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The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda

UNCTAD– ICTSD Project on IPRs and Sustainable Development

Evans Misati
Kenya Industrial Property Office

Kiyoshi Adachi
UNCTAD

Introduction

Exceptions to patent rights have been the subject of increased attention in intellectual property IP discussions and processes in recent years. Focus on such exceptions is part of wider efforts to ensure that intellectual property rules and practices are supportive of development goals and public policy objectives such as the protection of public health, including access to medicines and the protection of the environment.

Recommendation 22 of the World Intellectual Property Organization (WIPO) Development Agenda, for instance, stipulates that the WIPO Secretariat should address potential flexibilities, limitations, and exceptions to IP rights for Member States in its norm-setting activities. In this context, at its 12th session in June 2008, the WIPO Standing Committee on Patents (SCP) asked the WIPO Secretariat to prepare preliminary studies on four issues, among which was "exceptions from patentable subject matter and limitations to the rights, *inter alia* research exemption and compulsory licenses." Consequently, in February 2009, the Secretariat prepared a study on this issue,[1] which was discussed at the 13th session of the SCP in March 2009. The SCP decided that the study would remain open for further comments.

Against this background, one important exception to patent rights that has traditionally been recognized in many countries' laws and jurisprudence is the use of a patented product or process, without the consent of the patent holder, for certain research and experiments. Both society and scientists have a legitimate interest in being able to use patent disclosure to support the advance of science and technology, and inventors ought to be able to freely experiment using the patented invention or process to come up with better products or processes. This exception is grounded in the idea that "a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public."[2] The research exception has perhaps also taken on particular importance in the light of the global consensus reached in WHO's 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which specifically recognizes that a research exception could help to address public health needs in developing countries.

1 WIPO 2009.

2 *Canada-Patent Protection of Pharmaceutical Products* (hereafter EC-Canada), WT/DS114/R, 17 March 2000, para. 7.69.

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There has been, however, a great deal of debate on exactly what research and experimentation activities (hereafter "research activities") should fall under such an exception. In practice, the scope and coverage of the research exception have varied from country to country.

This Policy Brief aims at examining the practice of countries with respect to the research exception and a related exception that has an impact on a specific type of research, the regulatory review ("Bolar") exception. After examining the practice of various jurisdictions, the Brief attempts to extract some lessons. The main objective of the Policy Brief is to suggest the possible parameters of policy interventions that may be adopted at the national and international level by countries that wish to codify exceptions for certain research activities in a manner that will make patent law work more effectively for innovation, better adapt to local technological conditions, and increase the benefits of the patent system for the society at large.

Exceptions to Patents Rights at the International Level: The Research and Experimentation Exception

At the international level, exceptions to patent rights not expressly permitted under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) are permitted only if they meet the requirements of Article 30 of TRIPS[3], which provides that:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do 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.

The clause thus allows WTO Members to carve out exceptions to patent rights that meet the so-called "three-step test", i.e. that the exception: (1) is limited; (2) does not unreasonably conflict with normal exploitation; and (3) does not unreasonably prejudice the legitimate interests of the patent holder.

A broad exception for research and experimentation activities can be found in the legislation of a number of developing countries. The Brazilian Patent Act, for instance, exempts acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or research.[4] The Bangui Agreement establishing the Africa Industrial Property Organization (OAPI) 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."[5] In the absence of any further qualifying language, the language contained in these legal instruments would provide a safe harbor against patent infringement for practically all scientific and technological research activities.

Commercial vs. Non-Commercial Research

Jurisprudence, and legislation in a number of jurisdictions, shows that a research exception to patent rights has been recognized subject to some limitations. One way in which some jurisdictions have decided which research activities may or may not fall under the exception is by distinguishing between research and experimentation that is commercial and non-commercial.

In the United States (US), the scope of the research exemption has been governed by federal court decisions dating back to the 1813 *Whittemore v. Cutter* ruling that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[6] In the same year, *Sawin v. Guild* widened experimental use beyond machines and also introduced the concept of non-commercial use when the court excluded from infringement the exploitation of a patented invention unless it constituted "making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[7] Forty-eight years later (*Peppenhausen v. Falke*) it was "held, and no doubt is now

3 UNCTAD-ICTSD 2005, pp. 430-31.

4 Article 43(II) of Brazil's *Law* No. 9279/96, as amended.

5 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).

6 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17, 600).

7 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12, 391).

well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee."[8] In view of the above, the US, among others, has therefore had a long tradition of cases emphasizing that only non-commercial research is exempt from patent infringement liability.

Other jurisdictions, including developing countries, have followed suit. Kenya's patent law states that, "the rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts…done for scientific research."[9] The Lebanese patent law provides penalties for "a person infringing the rights of a basically published patent while being aware of such action" provided that exploiting the invention on non-commercial, nonindustrial personal aims or for scientific research reasons shall not be considered to be such infringement.[10] While not referring to non-commercial research as such, Section 47(3) of the Indian Patent Act stipulates that acts that constitute "*merely* of experiment or research" (emphasis added) are exempt from patent infringement.

In practice, it is often 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 relies on basic research done in universities and other research institutions. Other factors include legal developments such as the Bayh-Dole Act[11] and similar acts in other countries that encourage academia to apply for patents on their research to enable the commercialization of innovation.[12] This blurring has perhaps 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.[13] The research exemption does not arise when acts in question are considered in relation to private and non-commercial interests.[14] The recent UK case of *CoreValve Inc v Edwards Lifesciences AG & Anor* appears to have broadened the exception somewhat, however.[15] In this case, the court ruled that it is when the preponderant purpose of the research is to generate revenue, that the claim of infringement cannot be avoided. Research is permitted until the point that the user of the patented invention starts to generate revenue from the research, for example, by selling samples of the product for purposes beyond generating information about the product. In the US, 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 defense that universities, whose charters committed their institutions to pursue a non-profit objective, enjoyed a wide research exception defense against claims of patent infringement.[16]

Research "On" and "With" the Patented Product/Process

The distinction between research "with" and research "on" protected knowledge, information, and tools is also important. An invention protected by patent—a new pharmaceutical chemical compound, for example—may be primarily research subject matter, permitting others to research "on" the compound in order to advance further the knowledge about the compound. Researchers can study "on" the same compound to develop another drug candidate. In the case of research "with" the compound, the use of the invention could be a "research tool" or simply an ingredient in the new drug formulation. In both cases, the research could be conducted in relation to scientific experiments that in the long term would have commercial benefits.[17]

8 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861).

9 Article 58(1), Kenya Industrial Property Act (2001), as amended.

10 Article 42, Law No. 240 (2000).

11 35 U.S.C. §200-212.

12 See, for example, in India, The Protection and Utilization of Publicly Funded Intellectual Property Bill (2008).

13 The Court of Appeal in *SF&F v Evans* [1989] FSR 513 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".

14 *SF&F v Evans* [1989] FSR 513 and *McDonald v Graham* [1994] RPC 515 (CA).

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

16 *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).

17 O'Connor 2009, p. 3.

The continental European exceptions are generally not intended to cover research "with" the patented product/process. The revised Swiss patent law of June 2008, for instance, exempts research done for both non-commercial and commercial purposes, as long as the objective of the research is to generate new knowledge about the patented invention.[18] It distinguishes between research done "on" the patented invention and research "with" the patented invention, only exempting research "on" the patented invention while ensuring access to patented research tools through a right to claim a non-exclusive license to use the invention.[19]

The Regulatory Review ("Bolar") Exception

Not all countries make a distinction regarding the applicability of the research exception based on scientific purposes and research that have the immediate purpose of generating information for securing the marketing approval of the product. This has been, for example, true in continental Europe, according to the Australia Advisory Council on Intellectual Property:

> "Most of the case law on "experimental purposes" in European countries, and particularly in Germany, has been developed on the basis of pharmaceuticals….As in many other jurisdictions, the big question here has been, and still is, whether during the duration (period of protection) of a pharmaceutical patent, pre-clinical and/or clinical tests may be conducted. The situation in Germany is very liberal in allowing such tests. In most EU countries, including the United Kingdom…clinical trials are regarded as patent infringement….In all other technical fields…the experimental use exception has not caused any problems in case law in Europe. As long as tests/experiments are directed toward better understanding the content of a patent, or toward doing further research with regard to the invention, no essential problems have ever been observed."[20]

This observation has changed since the EC introduced Directive 2004/27/EC that exempts acts done for regulatory approval purposes. Many countries have moved to adopting a separate exception in the context of pharmaceutical clinical trials. This exception is known as the regulatory review exception and is also called the "early working" or "Bolar" exception, referring to a case involving a party of the same name.[21]

Legislation in the US has firmly established the right of generic pharmaceutical manufacturers to make use of the patented product prior to the patent expiry date and without the approval of the patent holder, for the purpose of engaging in preparatory acts with a view to obtaining marketing approval from drug regulatory authorities upon expiry of the patent.[22] Such use facilitates the entry of generic competition as soon as possible after the date of patent expiration; otherwise a generic competitor would only be able to start its bioequivalence and other testing only after patent expiry, which would result in the *de facto* extension of patent protection.

At the international level, in a landmark WTO case, the EC challenged the Canadian Patent Act that stated, *inter alia*, that "[i]t is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under the law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."[23] The EC requested that the WTO Panel establish that the regulatory review exception violated the provisions of Article 28.1 of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement (i.e., rights conferred under patent). The EC called particular attention to the fact that Section 55.2(1) of the Canadian Patent Act authorized the commercial sale of ingredients by fine chemical producers who often supply generic drug manufacturers with the ingredients needed to make test products. Canada defended its legislation, arguing that each of the provisions challenged by the EC is a "limited exception" to the exclusive rights conferred by a patent within the meaning of Article 30 of the TRIPS Agreement.

The Panel found that the manufacturing and stockpiling exception applied six months before the expiry of the patent is not a "limited exception" to the rights of the patentee

18 See Articles 9 and 40(b) of the Swiss Patents Act, entered into force 1 July 2008; French language version available at http://www.admin.ch/ch/f/rs/232_14/).

19 The case law in developed nations is not sufficiently developed to explain the applicability of the research exemption for research "with" a patented product, and other research tool patents.

20 ACIP. 2004, pp. 40–41

21 *Roche Products Inc. v. Bolar Pharmaceutical Co.* (733 F. 2d. 858, Fed. Cir., cert. denied 469 US 856, 1984).

22 See the *U.S. Drug Price Competition and Patent Term Restoration Act* (the Hatch-Waxman Act), 1984.

23 Section 55.2(1), *Canadian Patent Act*, R.S.C., 1985.

to prevent the "making" and "using" of the protected product. In contrast, the regulatory approval exception is a "limited exception" as long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process and no commercial use is made of resulting final products, even though the approval processes may require substantial amounts of test production to demonstrate reliable manufacturing.

Having been firmly grounded in WTO law, the Bolar exception 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 terms" of the patent.[24] 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".[25] India, which is the largest supplier of generic medicines, also maintains a Bolar exception in Section 107 of its Patent Act. In this regard, it should be noted that the European Community, which previously opposed a regulatory review exception, has adopted a version of its own.[26]

Finally, it should be noted that this exception has also been the subject of Free Trade Agreements (FTAs) from time to time, and mainly appears in such agreements in the form of a restriction of the exception. Musungu and Oh (2005) 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. These provisions thereby force tests and production of quantities necessary for marketing approval to be done country by country in the event of export.

Lessons from the Jurisdictional Variation in the Research and Experimentation Exceptions in Patent Law

The purpose of the intellectual property system, as established under the TRIPS Agreement, is to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations (Article 7 of the TRIPS Agreement).

Both the research and the regulatory review exceptions were conceived as exceptions to patent rights that permitted certain experimental activities that were deemed necessary to support important objectives, in line with Article 7. The research exception permits scientific research "on" or "with" patented subject matter that could result in better products or processes, bearing in mind that it is rarely in the interest of the holder of exclusive patent rights to voluntarily allow research that could potentially undermine the economic value of the patent. The regulatory review exception permits generic pharmaceutical companies to enter the market as soon as possible after the expiry of the patent, thereby lowering the price and helping to assure greater access to medicines.

The scope of both exceptions has been the subject of intensive policy debates and litigation. At the policy level, a typical means of attempting to distinguish between research activities that fit into the exception and those that do not is to decide whether the research is essentially of a commercial or non-commercial nature. In practice, however, it is becoming increasingly difficult to make such a distinction. In the US, for instance, the trend has been for courts to narrow the exception, since much scientific research could be said to have some commercial aspect, as in the case of research conducted by universities (i.e., the *Madey* case).

The legal and jurisprudential development on the application of the research exception to research activities "with" the patented subject matter is more demanding. For example, the Swiss patent law advanced

24 Article 43 of Brazil's Law No. 9279/96, as amended.

25 Article 10(2) of Egypt's Law on the Protection of Intellectual Property Rights (2002).

26 See Directive 2001/83/EC, as amended by Directive 2004/27/EC.

a solution that while research "on" the patented invention is permitted, ensuring access to patented research tools is still guaranteed through a right to claim a non-exclusive license to use the invention. Such an approach would seem to go some ways in addressing the situation where it is arguable whether the research in question takes place "on" or "with" the patented product or process.

As studies by WIPO (2009), Garrison (2006), and Correa (2005), have found, the practice in developing countries tends to be varied, with little uniformity even within regions. Some have patent legislation that exempts scientific research based on the commercial/non-commercial distinction. Others have legislation that exempts all scientific and technological research broadly, without reference to a commercial/non-commercial distinction.

In view of the above, the important lesson from these examples is that, while practically all countries recognize that there ought to be a research exception, the commercial/non-commercial distinction has paved the way for courts to narrow the scope of the exception, at least in certain common law jurisdictions. A broad exception covering all scientific and technological research activities would appear to be one way to preserve a wide exception, while the Swiss approach, distinguishing between research "with" and research "on" the patent, could be considered as a middle ground between a broad exception covering all research activities and the very limited exception permitted in countries such as the US. It should be noted, though, that the research exception has never been tested directly under the WTO Dispute Settlement procedures for its compliance with Article 30 of the TRIPS Agreement, except for some revelation of the understanding of the exception by the Panel in *EC-Canada*.

Conclusion

To inform existing and future negotiations, and given the wide variety of approaches on determining the type of research that falls under the exception, WIPO, especially its SCP and the Committee on Development and Intellectual Property (CDIP), may wish to consider providing a more detailed comparative study on the scope of the research exception in Member States' domestic laws, including its interpretation by the courts and possibly some case law.

The link with the activities of the CDIP is important, as the research exception is of particular interest under the WIPO Development Agenda, adopted in 2007. As previously mentioned, one of the recommendations under the cluster of activities involving norm-setting, flexibilities, public policy, and public domain, calls on the WIPO Secretariat, without prejudice to the outcome of Member States considerations, to "address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as: (a) safeguarding national implementation of intellectual property rules; (b) links between intellectual property and competition; (c) intellectual property-related transfer of technology; (d) *potential flexibilities, exceptions and limitations for Member States* and (e) the possibility of additional special provisions for developing countries and LDCs" (emphasis added, in Recommendation 22).

Another related and widely recognized exception is the "Bolar" exception, which covers a specific set of research activities, i.e., clinical trials and other preparatory activities "on" or "with" a patented pharmaceutical product prior to the expiry of the patent so as to enable generic competitors to file an application for marketing approval of the competing product(s) as soon as possible after the expiry of the patent. Based on WTO case law, many countries, including both developed and developing countries have already integrated this provision into their patent legislation.

These two exceptions are of particular importance in light of the World Health Assembly's passage of Resolution 61.21 in 2008. Under this resolution (WHO 2008), the international community agreed on a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property to encourage greater research and development into diseases affecting developing countries and greater access to health products including medicines and medical devices for developing countries, specifically recognizing the important role that intellectual property policies, rules, and practices play in supporting these efforts. Element 2.4(e) of the Plan of Action specifically requests Governments to consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with the TRIPS Agreement. A robust exception may, by eliminating the cost of negotiating and purchasing licenses, potentially lower the cost of research into certain neglected diseases affecting developing countries, and may encourage research that would not otherwise have taken place.

The Global Strategy and Plan of Action thus reaffirms the spirit of the 2001 Doha Declaration on the TRIPS Agreement

and Public Health, which stated that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines."

Ultimately, what the jurisdictional variation in the implementation of the research exception shows is that there is no "one size fits all approach" to the implementation of intellectual property rules. Such diversity should be taken fully into consideration in any future endeavors towards substantive patent law harmonization.

Beyond norm-setting, this legislative diversity is also relevant for the technical assistance and legislative advice provided by WIPO to developing countries. According to recommendation 14 of the WIPO Development Agenda, "WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement."

Consequently, WIPO's assistance and advice should present options for developing countries to include in their legislations a regulatory "Bolar" exception and to carve out the broadest possible research exception, in a manner that is not only consistent with international obligations, but also facilitates contribution to the diffusion of technological and scientific knowledge and to the realization of important public policy objectives.

KEY CONCLUSIONS AND RECOMMENDATIONS

- The research exception is one of the important exceptions to patent rights that has long been recognized in the patent laws of developed and developing countries alike.
- A research exception grounded upon the commercial/non-commercial distinction appears to be less workable as it has become increasingly difficult to distinguish research that is commercial and research that is non-commerical. Deciding what research falls under the exception based on the commercial/non-commercial character of the research has paved the way for courts to narrow the scope of the exception, at least in certain common law (and even some statutory) jurisdictions.
- The WHO's 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property specifically recognizes that a research exception could help to address public health needs in developing countries. In this context, further examination might be called for to consider the extent to which a robust research exception could encourage much-needed research into neglected diseases.
- Unlike the research exception, the regulatory review exception, also known as the "Bolar" exception, is firmly grounded in WTO case law. This exception permits clinical trials and other preparatory activities "on" or "with" a patented pharmaceutical product prior to the expiry of the patent so as to enable generic competitors to file an application for marketing approval of the competing product(s) as soon as possible after the expiry of the patent.
- Many developing and developed countries incorporate the "Bolar" exception into their national patent legislation. Countries that have not done so to date may wish to consider amending their legislation to incorporate this flexibility, as it is firmly grounded in WTO case law and in IP comparative state practice, provided it is not otherwise prohibited under their international commitments (for example, the country's free trade agreements [FTAs]).
- WIPO's legislative advice, in line with Development Agenda recommendation 14, should present options for developing countries to include in their legislations a regulatory "Bolar" exception and to carve out the broadest possible research exception, in a manner that is not only consistent with international obligations, but also facilitates contribution to the diffusion of technological and scientific knowledge and to the realization of public policy objectives.

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About the authors

Evans Misati is an Examiner with the Kenya Industrial Property Office (KIPO) and Kiyoshi Adachi is a Legal Officer with the United Nations Conference on Trade and Development (UNCTAD).

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