a form and manner that contravenes the public interest” (Article 75(3)). The substantive grounds for the grant of a government use license appear in Article 99:

“If the Government is of the opinion that a Patent in Indonesia is very important for the conduct of defence and security of the State and for an urgent need for the sake of public interest, the Government may itself exploit the relevant Patent.”

Government regulations may be promulgated to stipulate additional conditions and procedural requirements for compulsory and government use licenses.

The references to public interest in these articles are quite broad, and may indeed be wide enough to encompass certain competition concerns. However, the TRIPS language allows for the possibility not to comply with procedural requirements that are otherwise applicable in the face of a determination by the competition authority of anti-competitive

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<sup>118</sup> *Ibid.*, para. 62.

<sup>119</sup> Media release from the South Africa Competition Commission, dated 13 October 2003.

<sup>120</sup> See <http://www.wcl.american.edu/pijip/competitionpolicyproject.cfm>.

<sup>121</sup> The AIDS Law Project in South Africa estimates that prices for the subject ARVs were reduced under the settlement agreements by as much as between 58.3 % (for nevirapine) and 93.9 % (for lamivudine) of the price of the patented product at the time the complaint was lodged.

behaviour by a patent holder, namely the requirements to have had prior negotiations, notice and limiting the compulsory license to predominant supply of the domestic market. The remuneration rate of such a compulsory license can also take into account the anti-competitive behaviour. The current law therefore does not fully take advantage of these flexibilities.

Full use of these flexibilities require a determination of anti-competitive behaviour, and this determination is usually made, as can be seen in the cases of Italy and South Africa, by the country's competition authority. A major barrier in Indonesia to the use of compulsory licenses to remedy anti-competitive behaviour is, however, that Article 50(b) of the Competition Law excludes the consideration by the competition authority of cases arising from "agreements related to intellectual property rights, such as licenses, patents, trademarks, copyright, industrial product design, integrated electronic circuits, and trade secrets as well as agreements related to franchise". Field interviews with the Commission for the Supervision of Business Competition confirm that the competition authority does not at present get involved with any cases involving intellectual property rights,<sup>122</sup> thereby excluding the possibility of hearing cases regarding the abuse of exclusive rights granted through intellectual property rights under licensing agreements.

While the main purpose of this advisory study is to suggest amendments to the Patent Law, such amendments would have no effect on the ability to use compulsory licenses or government-use licenses as a remedy for anti-competitive behaviour in the absence of a commensurate change in the Competition Law. It is suggested here as cooperation in this area between the DGIPR and the Commission for the Supervision of Business Competition will be an important pre-requisite to any effective implementation of all of the recommendations in this Chapter.

*Recommendation: The DGIPR should enter into discussions with the Commission for the Supervision of Business Competition to discuss a possible amendment to the Competition Law, namely the removal of Article 50(b). This would open up the possibility for the Commission to hear cases related to, for example, excessive pricing or refusals to license based on a dominant position in the market and anti-competitive terms and conditions of contractual licensing agreements. A compulsory or a government-use license could be issued by the DGIPR in cases where the Commission finds abuse.*

*Recommendation: Provided that the DGIPR can secure a revision of Article 50 of the Competition Law, a subparagraph (4) should be introduced in Article 75 of the Patent Law that tracks the language of Article 31(k) of the TRIPS Agreement. A subparagraph should be introduced in Article 99 along similar lines, which would allow the possibility of issuing a government-use license upon a finding of anti-competitive behaviour.*

### **3.3 Licensing and Competition**

Article 71(1) the Patent Law states that a "licensing agreement shall not contain any provisions that may directly or indirectly damage the Indonesian economy, or to contain restrictions which obstruct the ability of the Indonesian people to master and develop

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<sup>122</sup> Interview with the Commission for the Supervision of Business Competition, 11 November 2010.

technology in general and in connection with the Patented Invention in particular.” The enforcement mechanism for this provision is set out in the sub-paragraph that follows, which states that the Directorate General shall refuse any request for registration of a licensing agreement containing provisions as referred to in Article 71(1). The effect of a refusal to register is that the licensing agreement cannot be enforced against third parties, but does not affect the relationship between the licensor and the licensee.

Unlike a number of other countries, licensing contracts are evaluated under the Patent Law by the DGIPR, as opposed to the national competition authority. This is mostly due to a strict separation of powers between the DGIPR and the Commission for the Supervision of Business Competition, which is entrusted with the implementation of the Law Concerning the Prohibition of Monopolistic Practices and Unfair Business Competition. Article 50(b) of the Competition Law stipulates that IP issues are excluded from the scope of the Competition Law.

The text of Article 71(1) of the Patent Law is certainly broad enough to encompass some of the practices that are enumerated under the TRIPS Agreement that may constitute an abusive licensing practice, including, for example, grantback clauses, coercive package requirements and conditions preventing challenges to the validity of a patent. The problem with the current approach, however, is that the DGIPR is put in the position of having to assess the competition effects of certain licensing agreements.

Article 40.2 of the TRIPS Agreement leaves Members the possibility to frame their own measures to remedy the types of practices referred to above. 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). There is nothing in the TRIPS Agreement that prevents the DGIPR from making determinations on whether or not a licensing contract is abusive. But, Article 40.2 by referring to "particular cases" makes clear that the control of IP licensing should be done on a case-by-case basis. This means that not all grantback clauses, coercive package requirements and conditions preventing challenges to patent validity would automatically be considered abusive. The examination of whether these clauses are abusive from a competition standpoint should take place "in reasonably detailed circumstantial form and by reference to their actual impact on the conditions of competition existing in the markets concerned".<sup>123</sup> An IP office is usually not staffed to be able to undertake this kind of analysis.

There are several possible ways that Indonesia may wish to address this problem. The first would be to make the competition authority the arbiter of whether a licensing agreement provision is abusive from the point of view of competition law. The advantage to such an approach would be to have competition experts assess the market impact of any particular provision, in strict compliance with the letter of Article 40.2 of the TRIPS Agreement. The potential drawback of this approach is that it is not always that easy to establish a case under competition law. It could very well be that certain cases where, for example, a licensing contract provision discourages competition, innovation and technology transfer may not rise to the level of a competition law violation, since competition law exists primarily as a check on the exercise of market power.

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<sup>123</sup> UNCTAD-ICTSD Resource Book, p. 559.

A second approach would be for Indonesia to establish a set of rules of certain licensing practices that are *per se* abusive, subject to certain exceptions. An example of a permissible practice is Article 4 of the EU Commission's Regulation on Technology Transfer Agreements, which specifies certain restrictions in licensing agreements that shall be considered prohibited *per se*, but at the same time lists all the exceptions from this prohibition.<sup>124</sup> It is recommended that in such a case, the list and the exceptions be formulated through consultations between the DGIPR and the Commission for the Supervision of Business Competition.

A third approach would be to separate out licensing rules that deal with competition concerns and those that deal with innovation and technology transfer, where the competition authority is empowered to assess provisions in licensing contracts that may constitute abuse of IPRs from a competition perspective, while the DGIPR will assess provisions in licensing contracts that are potentially harmful to innovation and technology transfer.

In this regard, Article 8.2 of the TRIPS Agreement 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**" (emphases added).

It should be noted that Article 8.2 refers to practices adversely affecting the international transfer of technology. Technology transfer is one of the expressly stated objectives of IPR protection and its enforcement (Article 7, TRIPS Agreement). 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>125</sup>

Given that the DGIPR may not have the capacity to undertake an analysis of competition effects of licensing agreements, this report recommends either the second or third approaches noted above. Either way, and also in line with the recommendation concerning the issuance of compulsory and government-use licenses as a remedy for anti-competitive behaviour, the restriction in Article 50(b) of the Competition Law that prevents the Commission for the Supervision of Business Competition from examining intellectual property issues should be removed. The enabling clause in the Patent Law appears to be broad enough to permit the elaboration of appropriate guidelines on prohibited licensing practices and applicable exceptions.

*Recommendation: As in the recommendation regarding remedies for anti-competitive behaviour, the DGIPR and the Commission for the Supervision of Business Competition should discuss the removal of the restriction in Article 50(b) of the Competition Law preventing the national competition authority from determining abusive licensing practices involving IP. This would pave the way for*

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<sup>124</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>125</sup> See Berger, p. 184.

*discussion between these bodies on a set of guidelines on prohibited licensing practices, and any possible exceptions. The DGIPR and the Commission may wish to issue separate guidelines for competition and technology transfer issues or they may wish to combine all licensing guidelines into one document.*

### **3.4 Working Requirements**

Up to this point, this chapter has focused on the use of the substantive body of competition law as a means to check abuses on the exercise of IPRs. The central question in these cases has been whether there has been a violation of competition law. The following sections look at competition in a different context – i.e., the use of certain patent law flexibilities permitted under the TRIPS Agreement to ensure greater competition generally, without reference to violations of competition law.

Working requirements require a patent to be exploited in the country in which the patent is granted, for which the failure to do so results in some type of penalty under the relevant patent law. The rationale for a local working requirement is to deter patent holders from simply holding a patent to block would-be competitors, and to ensure that the technology for which a patent has been granted in a country is diffused into that country. In that regard, working requirements are as much an instrument to further technology transfer as it is an instrument to ensure that competition policies and IP policies are mutually supportive.

One feature of the Indonesian Patent Law is the extensive use of working requirements. Article 17(1) stipulates that “a Patent holder shall be obliged to make products or to use the process that has been granted a Patent in Indonesia”. Not working the patent in Indonesia for 36 months from the date the patent has been issued opens up the patent holder to the possibility that a third party may file for a compulsory license in respect of the invention. In fact, the only substantive grounds for a third party to request the issuance of a compulsory license by the DGIPR under the Patent Law is that “the relevant Patent has not been implemented or only partially implemented by the Patent holder” (Article 75(2)). Additionally, the right to prevent importation of products made by patented processes is only available if the process patent has been exploited in Indonesia (Article 19).

The working requirement is relatively controversial in international IP law. 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 locally, rather than import<sup>126</sup>). Arguably, because the TRIPS Agreement incorporates the substantive provisions of the Paris Convention, working requirements for compulsory licenses would appear to be permitted under the former. The question, however, is whether the non-discrimination requirement under Article 27.1 of the TRIPS Agreement was intended to supersede the authorization of local working requirements under Article 5A(2) of the Paris Convention.<sup>127</sup> This is not entirely clear, as the negotiating history of

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<sup>126</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>127</sup> See UNCTAD-ICTSD Resource Book, p. 482.

the TRIPS Agreement indicates that countries participating in the Uruguay Round negotiations did not agree on whether the non-discrimination requirement was paramount.<sup>128</sup>

By contrast, the history of patent law reveals that patents were traditionally viewed by its proponents as a vehicle to promote a country's domestic industries.<sup>129</sup> With respect to developing countries, the interpretation of Article 27.1 of the TRIPS Agreement to exclude a local working requirement through the non-discrimination clause has been criticized in the literature as reversing the patent objective, resulting in the protection of foreign assets at the cost of domestic technological development.<sup>130</sup> As mentioned above, Article 2.1 of the 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 IP abuse (the broad notion of sitting on a patent to block competition, without diffusing the benefit of the technology to the society which granted the exclusive right), which in turn may be addressed through appropriate measures under Article 8.2 of the TRIPS Agreement.<sup>131</sup> For this reason, under the TRIPS Agreement, a compulsory license can be issued only on a case-by-case basis and after unsuccessful negotiation for voluntary license, except where the non-working of the patent is deemed anti-competitive.

There has to date been no case at the WTO on this issue. The United States had initially launched a case against Brazil for legislation that permitted the granting of compulsory licenses and parallel imports when the underlying patent in Brazil was not locally worked.<sup>132</sup> Later that year, the US withdrew their case. It should also be noted that, in addition to a number of other countries, Egypt also has a mandatory local working requirement in their Law Pertaining to the Protection of Intellectual Property Rights.<sup>133</sup>

A discussion on working requirements and compulsory licenses is already contained in the earlier chapter on compulsory licenses and access to medicines. It suffices to say here that in the more general context, there is no overarching policy statement such as the Doha Declaration on Public Health to rely on in the event that Indonesia is challenged under WTO Dispute Settlement for having a general working requirement as grounds for granting a compulsory license in its Patent Law. By no means does this imply, though, that compulsory licenses can only be issued on grounds of public health. A number of countries invoke compulsory licenses on a wide variety of grounds, such as national security and to preserve the general public order. While the position of this report is that working requirements tied to compulsory licenses are indeed within the ambit of flexibilities that are defensible given the TRIPS negotiating history and the ambiguity of the final TRIPS text, the lack of an affirmative political statement such as the Doha Declaration makes a working requirement, outside the area of medicines, slightly more ambiguous.

There is currently little literature available concerning a requirement wherein the holder of a process patent in the country would have a cause of action against the importation of

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<sup>128</sup> *Ibid*, pp. 464-465.

<sup>129</sup> See Halewood, M., "Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law", *Osgoode Hall Law Journal*, Vol. 35, No. 2, 1997, p. 260.

<sup>130</sup> Halewood, *ibid*.

<sup>131</sup> *Ibid*, p. 257.

<sup>132</sup> See Brazil - Measures Affecting Patent Protection, Request for the Establishment of a Panel by the United States, 9 January 2001, WT/DS/199/3.

<sup>133</sup> See Article 23, Law No. 82 of 2002.

products made using that process only if that process had been worked domestically. As shown above, most of the existing literature concerns compulsory licenses and working requirements. The same analysis, both in terms of rationale and risks, on the non-discrimination clause in Article 27.1 of the TRIPS Agreement in relation to compulsory licenses and working requirements, would appear to be equally applicable to a requirement to have locally worked a process patent in order to have a cause of action against an importer of a product made through that patented process. As noted above, the negotiating history is inconclusive as to whether the non-discrimination requirement in Article 27.1 can be construed to prohibit a local working requirement, and for countries that adopt such a working requirement, to specify consequences be they compulsory licenses or losing a cause of action against importers. As noted above, the risk is that there has been no WTO precedent on this issue, as is the case with compulsory licenses, working requirements and non-discrimination.

From a drafting perspective, Indonesia may wish to specify a date by which a patent must be worked or subject to the loss of the right to prevent importation of products made using a process patent. Such a date is already specified for compulsory licenses: Article 75(1) of the Patent Law stipulates that any party, after the expiration of a period of 36 months commencing from the date of grant of a patent, may file a request for a compulsory license with the DGIPR. Including a time period in the Patent Law would help shield the DGIPR from accusations of arbitrariness in importation cases.

A potential alternative way of introducing time limits by which a patent ought to be worked is to introduce such time limits by patent category in regulations, rather than a uniform working requirement. Such an approach may be risky, however, since Article 27.1 of the TRIPS Agreement requires Members to ensure that patents are “enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” There may be a case, though, if a uniform period to work a patent is established, but a longer working requirement is made available exceptionally in view of the characteristics of the field of technology involved (it may take, for instance, longer to obtain regulatory approval in certain fields of technology). In any event, there would appear to be nothing to limit the ability of Indonesia to adopt different periods of time to invoke the right to petition for a compulsory license and the right to prevent imports of products made from patented processes, so long as they are *prima facie* applicable across all fields of technology without distinction as to whether they are imports or domestically produced.

*Recommendation: The local working requirement in the Patent Law can likely be maintained on the grounds that the TRIPS negotiators have left this issue ambiguous. Where the Patent Law does not already specify a time limit, such as in the case of the right to prevent imports of products that are made using patented processes, consideration should be given to introducing a time element whereby a patent holder would be given a sufficient amount of time to begin working the underlying patent or expose him/herself to the loss of rights. While there is no reason why different time periods in which a patent holder needs to work his or her patent could be adopted before s/he risks a compulsory license or a right to import a product that is made using a process-patent, such time periods should generally be uniform across patent categories.*

### **3.5 Pre-Grant and Post-Grant Opposition Procedures**

Opposition procedures exist as a check to ensure that only patents that truly meet the three criteria of novelty, inventive step and industrial application obtain the right to exclude others. Wrongly granted patents provide exclusive rights over inventions that should be made freely available (i.e., in the public domain) to all competitors, or potentially denies a bona fide owner of technology of a patent.

Pre-grant observation/opposition refers to the practice of providing 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. In post-grant opposition, a third party may file an opposition with the patent office *after* a patent has been granted with the purpose of providing evidence that the patent was mistakenly issued and requesting its cancellation. Through these procedures, IP offices can help to ensure that only *bona fide* patents are awarded exclusive rights, leaving descriptions of inventions that do not meet the criteria for patentability in the public domain for competitors to use as they see fit.

Pre-grant and post-grant opposition procedures are not mutually exclusive – a patent law may contain one or the other, or both. The latter (i.e., both) is the case with the Indonesian Patent Law. Under the current Indonesian Patent Law, pre-grant observation/opposition procedures are set out in Article 45. Any person may file in writing his or her comments or observations with the DGIPR during the six (6) months for which the patent application is announced. The applicant has the right of response to the comment and/or objection, but the ultimate arbiter of the patent application remains the DGIPR, which is responsible for the substantive examination of the application. Post-grant opposition procedures are also set out in the Patent Law. Article 91 permits a cause of action for revocation where the relevant patent should not have been granted. This cause of action takes place at the Commercial Court, rather than at the DGIPR, under Article 91(2). The grounds for post-grant opposition appear to be similar to that for pre-grant observation/opposition, in so far that the main argument would be to explain why the patent should not have been granted (i.e., that patentability criteria have not been met).

It can be presumed that the difference in pre-grant and post-grant procedures reflects two things: first, a preference that patent rights are not mistakenly granted in the first place (hence a policy whereby comments are collected and by the DGIPR and taken into consideration as appropriate in assessing the merits of a patent application); and second, a hierarchy where granted rights should be subject to a judicial, rather than an administrative, procedure (as well as an intent to ensure that there is no conflict of interest or institutional bias).

There is nothing inherently problematic about such a rationale for this distinction. It should be noted that the TRIPS Agreement provides no particular restrictions on the establishment of procedures for patent opposition, be it pre-grant or post-grant. If Indonesia also wanted, for instance, to have the DGIPR adjudicate post-grant opposition claims in an administrative proceeding, it is free to do so, although having an outside institution such as a court act as a check on whether DGIPR made a correct decision to grant a patent is not necessarily a bad idea.



That having been said, from a policy making perspective, the DGIPR should first assess the extent to which mistakenly granted patents are a serious problem in Indonesia. If it is indeed found to be a problem, then it can consider various policy options, including extending the time for pre-grant announcement so pre-grant review can take place for a longer period of time, greater outreach to local inventors so that they are aware of the pending patent applications.

*Recommendation: Opposition systems that allow for patents to be challenged either before or after a patent has been granted, are important checks on the issuance of bad quality patents. No change in the pre-grant and post-grant opposition systems in the Patent Law should be made until the DGIPR has assessed the extent to which mistakenly granted patents are a problem in Indonesia.*



## **Conclusion**

Patents are a valuable tool, but simply increasing the ease of patentability will not necessarily support the unique development objectives of Indonesia. In this regard, one need only look to the current status of patents applied for and granted in the country: foreign patents still outnumber those taken out by domestic stakeholders. The TRIPS Agreement, to which Indonesia is a party, leaves countries a great deal of 'policy space' to frame patent legislation in a way that is supportive of development objectives. For this reason, UNCTAD provides advisory services to governments who seek an independent analysis of how intellectual property legislation can be better tailored to meet specific development objectives, in accordance with its mandate under the Accra Accord, paragraph 153.

Conformity with the provisions of the TRIPS Agreement seems to have been a major concern when the 2001 Patent Law was drafted in Indonesia. While the current law is certainly TRIPS compliant, it does not always take full advantage of the flexibility in drafting individual national patent laws that is afforded to WTO Members. This DDIP report makes suggestions as to how these flexibilities can be taken on board into an amended Patent Law.

With respect to the objective of public health and greater access to medicines, the recommendations contained in this report are premised on the fact that Indonesia has a thriving and growing domestic generic medicines industry, and that certain areas of patent legislation could be revised so that the industry is able to take advantage of available TRIPS Agreement flexibilities including on patentability criteria, important limitations and exceptions, and the use of compulsory and government-use licenses. It is recognized that IP law alone will not result in increased access to medicines; but it is certainly relevant and part of the set of policies that affects the supply of certain medicines in the country.

On transfer of technology, the underlying premise of this report is that efforts can be made to build capacity in domestic innovative capabilities, which would thereby encourage greater technology transfer. This can be done by, for example, improving the system of utility models (simple patents) that encourages incremental innovation. Such a system is already incorporated into the Patent Law, but could be refined in order to reward domestic inventors and to encourage them to apply to take out rights. At the same time, there are areas where Indonesia has a strategic interest such as in biodiversity-based products. The Patent Law could be amended to support the development of local biodiversity-based products, for example by requiring disclosure of origin.

With respect to competition policy and the Patent Law, there needs to be increased understanding of the complementarities of these two regimes. To date, competition authorities have been reluctant to address cases where there exists an abuse of exclusive rights conferred by patents, and have ceded this role to the DGIPR. The experience of other countries shows, however, that abuse of IP rights can indeed constitute market abuse, and therefore legitimately falls under the jurisdiction of the competition authority.

Moreover, the Patent Law can be structured in such a way as to maximize competition more generally, for example to ensure that generic medicines are able to enter the marketplace soon after the expiration of a patent (i.e., by having a Bolar exception that makes it clear that those taking advantage of the exception are not subject to both civil or criminal liability).

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