

THE INTERNATIONAL DIMENSION OF THE RESEARCH EXCEPTION

By Carlos M. Correa

January 2005

SUMMARY

I. Introduction 3

II. Exceptions to exclusive rights 4

III. Research exceptions under article 30 of TRIPS 6

History of negotiations 6

The three-step test under article 30 of TRIPS 8

Limited exception 9

Not unreasonably conflict with normal exploitation 10

Not unreasonably prejudice the legitimate interests of the patent owner 14

Legitimate interests of third parties 15

Applying the three-steps test to the research exception 16

The research exception in the WTO panel ruling in the EC-Canada case 17

IV. The experimental exception in developing countries and economies in transition 19

Who may invoke the exception? 19

What kinds of activities are exempted? 19

Experimentation 19

Scientific Research 20

Technological research 20

Non-commercial purposes 21

Commercial purposes 22

Exempted acts 22

Effects of acts on patent holder's interests 24

Assessment of exceptions conferred 24

V. Follow on innovations 25

Independent innovation 26

Box 1. Patents vs. utility models 26

Dependent innovations 28

VI. Conclusions 29

I. Introduction

Article 8.1 of the TRIPS Agreement permits Members to adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development. More specifically, article 30 of The TRIPS Agreement provides that Members can establish limited exceptions to the exclusive rights conferred by a patent.

This paper discusses, first, the extent to which “experimental” or “research” exceptions are permissible under the TRIPS Agreement. It elaborates on the scope of article 30 of the Agreement, in the light of accepted principles of treaty interpretation (as contained in the Vienna Convention on the Law of the Treaties) and WTO jurisprudence. In particular, it explores the possible room for research exceptions for scientific or commercial purposes. Second, the paper examines some examples of research exceptions in national laws of developing countries and economies in transition.¹ Finally, it briefly discusses the legal treatment of follow on innovations eventually made under a research exception provision. In particular, it considers under which conditions such innovations may be independently protected and commercialized.

¹ The legal practices in developed countries will be examined in other papers prepared for SIPPI.

II. Exceptions to exclusive rights

Patents grant the right to prevent third parties from acts of making, using, offering for sale, selling, and (subject to the principle of exhaustion of rights) importing for those purposes a patented product as well as to prevent the use of a patented process.²

² See articles 28.1 and 28.2 of the TRIPS Agreement. See also UNCTAD-ICTSD, 2004.

The main aim of the exclusive rights conferred under a patent is to avoid the illegitimate enrichment of someone by using another's property or, put differently, to ensure that the patent owner is the only one who commercially benefits from the invention. However, such rights are not absolute. On the one hand, the patent holder has no residual right once the patent has expired. On the other, patent exclusive rights can be subject to various exceptions, whose scope would depend on the social and economic objectives of the patent system under which such rights are recognized. Thus, a system strongly focused on protection, as a means to favour investment in R&D, may limit exceptions so as to ensure that inventors be offered a maximum incentive. If, instead, the intended goal were to favour the dissemination of knowledge and innovation, exceptions to exclusive rights must be broader (Reichman, 1995, p. 22-23). However, even when a high level of protection is proposed, there is reason to balance such protection against other important values in society, among which are the interests of education and scientific research.³

The TRIPS Agreement adopted a protection paradigm that aims at reconciling the interests of innovators with those of users of technology. It aims at favouring the process of technological innovation, diffusion and improvement. Pursuant to article 7 of the Agreement:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

³ See the preparatory work of the WIPO Copyright Treaty (1996), WIPO CRNR/DC/4, para. 12.09.

Thus, patents allow inventors to obtain an extraordinary benefit during the term of the patent. Patents are not granted, however, to make inventors rich but to encourage research in society's benefit. The information generated under the stimuli offered by patents, is not only output but also an input of the knowledge production process, and should be available for further experimentation and research for the sake of scientific and technological progress. "Users of technology" under article 7 of the TRIPS Agreement, hence, should be interpreted as encompassing consumers and down-stream producers of goods and services, as well as follow on innovators who use protected knowledge to develop new innovations.

Moreover, article 30 of the TRIPS Agreement makes clear that the patent holder does not enjoy absolute exclusive rights, as they may be subject to "limited exceptions". One of the possible is for third parties' use of the protected subject matter for experimentation or research.⁴ An exception of this type has been incorporated into many national laws with regard to patents and other types of IPRs, such as copyright,⁵ integrated circuits designs⁶ and trade secrets.⁷

While experimentation or research *as such* are not enumerated exclusive rights of the patent owner, in order to conduct those activities it is normally necessary to make or use the patented product, or to use the patented process. This is the reason why an exception regarding experimentation or research *on* a patented invention⁸ may be necessary. Such an exception can be designed to promote follow on innovation, encourage the licensing of patented inventions or the invalidation of wrongly granted patents. In some countries, an exception has also been established for allowing the early introduction of generic versions of patented medicines (the so called "Bolar exception").⁹

⁴ Although in this paper the concept of "research exception" is used interchangeably with "experimental use" and "experimentation" exception, not all experimentation actually entails research (e.g. the execution of a patented invention in order to test whether it is reproducible or not as disclosed), while research can be made without experimentation, such as in the case of purely theoretical investigations.

⁵ Copyright is governed by the idea/expression dichotomy, according to which copyright protection extends only to the expression of the ideas contained in a work, but not to ideas themselves. In addition, most laws admit some form of fair use or similar exceptions that allow the reproduction of works for research and/or educational purposes. See, e.g., Correa, 2002; Ricketson, 2003.

⁶ See, e.g., Correa, 1990.

⁷ Reverse engineering and experimentation with regard to trade secrets are accepted practices, for example, in U.S. law (See Neff and Smallson, 1994, Chapter 8).

⁸ The distinction between experimentation *on* as opposed to *with* a patented invention permits to address cases in which the subject matter itself is intended or can be used for research or experimentation (e.g., "research tools" employed in biotechnology).

III. Research exceptions under article 30 of TRIPS

History of negotiations

The need to mitigate the exclusive rights conferred on the patent owner was widely recognized in TRIPS negotiations. The EC,¹⁰ Brazil¹¹ and Canada¹² proposed the incorporation of a non-exhaustive list of specific exceptions to patent exclusive rights, separately from any provisions on compulsory licenses. The USA, however, suggested that Contracting parties limit the patent owner's rights "solely through compulsory licenses".¹³ The negotiation on this issue centered around the scope of the exceptions to be allowed, as well as the way in which they would be formulated. The draft of July 23, 1990 (W/76) reflected the non-exhaustive list approach. It included a specific exception for "experimental purposes":

1. [Provided that the legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts , such as :

- 1.1 rights based on prior use.
- 1.2 acts done privately and for non-commercial purposes.
- 1.3 acts done for experimental purposes.
- 1.4 Preparation in pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared.
- 1.5A acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent hanged in accordance with procedures for effecting changes to patents after grant.
- 1.6B acts done by government for purposes merely of its own use.

⁹ Due to the application of specific State regulations for the marketing of medicinal products, in the absence of a "Bolar" type of exception the patent owner may profit from a **de facto** market exclusivity beyond the term of the patent. Patentee's rights are not affected if testing, production, etc. leads to competition with his own product after the expiry of the patent. Hence, an exception that does not lead to the actual commercialization of a product during such period does not impair the patentee's right to exclusively profit from his invention while he has the privilege to do so.

¹⁰ See MTN.GNG/NGII/W/26, 7 July 1988 (section D.a.(i))

¹¹ See MTN.GNG/NGII/W/57, 11 December 1989.

¹² See MTN.GNG/NGII/W/47, 25 October 1989.

¹³ See MTN.GNG/NGII/W/70, 11 May 1990.

Despite the support that establishing a (non exhaustive) list of the exceptions had from a large number of countries, the final text of article 30, adopted a more general formulation. It was modeled on the basis of article 9(2) of the Berne Convention, without specification of the particular acts that could be exempted. The interpretation given to this article of the Berne Convention, and even its negotiating history has become, hence, relevant to the interpretation of article 30 of the TRIPS Agreement. Thus, in the *United States-Section 110(5) of the U.S. Copyright Act* case on copyright¹⁴, and in the *Canada- Patent Protection for Pharmaceutical Products* case¹⁵ (hereinafter the “EC-Canada case”), WTO panels supported their interpretation of the TRIPS Agreement by reference to the negotiating history of the Berne Convention (which became part of the Agreement TRIPS).¹⁶

According to article 30 of TRIPS, the exceptions should be “limited” and not “unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties”.

The formulation of article 30 as a general clause based on the three-step test without a list of exempted acts raises delicate issues of interpretation. WTO Member countries have the right to implement it according to their policy objectives and legal systems.¹⁷ But other Members may challenge national interpretations and request a ruling under the WTO Dispute Settlement Understanding (DSU), if they considered domestic exceptions inconsistent with that provision.

While panels and the Appellate Body may examine exceptions adopted by national laws under article 30 of TRIPS, their task is confined to the *clarification*¹⁸ of the meaning of the WTO provision, and to an analysis of consistency of the challenged national provision with the TRIPS standard. Panels and the Appellate Body are not allowed to make an inquiry into the legitimacy of the public policy purpose of the Member implementing an exception. Thus, in a case initiated by the EC and their Member States against the USA,¹⁹ while examining whether the U.S. exception constituted a “special case” under article 9(2) of the Berne Convention and article 13 of the TRIPS Agreement, the panel focused on quantitative findings rather than on the policy objective of the exception (para. 6.111-112).

¹⁴ See WT/DS160/R, July, 7 2000, para. 6.18.

¹⁵ WT/DS114/R, 17 March 2000.

¹⁶ For instance, the panel referred to the report of the drafting committee for Article 9(2) of the Berne Convention, which stated that measures not in conflict with “normal exploitation” could nonetheless prejudice the “legitimate interests” of the copyright owner (para 7.72).

¹⁷ See article 1.1 of the TRIPS Agreement.

¹⁸ See article 3.2 of the DSU.

¹⁹ See United States- Section 110(5) of the US Copyright Act, WT/DS160/R, July, 7 2000.

The three-step test under article 30 of TRIPS

The meaning of article 30 of the TRIPS Agreement was clarified in the EC-Canada case, where a WTO panel addressed the TRIPS-consistency of Section 55(2)(1) and (2) of the Canadian Patent Act regarding the “early working” (also called “regulatory review” or “Bolar”) exception. This exception permits the use of a patented invention, without the consent of the patent holder, for testing required for the submission of data to obtain marketing approval for pharmaceutical or other products. The request for a panel was submitted in November 1998 by the EC and their Member States. In March 2000, the panel concluded that Canada was not in violation of the TRIPS Agreement. However, Canada was found to be acting inconsistently with TRIPS with regard to the rule allowing manufacturing and stockpiling of pharmaceutical products during the six months immediately prior to the expiry of the twenty-year patent term.

The admissibility of exceptions to patent rights is subject, under article 30, to three conditions which in the view of the panel in the EC-Canada case, are “cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed” (para. 7.20). The panel added that:

The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be “limited” and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not “unreasonably conflict with normal exploitation” could nonetheless “unreasonably prejudice the legitimate interests of the patent owner (para. 7.21).

Limited exception

The first condition to be met is that the exception must be “limited”. According to its ordinary meaning, “limited” is “confined within definite limits; restricted in scope, extent, amount, etc. It is also “small” in relation to an amount or number; or “low” in relation to an income.²⁰

²⁰ New Shorter Oxford Dictionary, p. 1592.

The panel provided an interpretation of what “limited” means in article 30:

The word "exception" by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question (para. 7.30).

In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged.²¹ The term "limited exceptions" is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with (para. 7.31).

In adopting a narrow concept of “limited”, the panel focused on the extent of the curtailment and not on the extent of the economic implications thereof. Hence, an exception with little economic effects might be disallowed under this doctrine even if the patent owner is not negatively affected in practice. In the panel’s view, the economic impact of the exception must be evaluated under the other conditions of article 30.

Given that panel reports do not create binding precedents (and the fact that this particular report was not subject to appeal), nothing would prevent future panels and the AB to adopt a broader concept on this matter, as suggested by Canada in its submission.²² An exception may be deemed limited when it is subject to certain boundaries, for instance, with regard to the *acts* involved (e.g. importation, exportation, evaluation), the *purpose* of the use (e.g. for private purposes or education), the *outcome* of the invention’s use (e.g. preparation of individual medicinal prescriptions), the *persons* that may invoke the exception, or its *duration*. An exception may be limited in relation to a *field of technology* as well (e.g. food or pharmaceuticals). While the consistency of this latter kind of limitations with the non-discrimination clause of article 27.1 was addressed by the panel in the EU-Canada case, the panel did not give a definite interpretation on the issue.²³

²¹ The interpretation of the second and third conditions of Article 30 are explained under F(1)(b) and (c) below.

²² See Canada’s submission in the EC-Canada case relating to the limited nature of the products, the persons that may invoke the exception and its duration, and the panel’s critical position on these arguments in relation to article 52.2(2) of the Canadian Patent law (para. 7.37).

Not unreasonably conflict with normal exploitation

The second condition established by article 30 is that the exception should not “unreasonably conflict with the normal exploitation” of the patent. This language, substantially borrowed from article 9 (2) of the Berne Convention, requires a determination of whether there is a conflict with the “normal” exploitation of a patent and, if a conflict exists, whether it is unreasonable. The literal method of interpretation followed by GATT/WTO panels requires a careful understanding of these key elements.

Two approaches have been suggested for the interpretation of this test under article 9(2) of the Berne Convention: an *empirical* meaning of “normal” as a reference to the usual or regular course of events, and a *normative* connotation in the sense of what “normal” is according to certain standard (Senftleben, 2004, p. 168). The empirical approach requires an investigation into what are the ways in which the title holder can exploit his IPRs in the normal course of events, possibly leading to the conclusion that there are certain modes of exploitation for which he would not ordinarily receive a remuneration. This approach puts an emphasis on actual markets. In contrast, the normative approach also includes potential markets.²⁴ If the concept of “potential” markets, however, is drawn too widely, this test may be insuperable and the exception rendered meaningless, since it would cover each and every possibility of deriving profit from protected subject matter (Senftleben, 2004, p. 178, 181, 185).

Canada took the position in the EC-Canada case that “exploitation” of the patent involves the extraction of commercial value from the patent by “working” the patent, either by selling the product in a market from which competitors are excluded, or by licensing others to do so, or by selling the patent rights outright. The European Communities also defined “exploitation” by referring to the same three ways of “working” a patent. The parties differed primarily on their interpretation of the term “normal” (para. 7.51).

²³ The panel held that “Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers” (para. 7.92).

²⁴ According to the study group which tabled the proposals for revising the substantive provisions of the Berne Convention at the 1967 Stockholm conference, “all forms of exploiting a work, which have, or are likely to acquire, considerable economic or practical importance, must be reserved to the authors” (quoted by Senftleben, 2004, p. 177).

The panel noted that, literally interpreted, “normal” is "regular, usual, typical, ordinary, conventional".²⁵ The panel did not take a position with regard to the empirical or normative connotation of the concept. It held that

the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word "normal" was being used in Article 30 in a sense that combined the two meanings (para. 7.54).

The panel’s reluctance to opt for one of the approaches left this important aspect without clarification and open to controversy. It also stated that

The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws (para. 7.55).

The panel’s reasoning is questionable. The right to exclude the use of the patented subject matter by third parties is not a form of exploitation of the patent, but a legal power established by law that may be exercised or not. The exploitation consists of the acts of making, using or commercializing the inventions without third parties’ competition. In addition, the panel went too far in considering “all forms of competition” since competition may legitimately proceed through the improvement of the patented technology. The normal exploitation of a patent should be deemed limited to uses of the invention that are shielded from competition by law.

²⁵ The New Shorter Oxford English Dictionary, p.1940.

Another important interpretive issue is whether the encroachment upon the economic value of the patent is to be assessed as a whole or separately for each individual exclusive right. In the *Section 110(5) of the US Copyright Act* case, the panel stated that “whether a limitation or an exception conflicts with a normal exploitation of a work should be judged for each exclusive right individually” (para. 6.173). It also argued that an exception raises to the level of conflict with a normal exploitation of the work “if uses, that in principle are covered by that right but exempted under the exception or limitation, enter into economic competition with the ways that right holders normally extract economic value from that right to the work (i.e., the copyright) and thereby deprive them of significant or tangible commercial gains” (para. 6.183).

However, it is unclear the rationale for this opinion. Not all exclusive rights generate the same level of income. A 10% limitation to an important income-generating exclusive right (e.g. right to sell) may be more significant than a 100% limitation to another exclusive right (e.g. the right to make when products are imported). Instead of considering different exclusive rights separately, it would be more appropriate to evaluate the extent to which an exception impairs the overall commercialization of the subject matter (Senftleben, 2004, p. 193).

Finding a “conflict with the normal exploitation” of a patent does not mean, however, that an exception is proscribed. The conflict must be “unreasonable”. The panel in the EC-Canada case did not address what “unreasonably” means in this context, since its analysis led to the conclusion that there was no conflict with the normal exploitation of a patent, and therefore it was not necessary to elucidate whether the Canadian exception was reasonable or not. If a conflict of such kind were found, however, the way in which “unreasonably” is to be interpreted would acquire crucial importance.

Member countries have considerable latitude to interpret what “unreasonable” is. In the last instance, the unreasonableness of an exception will depend on the conceptual framework that underpins the granting of patents in a given jurisdiction and at a certain point in time. The panel in the EU-Canada case took the view that

Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined (para. 7.55).

This statement hints the panel's conception on the role and objectives of the patent system. The panel seems to have ignored that there is no *universal* patent system, and that the national patent laws have historically reflected different philosophies and objectives (Gutterman, 1997; May 2000) largely correlated to different levels of economic and technological development. Moreover, while emphasizing the stimulation to innovation, the panels' view failed to consider other essential objectives of the patent system, such as the diffusion of knowledge and its continuous improvement. In the last instance patents were instituted to serve the public interest and not to benefit individual inventors (Welfens *et al*, 1999, p. 138). It is important to note, in this regard, that in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health,²⁶ Members stated that

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles [para. 5 (a)].

Developing countries have, in particular, stressed the need to construe the "purpose" of the Agreement and of the protection conferred thereunder on the basis of article 7 of the Agreement.²⁷ The panel seems to have focused, however, on the protection of private rights and overlooked the social objectives that underpin the recognition of patents.

²⁶ "Doha Ministerial Declaration on the TRIPS Agreement and Public Health", WT/MIN(01)/DEC/W/2, 14 November 2001.

²⁷ See the submission by the African Group Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (IP/C/W/296): "Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23, May 1969), which establishes, in Article 31, that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose" (para 17). "Article 7 is a key provision that defines the objectives of the TRIPS Agreement. It clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights. Some of the elements in Article 7 are particularly relevant, in order to ensure that the provisions of TRIPs do not conflict with health policies: the promotion of technological innovation and the transfer and dissemination of technology; the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations (para. 18).

Not unreasonably prejudice the legitimate interests of the patent owner

The third condition of article 30 requires that the exception does “not unreasonably prejudice the legitimate interests of the patent owner”. This condition puts on the same footing the “legitimate interests” of the patent owner and those of third parties in using the invention. Only the patent owners’ interests that are “legitimate” require protection. In addition, they may be deemed harmed to the extent that the prejudice caused by the exception is unreasonable.

This condition raises, on the one hand, the issue of what “legitimate interests” are and, on the other, of when such interests are “unreasonably” prejudiced.

The EC argued in the EC-Canada case that that "legitimate interests" were essentially “legal” interests. The panel rightly rejected this interpretation. It considered that

To make sense of the term "legitimate interests" in this context, that term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as "X has no legitimate interest in being able to do Y". (para. 7.69).²⁸

The panel added that “a definition equating “legitimate interests” with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the “legitimate interests” of third parties” (para. 7.68).

²⁸ It should be noted that in *United States- Section 110(5) of the US Copyright Act*, the panel adopted a more positivist perspective. It argued that “one-albeit incomplete and thus conservative-way of looking at legitimate interests is the economic value of the exclusive rights conferred by copyright on their holders” (para. 6.227). However, it observed that the term “legitimate” also had “the connotation of legitimacy from a more normative perspective, in the context of calling for the protection of interests that are justifiable in the light of the objectives that underlie the protection of exclusive rights” (para. 6.224).

Proof that a prejudice is caused to the patent owner's legitimate interests is not sufficient to outlaw a "limited exception" (provided it fulfills the second condition referred to above). A test of reasonableness also needs to be applied. Such test may be equated to the principle of *proportionality* as developed under EC law, which requires that the means used to achieve an end bear a reasonable relationship with the end achieved (Senftleben, 2004, p. 211). However, WTO Members have significant leeway to define how such test will be defined and applied. They have the right to craft the exceptions they deemed necessary for public policy purposes, whatever the economic or non-economic importance of the legitimate interests of the patent owner are. The only limitation is that the scope of the exception should not be excessive in relation to its intended objective.

Legitimate interests of third parties

The last part of article 30 ("taking account of the legitimate interests of third parties") is absent in Article 9(2) of the Berne Convention, which inspired drafters of article 30. However, said article has been understood as calling for a weighing process between the interests of authors and third parties. Thus, it has been suggested that although strong user interests may underlie a limitation, the prejudice to the legitimate interests of the author must be proportionate (Senftleben, 2004, p. 153).

In the EC-Canada case, the panel alluded to the new wording introduced by article 30. It noted that

[A]bsent further explanation in the records of the TRIPS negotiations, however, the Panel was not able to attach a substantive meaning to this change other than what is already obvious in the text itself, namely that the reference to the "legitimate interests of third parties" makes sense only if the term "legitimate interests" is construed as a concept broader than legal interests (para 7.71).

Clearly, the legitimate interests of the third parties at stake must be in competition with the legitimate interests of the patent owner, in order for this part of the provision to apply. The interests to be taken into account may include those of follow-on innovators, competitors, and users, as well as the interests of society at large, for instance, in addressing a public health crisis or in ensuring the advancement of science and technology.

Applying the three-steps test to the research exception

A research exception seems to fulfill the first test under article 30 of the TRIPS Agreement without difficulty. Such exception generally involves acts of making and/or using the patented subject matter on a laboratory scale, for the purpose of generating knowledge. Such acts are relatively short in duration (as compared to the lifetime of a patent). The limited character of the exception is evident when the research is conducted by institutions which are not in direct competition with the patent owner, but it is also arguable when it is made with a commercial intent by actual or potential competitors.

Based on the analysis made above, it is also arguable that a research exception fulfils the second test in article 30. Undertaking research *on* a patented invention does not conflict with the “normal” exploitation of the patent. There is neither an exclusive right relating to research or experimental activities as such, nor a patent extends to the improved, substitute or alternative products that third parties may generate. As noted above, it is the limited use or making of the invention, as required for those purposes, what may be seen as an infringement. Third parties’ experimentation or research does not deprive the patent owner of the benefits generated by the market exclusivity he enjoys. He is not conferred the power to control new or improved products or processes created on the basis of his invention, but only rights to exclude certain commercial acts relating to the product or process (and their equivalents) he has himself invented.

It may be concluded, hence, that there is no conflict in the case of a research exception with the “normal” exploitation of a patent and, hence, an investigation whether such conflict is reasonable or not would be unnecessary. If a conflict were found, however, the prejudice possibly caused to the patent owner should be weighed against the third parties’ and society’s interest in establishing the validity of the patent or its potential use (under voluntary or compulsory license), or in developing improved, substitute or alternative products. Moreover, as examined below, the cumulative nature of technological development in most sectors require the preservation of the ability to innovate, as a matter of public policy. A patent regime that impedes follow-on innovation will defeat its very purpose.

A research exception, hence, would seem to be validated under the first and second steps of article 30 without great difficulty. The patent holder's legitimate interests, do not include the power to control research and, therefore, there would be no need to balance those interests with those of third parties. If, however, a research exception were hypothetically subject to analysis under the third step in article 30, the interest in ensuring a sustained scientific and technological progress, would constitute a reasonable justification for any prejudice that the patent owner may suffer. There also reasons of intergenerational equity that justify such exception as the patent owner cannot be given the power to prevent new generations of innovators to rely on an invention that, in turn, was derived from the pool of knowledge available to the inventor. Innovators ought to have the possibility of using their predecessors' work to develop their own creative and inventive capacities.

Finally, in considering the legitimate interests of third parties, there is no need to limit the analysis geographically. Such parties may include users in different territories (for instance, potential receivers of a vaccine against diseases that prevail in poor countries).

The research exception in the WTO panel ruling in the EC-Canada case

Interestingly, both the EC and Canada accepted in their submissions in the EC-Canada case that experimental use exceptions could be found in the laws of many Members of WTO, and that they were TRIPS compliant. While the panel specifically examined in this case the consistency of the Canadian "early working exception", it also mentioned in its ruling the experimental use exception, as follows:

-- To the extent that some development activity might be permitted, consistently with Article 30 of the TRIPS Agreement, under other exceptions such as the traditional exception for experimental use of the patented product, the delay in entering the market would be correspondingly less (para. 7.3).

-- If there were no regulatory review exception allowing competitors to apply for regulatory approval during the term of the patent, therefore, the patent owner would be able to extend its period of market exclusivity, de facto, for some part of that three to six-and-half year period, depending on how much, if any, of the development process could be performed during the term of the patent under other exceptions, such as the scientific or experimental use exception. (para. 7.48)

-- We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion 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. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a "legitimate interest" in using the patent disclosure to support the advance of science and technology. **While the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement,** it does adopt the general meaning of the term "legitimate interests" contained in legal analysis of this type (para. 7.69) (emphasis added).

Although the panel, as noted in paragraph 7.69 quoted above, did not specifically examine a research exception as such, it clearly hinted an opinion favorable to its TRIPS-consistency. The panel referred to "the traditional exception for experimental use of the patented product" thereby suggesting that at the time of the adoption of the Agreement that exception was a widely accepted norm in patent law. It also suggested that the early working of a pharmaceutical product could be performed "under other exceptions, such as the scientific or experimental use exception". Finally, the panel illustrated the meaning of the concept of "legitimate interest" by reference to society's and scientists' interest in the advance of science and technology. None of these statements could be expected, should the panel thought that an experimental/research exception would have been, in principle, outside the scope of article 30 of the TRIPS Agreement.

Several analyses of the ruling in the EC-Canada case have pointed out the panel's opinion favorable to the TRIPS-consistency of a research exception. Thus, the Australian Law Reform Commission (2004) noted that in the panel's view there was no conflict with the normal exploitation of the patent as a consequence of the "basic patent deal", according to which others may use the patent holder's invention to further develop the state of the art (para.13.73). Similarly, Senftleben has noted that "the line of argument of the Patent Panel runs as follows: if one is ready to conceive of patent protection as a means to induce inventors to disclose their invention to the public in order to facilitate the dissemination and advancement of technical knowledge, it appears illegitimate to prevent experimental use during the term of the patent" (Senftleben, 2004, p. 229).

IV. The experimental exception in developing countries and economies in transition

This section presents an overview of the treatment of the experimentation/research exception in developing countries and economies in transition. Most countries reviewed (see table in Annex) have adopted a research exception, defined on the basis of different criteria, as examined below.

Some countries (e.g. Guyana, Haiti, Kuwait, Libya, Madagascar, Nigeria, Sudan, Yemen, Vietnam, Zimbabwe) do not provide for a specific exception for experimental or research activities. The admissibility of such exception would depend in these cases on the scope of the conferred exclusive rights. Some laws circumscribe them to acts carried out for industrial or commercial purposes (e.g. Ordinance 89-109 of Madagascar). This wording would seem to legitimize third parties' experimental and research activities, if conducted without commercial intent.

Who may invoke the exception?

In the great majority of reviewed laws, the research exception may be invoked by any party. In a few cases, however, reference is made to certain categories of beneficiaries or to activities done in certain circles. For instance, in the case of the Mexican and Argentine laws the exception applies to a third party who performs research "privately or in an academic environment" (article 22(1) and 36(a) respectively).

What kinds of activities are exempted?

Experimentation

The laws of many countries include an exception for "experimentation" or "experimental purposes". Thus, the patent laws of Belize (article 33(4)(c), Bhutan (article 4.a.iii), Botswana (article 24.3.a.iii), Cambodia [article 44 (iii)], Chile [article 62 (c)], El Salvador [Law No. 35, 1996, article 19(2)], Guatemala [article 130(b)], Mongolia, [article 18(2)(1)], Pakistan [article 30(5)(c)], Philippines [article 72(3)], Singapore [article 66(2)(b)], South Korea (article 96.1.i), Trinidad and Tobago [article 42(b)], Tunisia [article 47(b)] and Turkey [article 75(b)] establish that the rights under the patent shall not extend to acts done for experimental purposes relating to a patented invention.

In many cases the exception is qualified by the indication that acts should be conducted *only* or exclusively for experimental purposes. In the case of India, for instance, section 47(3) of the Patent Act of 1970 stipulates that: “any machine or other article in respect of which the patent is granted and any process in respect of which the patent is granted may be made or used by any person, for the purpose *merely* of experiment or research including the imparting of instructions to pupils” (emphasis added).

Scientific Research

In many countries an exception is provided for research conducted for scientific purposes only.

Reference to scientific research is made, for instance, in the patent laws of Algeria [article 12(1)], Barbados [article 6(1)], Cuba [article 54(3)], Egypt [article 101(1) (1)], Guinea-Bissau [article 4(c)], Kenya [article 58(1)], Lebanon (article 42) Malaysia [article 37(1)], Saudi Arabia (article 24) and Uganda [article 29(a)]. In the case of Armenia (Law on Patents, 1999), the exception refers to “scientific experiment or scientific research” [Article 13(1)(1)]. The Patent Regulation of the Cooperation Council for the Arab States of the Gulf (Law No. 1, 2004) provides an exception for “acts carried particularly for scientific research purposes” (section 14/1).

In some laws, the exception is provided for both scientific research *and* experimental purposes. For instance, in Panama (Law No. 35, 1996, article 19.2) there is no patent infringement when “an industry or enterprise... engages in acts of manufacture or use of the invention for experimental purposes relating to the subject matter there or for purposes of scientific or education research.”

The Patent Law of the People’s Republic of China states in section 62 that using the patent concerned solely for the purposes of scientific research and experimentation is not considered to be an infringement of the patent right. Similarly, Decision 486 of the Andean Community exempts both “acts performed for exclusively experimental purposes” as well as those “performed solely for the purposes of teaching or scientific or academic research” (article 53 (b) and (c)).

Provisions that exempt *both* experimentation and scientific activities are also contained in the patent laws of Costa Rica [article 16(2)(b)and (c)], Cyprus [article 27 (3) (iii)], Guatemala [article 130(c)], Kazakhstan. (article 12), Kyrgyzstan [article 13(ii)], Mauritius [article 21(4)(d)], Mongolia [article 18(2)(2)], Nicaragua [article 46(a) and (b)], and Paraguay [article 34 (a) and (b)].

Technological research

While in many laws the exception is confined, as mentioned, to scientific activities, in others reference is also made to “technological” or “technical” activities. For instance, the Brazilian Industrial Property Code, 1996, refers to “acts practiced by non-authorized third parties, with an experimental purpose, related to scientific or technological studies or research”. In the Bangui Agreement (revised in 1999), the exception alludes to “acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research” (article 8(1)(c)).

The reference to technological activities may have important implications to determine the scope of the exception. While science is concerned with the advancement of knowledge *per se*, technology relates to the application of knowledge to a particular problem. Scientific activities have no direct commercial intent; technological development, in contrast, is generally driven by market forces and is made with a commercial purpose (Freeman, 1991, p. 15-16). An exception for “technological” research or experimentation, hence, may be read as encompassing for-profit activities.

Non-commercial purposes

In another group of countries, acts for experimental purposes are subject to an exception but only if done for non-profit.

Thus, in the Republic of China (Taiwan) (Patent Law, as amended, article 57.1) a third party is allowed to use the invention for “research or experimental purposes only, with non-profit acts or intention involved therein” .

According to the Mexican law (Industrial Property Law, 1991 as amended in 1994, article 22.I) an exception applies in respect of a person who

in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or process identical to the one patented.

Similarly,²⁹ the Argentine patent law (Law 24.481, 1995, article 36.a)) exempts a person who “without gainful intent, conducts scientific or technological activities for purely experimental, testing or teaching purposes and to that end manufactures or uses” (the invention).

²⁹ See also the law of El Salvador (article 116 (b)).

It is interesting to note that the law of Moldova allows the exception for non-commercial purposes, as well as “for assessing the application of the subject matter” (article 24(1)(b)). This wording seems to open up the possibility of experimentation with commercial intent, though limited to an assessment of the invention.

Commercial purposes

None of the reviewed laws contain an explicit exception for experimentation or research conducted with commercial purposes. As mentioned above, however, the admissibility of activities with commercial intent (e.g. research aimed at improving on a patented technology) may be presumed when unqualified reference to “experimentation” or “technological” activities is made, as it is the case in numerous laws.

Exempted acts

In general, the reviewed exceptions broadly apply to experimentation/research “related to” a patented invention. In some cases, there is more specificity with regard to the acts allowed. Thus, in the case of the patent law of Croatia (article 5.2) and Decision 486 of the Andean Community, reference is made to experimentation *on* a patented invention (article 53 (b), in line with the distinction made by European jurisprudence between research *on* and *with* patented subject matter.

Some countries have incorporated the so-called “Bolar exception”. This exception deals with the use of an invention relating to a pharmaceutical product to conduct tests and obtain the approval from the health authority, before the expiration of the patent, for commercialization of a generic product, after the expiration of the patent.

The Bolar exception is provided for in some cases as a part of the experimental exception. Thus, the patent law of Croatia (1999) exempts

acts done for the purposes of the research and development of the subject matter of the protected invention, in particular: making, using, offering for sale, importation, or exportation of the protected product, where such acts are reasonably connected with the experiments and tests necessary for the registration of the human and veterinary medicines, medical and veterinary products or preparations for the protection of plants (article 5.2).

An exception of this type, but without reference to exportation, is included by the patent law of Jordan (article 21(c)).

In other cases, a specific Bolar exception, differentiated from the general exception on experimentation or research, has been established. For example, Article 8 of Argentine law 24.766 of December 1996 states that

When a product or process is protected by a patent, any third party shall be able to use the invention before the expiration of the patent, with experimental aims and to gather the information required for the approval of a product or process by the competent authority, for its commercialization after the expiration of the patent.

The Thai Patent Act B.E 2522 (1979), as amended by B.E 2535 (1992), provides that the patentee's exclusive rights shall not apply to

any act in respect of applications for drug registration, the applicant intending to produce, sell or import the patented pharmaceutical when the patent expires (article 36.5).

Both the Argentine and the Thai “Bolar” exceptions³⁰ seem to allow acts for the *domestic* registration of drugs. Taking advantage of the precedent set by the Canadian Bolar exception, which was tested in the EC-Canada case, other countries also allow acts aiming at the registration in foreign countries. The case of Croatia has been already mentioned above. Brazilian Law 10.196 (2001) contains an exception for acts performed by non-authorized third parties, regarding patented inventions, which aim exclusively at the production of information, data and test results directed to procure commercial registration, in Brazil or any other country, to allow the exploitation and commercialisation of the patented product, after the termination of the patent (Article 43 (VII)).

It should be noted that the Bolar exception (as provided for in Argentina, Brazil and other countries) is not linked to an extension of the term of the respective patent, as it is the case, e.g., in the USA, Israel and Australia. In fact, there is nothing in the TRIPS Agreement or in other international instruments requiring an extension of the patent term as a condition for providing for a Bolar exception. Canadian law, scrutinized in the EU-Canada case and found TRIPS-consistent (except with regard to the storage of products) did not grant such extension either.

³⁰ A similar exception is contained in the Egyptian Intellectual Property Law 82 of 2002 (article 1001(1)(5)).

A Bolar-type exception is likely to be allowed where an exception for experimental acts, not limited to non-profit acts, is provided for. In other cases, the admissibility of the exception may depend on some aspects of the applicable law, such as the definition of conferred exclusive rights. For instance, the Patent Law of South Africa of 1979 (as amended in 1979, 1983, 1986, 1988 and 1996) provides that the "effect of patent" is "to exclude other persons from making, using, exercising or disposing of the invention, so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention" (article 45.1). At least in one case the courts considered whether acts conducted after the expiry of the patent, but related to testing that had taken place before, constituted infringement. Since the early testing would have secured the defendants a springboard based on infringing acts, a trial judge considered that they were not entitled to the data they have collected and that they had no right to submit them to the health authority for registration of the generic product. The judge ordered the delivery up of the application for approval to the plaintiffs, jointly with the registration granted to the defendants. The appeal court, however, overturned this decision, on the basis that the patent was not in force (Cook, 1997).

Effects of acts on patent holder's interests

Finally, in some cases, the admissibility of the research exception is not defined only on the basis of the nature of the activities, type of acts or their purpose, but subject to conditions aimed at balancing the patentee's and third parties' interests.

For instance, in Indonesia the patent law (amended in 2001) provides for an exception if the use of the patent is "for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the patent holder" (article 16(3)) (unofficial translation).

In the case of Egypt, *in addition* to an exception for "scientific research purposes", the law contains a general provision exempting

...any other acts by third parties, provided that they shall not unreasonably hamper the normal exploitation of the patent, and shall not be unreasonably prejudicial to the legitimate interests of the patent owner, taking into consideration the legitimate interests of others [Article 10(1)(6)].

This wording, obviously drawn from article 30 of the TRIPS Agreement, may permit experimental or research not limited to scientific activities.

Assessment of exceptions conferred

As the previous review shows, there is considerable diversity in the way developing countries and economies in transition have stipulated an experimentation or research exception. Different models have been followed. The majority of laws exempt scientific and/or research activities. In many cases, the scope of the exception is limited to non-commercial purposes, or is subject to several other restrictions. Although in no case, experimentation or research with commercial purpose is specifically allowed, the unqualified reference to “experimentation” or to “technological activities” suggests that activities with that aim may be deemed covered by the stipulated exceptions.

Overall, it would seem that policy makers in developing countries and economies in transition have not paid significant attention to the problems associated to experimentation or research on patented inventions. Notably, some of the countries with significant scientific and technological potential (such as India and China) have not fully utilized the room left by the TRIPS Agreement to provide for broad research exceptions.

V. Follow on innovations

Innovations may be “radical” or “incremental”, depending on their distance from the pre-existing knowledge. The former, also known as “major” innovations, are discontinuous events, which are generally the outcome of deliberate efforts in R&D. In contrast, “incremental” innovations are of cumulative nature. They may be the result of organized research and development programmes, but usually happen as a consequence of improvements introduced by engineers or other people directly involved in the production process, or as a result of users’ initiatives and suggestions rather than of a deliberate R&D activity (Freeman, 1987. p. 78-79).

The nature of technological innovation varies in different sectors. Thus, incremental innovations are of particular importance in technologically mature sectors as well as in some of the most dynamic sectors of the modern economy. This type of innovation prevails, for instance, in the car industry. It is also the dominant form of innovation in the electronic and computer industries as well as in software development. Due to the increasing importance of incremental innovation, technological innovation is largely driven today by the “routine exploitation of existing technologies” (Foray, 1995, p. 120).

Given the importance of follow-on innovation, it would be logical for States to adopt policies that promote it. A crucial aspect of such a policy relates to the legal status of the innovations made under the umbrella of experimentation or research exceptions. The way in such status is defined may provide incentives or generate disincentives for the use of research exceptions. The broader the rights conferred on the follow-on innovator to control his innovation, the greater the incentives will be to make use of research exceptions, and vice versa. Clearly, the incentives would be greatest if he could independently protect and commercialize his innovation, or at least to easily obtain a compulsory license for a dependent patent.

Independent innovation

Experimentation or research on a patented invention, if permitted under the applicable law, may allow a third party to develop new technology the use of which does not infringe the patent on which research was based³¹. The analysis of this doctrine is outside the scope of this paper. A follow on innovation that meets the patentability standards and that does not infringe upon the original patent, may obtain patent protection and exercise his rights independently from the original patent owner. Some countries have introduced “utility models” or “petty patents”, which may also provide an independent title to the follow-on innovator with regard to improvements that are not patentable. Utility models protect the *functional* aspect of models and designs.³² Though novelty and inventiveness are generally required, the criteria for conferring protection are less strict than for patents³³. The term of protection also is shorter.

Utility models (or petty patents) are useful to protect minor or incremental innovations, particularly in the mechanical field. The main differences with patents, as described by WIPO,³⁴ are presented in Box 1.

³¹ The extent to which a follow-on innovation, which is close to the original invention, is infringing or not would be judged under the “doctrine of equivalents”.

³² A peculiar feature of the utility models system in Germany is that legislation has tried to make utility models and patents as similar as possible. Whereas the Patent Act requires an “inventive activity”, a utility model requires an “inventive step”. However, this difference is of little practical relevance (Schuster and Hess, 1997, p. 27). This allows applicants to simultaneously file and obtain patents *and* utility models in parallel, since both can co-exist. The registration of the utility model grants the applicant immediate protection (since examination is not necessary), while under patent law an injunction against infringers can only be obtained after the issuance of the patent.

³³ Utility models are concerned with the way in which a particular configuration of an article works, unlike *industrial designs* which are only concerned with the aesthetic character of an article.

³⁴ WIPO at www.wipo.org/sme/en/ip_business/utility_models/

Box 1. Patents vs. utility models

- The requirements for acquiring a utility model are less stringent than for patents. While the requirement of “novelty” is always to be met, that of “inventive step” or “non-obviousness” may be much lower or absent altogether. In practice, protection for utility models is often sought for innovations of a rather incremental character which may not meet the patentability criteria.
- The term of protection for utility models is shorter than for patents and varies from country to country (usually between 7 and 10 years without the possibility of extension or renewal).
- In most countries where utility model protection is available,³⁵ patent offices do not examine applications as to substance prior to registration. This means that the registration process is often significantly simpler and faster, taking, on average, six months.
- Utility models are much cheaper to obtain and to maintain.
- In some countries, utility model protection can only be obtained for certain fields of technology and only for products but not for processes.

In Australia, an “innovation patent” was introduced in 2001, with the aim of providing a low-cost entry point into the intellectual property system, particularly for minor innovations and for products with a short shelf life. This regime replaces the petty patent system. It provides a longer term of protection (eight years as opposed to six), allows for up to five claims (as opposed to three). A new e-business centre to process on-line applications and payments for innovation patents was also established.

³⁵ Currently, utility model (petty patent) protection is granted in, Argentina, Armenia, Austria, Belarus, Belgium, Bulgaria, China, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Malaysia, Mexico, Netherlands, members of the African Organization of Intellectual Property (OAPI), Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan.

The European Commission prepared a proposal for the adoption of a Directive harmonizing the utility model protection in Europe,³⁶ to enable small and medium enterprises (SMEs) to accede to IPRs protection in a less complicated and cheaper way than under patents. Protection would be given for ten years if the invention is “not very obvious to a person skilled in the art”. There would be no formal examination of validity, and search examination would only be made upon request or in the case of litigation. Upon a proposal by the European Parliament, the scope of the Directive was revised in order to cover software.³⁷ The approval of this directive is still pending.

Dependent innovations

In some cases, follow on innovations cannot be exploited without using the original invention. This was recognized in some patent laws of the XIX Century which incorporated the concept of “improvement” or “additional” patent. For instance, under Argentine law No. 111 of 1864, inspired on the French law of 1844, the patent holder or a third party could acquire an additional patent (or certificate) on the improvements made on a patented invention. The improvement patent, which expired with the original patent, could be exploited, if the improvement were made by a third party, against payment to the original patent owner or, at his option, against a cross-license to exploit the improvement (articles 27-32).³⁸

Improvement patents gradually disappear in the xx century, as the requirement for patentability became less stringent and fully independent patents could be growingly obtained for follow-on innovations. This is common, for instance, in the pharmaceutical sector, where R&D-based companies are active in patenting salts, polymorphs, isomers, new formulations and other variations of existing products, and in pursuing generic firms on the allegation of infringement. Although in many cases the allegations are dismissed,³⁹ high litigation costs and uncertainty keep some competitors out of the market.

³⁶ See COM (1999) 309, 12.7.99.

³⁷ In contrast, chemical substances or processes would not be protectable. The chemical industry was unhappy with the idea of utility models, probably because the value of patents could be undermined by the proliferation of unexamined utility models. See Leith, 2000.

³⁸ The Argentine patent law, adopted in 1995, that replaced law 111, retained the concept of improvement patents, which may be obtained by anyone who improved a patented invention. The improvement patent expires with the original one (articles 51 and 52, Law 24.481).

³⁹ A study by the U.S Federal Trade Commission found that generic companies had a success rate of nearly 75% in patent litigation (FTC, 2003)

A third party who, on the basis of a research exception, develops an improvement on a patented invention can also obtain a separate patent in his own name that he may not be able to exploit without the consent of the original patent owner, if use of the second patent implies infringement of the original one. At the same time, the owner of the second patent may prevent the original patentee from exploiting his improvement. Compulsory licenses can provide a solution to this situation of mutual exclusion.

A detailed provision on compulsory licenses grounded on the dependency of patents is contained in article 31.1) of the TRIPS Agreement. It specifically allows Members to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), under the following conditions:

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

These conditions tend to limit the use of patents on improvements as a mechanism to easily get access to patented technology.⁴⁰ Key for the actual operation of these compulsory licenses is the interpretation of what the economic and technical importance of the second invention would be in a particular case. If the standard is too high, the system may discourage follow-on innovation by third parties as a compulsory license will be difficult to obtain. Countries that incorporated this ground for compulsory license have generally reproduced the text of the TRIPS Agreement without further elaboration. There are no records of licences granted under this modality. This indicates that original patent owners and improvers generally reach agreements to cross-license or that the restrictive terms of article 31(e) make this form of compulsory license an unattractive option that provides little or no incentive to follow-on innovations.

VI. Conclusions

In order for patent law to secure a sustainable process of innovation, a research or experimental use exemption needs to be recognized.

⁴⁰ For instance, before the reform of the Spanish law to adapt it to the TRIPS standards, it was possible for a party that developed a process to obtain a compulsory license over a patented product.

Such an exception is especially justified in areas where cumulative innovation is crucial, since the flow of innovation decisively depends on the absence of barriers to the use of already protected knowledge. The exception is also essential in fields of radical innovation, since research and experimentation on existing technologies determines ensuing technological progress and, in particular, the development of new applications.

Narrow research exceptions (as well as the lack of use of permitted exceptions) may slow down important research by restricting or delaying access to patented technologies that may be necessary and for which licences are sometimes not available or are too expensive to obtain.

An exception for research or experimentation fulfils without difficulty the three-steps test established by article 30 of the TRIPS Agreement. The panel in the EC-Canada case already hinted its opinion on the TRIPS consistency of such exception, opinion that it is likely to be confirmed if the issue were specifically raised in a WTO dispute. Such consistency can be predicated with regard to exceptions that encompass only scientific, non-profit research or experimentation, as well as in cases where research with commercial intent is included, provided that research or experimentation is conducted on and not with the patented subject matter.

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

REFERENCES

- Australian Law Reform Commission (2004), Genes and Ingenuity: Gene Patenting and Human Health, available at <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>
- Cook, Trevor (1997), "Pharmaceutical Patents and the generics sector in Europe", Patent World, February.
- Correa, Carlos (1990), "Legal protection of the layout designs of integrated circuits: the WIPO Treaty", European Intellectual Property Review, vol. 12. No. 6.
- Correa, Carlos M (2002), "Fair use in the digital era", in International Review of Industrial Property and Copyright Law (IIC), vol. 33, No. 5.
- Federal Trade Commission (FTC) (2003), To promote innovation: the proper balance of competition and patent law policy, available at <http://www.ftc.gov>
- Foray, Dominique (1995), Production and Distribution of Knowledge in the new systems of innovation: the role of intellectual property rights, STI, No.16.
- Freeman, Cristopher, (1987), El reto de la Innovación, Editorial Galac, Caracas.
- Freeman, Christopher (1991), The economics of industrial innovation, France Pinter, London (2nd. edition).
- Neff, R. y Smallson, F. (1994), NAFTA. Protecting and enforcing intellectual property rights in North America, Shepards's/McGraw Hill, Colorado Springs.
- Reichman, J.H., (1995), Intellectual Property Rights and the Dissemination of Technical Knowledge: A Pro-Competitive Strategy for Compliance with the TRIPS Agreement, Paper presented to the UNCTAD Experts Meeting on New Issues in the Area of Intellectual Property Rights and the Transfer of Technology, Competitiveness, and International Trade, Division for Science and Technology, Geneva.
- Ricketson, Sam (2003), WIPO study on limitations and exceptions of copyright and related rights in the digital environment, SCCR/9/7, April 7, Geneva.

Schuster, Reinhardt and Hess, Peter (1997), "Enforcing utility models in Germany", Managing Intellectual Property, November.

Senftleben, Martin (2004), Copyright limitations and the three-step test. An analysis of the three-step test in international and EC copyright law, Kluwer Law International, The Hague.

UNCTAD-ICTSD (2004), Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, available at www.ictsd.org

ANNEX

Legislation in Developing Countries and Countries in Transition on the Research/Experimental Exception to Patent Rights⁴¹

Country	Law	Article
Afghanistan	No patent law	
Albania	Law No. 7819 on Industrial Property, April 1994, as amended by Law No. 8477, April 1999.	<p>Article 27 (3): The owner of a patent shall have no right to prevent third parties from performing without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:</p> <p>b) where the act is done privately and for non-commercial purposes, provided that it does not significantly prejudice the economic interests of the owner of the patent</p> <p>c) where the act is done for purely experimental purposes or for scientific research;</p>
Algeria	<p>Law No. 03-18 on Patents (9 Ramadhan 1424, November 4, 2003) approving Ordinance No.03-07 (19 Joumada El Oula 1424 of July 19, 2003)</p> <p>Ordinance No. 03-07 on Patents (19 Joumada El Oula 1424 of July 19, 2003)</p>	Not available. The laws have been withdrawn while they are being amended so as to comply with TRIPS.
Angola (LDC)	Industrial Property Law No. 3/92, February 1992.	Not available.

⁴¹ Compiled with the assistance of D. Shabalala.

Antigua and Barbuda	The Patents Bill of 2001	Not available.
Argentina	Law No. 24.481 on Patents and Utility Models (as amended by Law No. 24.572)	Article 36(a): a third party who privately or in an academic environment and without gainful intent, conducts scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or applies a process identical to the one patented;
Armenia	Law on Patents (of October 26, 1999)	Article 13: The use of industrial property subject matter protected by a patent shall not be considered to infringe a patent owner's exclusive right: (1) as the subject of a scientific experiment or scientific research
Azerbaijan	Law No. 312 – IQ “On Patents”, June 1997 (entered into force in August 1997).	No English, French or Spanish translation available.
Bahamas	Industrial Property Act 1965 No: 85, commenced June 1967. Industrial Property (Amendment) Act 1975 No. 18, commenced September 1976.	Not available.
Bahrain	The Law No. 1 of the year 2004 was published in the Official Gazette No. 2619 dated January 28, 2004. Patent Regulation of the Cooperation Council for the Arab States of the Gulf (http://www.gulf-patent-	Article 14: The rights under the patent shall not extend to: (1) Acts carried out particularly for scientific research purposes.

	<p>office.org.sa/bahrainframe.htm) Member of Gulf-Cooperation Council</p> <p>Draft Law 2001 on Patent and Utility Models</p>	<p>Article 13: Rights conferred to the owner by a patent shall not cover the following:</p> <p>a) the use of the patent for personal purposes, which are non-commercial and non-industrial, or for research purposes</p>
Bangladesh LDC	Patents and Designs Act No. 11, March 1911.	Not available.
Barbados	Patents Act, 2001-18, entered into force August 2001.	<p>Article 6(1): The rights vested in the owner of a patent by section 5 in respect of any invention do not apply to:</p> <p>(a) the use of the invention for scientific research only;</p>
Belarus	LAW of the Republic of Belarus <u>on</u> “ <u>patents for inventions, utility</u> <u>models and industrial designs</u> ” of 16.12.2002, No. 160-Z	<p>Article 10: The following is not recognized as violations of the exclusive right of the patent-holder:</p> <p>conducting the scientific research or experiment on the method in which the invention, industrial model or industrial design protected by the patent are used; (not an official translation)</p>
Belize	Patents Act (CAP. 253 of the Substantive Laws of Belize) 2000.	Article 33(4): The rights under the patent shall not extend to:

		(c) acts done only for experimental purposes relating to a patented invention;
Benin (LDC)	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Bhutan	The Industrial Property Act of the Kingdom of Bhutan, 2001.	Article 13(4)(a): The rights under the patent shall not extend (3) to acts done only for experimental purposes relating to a patented invention;
Bolivia	Decision No. 344, Common Provisions on Intellectual Property – of the Commission of the Cartagena Agreement October 1993, in force since September 1996. Article 35(c)	Article 35(c): The owner may not exercise that right in any of the following cases: where the use is made at an experimental, academic or scientific level and for non-profit-making purposes.
Bosnia and Herzegovina	Law on Patents and Distinctive Signs, July 1993. - Law on Industrial Property of Bosnia and Herzegovina (effective as of August 27, 2002).	Not available.
Botswana	Industrial Property Act No. 14, 1996.	Article 24(3)(a) The rights under the patent shall not

	Industrial Property (Amendment) Act No. 19, 1997.	extend to: iii) acts done only for experimental purposes relating to a patented invention.
Brazil	Law No. 9.279, May 1996, entered into force May 1997, as amended by Provisional measure 2014-1, December 1999. Law 10.196, of February 14, 2001.	Article 43: The provisions of the previous Article do not apply: (II) to acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches; (VII) to acts performed by non-authorized third parties, regarding patented inventions, which aim exclusively the production of information, data and test results directed to procure commerce registration, in Brazil or any other country, to allow the exploitation and commercialisation of the patented product, after the termination of the terms provided in article 10."
Burkina Faso (LDC)	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Burundi (LDC)	Loi d'août 1964 relative aux brevets. Patent Law, August 1964. Décret-loi No. 1/170 de juillet 1968 portant modification de la Loi	Not available.

	d'août 1964 relative aux brevets. Arrêté ministériel No. 040/750 de juillet 1965 portant mesures d'exécution de la Loi d'août 1964 sur les brevets.	
Cambodia (LDC)	Law on Patents, Utility Model Certificates and Industrial Designs, in force since January 2003.	Article 44: The rights under the patent shall not extend: iii) to acts done only for experimental purposes relating to a patented invention;
Cameroun	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8 (1) The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Cape Verde	No patent legislation in operation.	
Central African Republic (LDC)	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Chad (LDC)	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical

		research;
Chile	Industrial Property Law No. 19.039, January 1991.	<p>Article 52. The following persons shall be liable to a fine of 100 to 500 monthly accounting units payable to the State:</p> <p>(c) any person who fraudulently makes use of a patented procedure. This provision shall not apply where the use of the patented procedure is exclusively for experimental or teaching purposes;</p>
China	<p>Patent Law, March 1984, as amended by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, September 1992, and by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, August 2000.</p>	<p>Article 63. None of the following shall be deemed an infringement of the patent right:</p> <p>(4) Where any person uses the patent concerned solely for the purposes of scientific research and experimentation.</p>
Colombia	Decision No. 486, Andean Community Common Regime on Industrial Property, December 2000.	<p>Article 53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:</p> <p>(a) acts performed in a private circle for non-profit-making purposes;</p> <p>(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;</p> <p>(c) acts performed solely for the purposes of teaching or scientific or</p>

		<p>academic research;</p> <p>(d) acts referred to in Article 5ter of the Paris Convention for the Protection of Industrial Property;</p> <p>(e) where the patent protects biological material, that can be reproduced, other than plants, using that material as the basis with which to obtain viable new material, except where to do so requires repeated use of the patented subject matter.</p>
Congo	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	<p>Article 8(1): The rights deriving from the patent shall not extend:</p> <p>(c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;</p>
Costa Rica	Law on Patents, Industrial Designs and Utility Models No. 6867, June 1983, as amended by Law No. 7979 of January 2000.	<p>Article 16(2) Siempre que las siguientes excepciones no atenten de manera injustificable contra la explotación normal de la patente, ni causen un perjuicio injustificado a los legítimos intereses de su titular o su licenciatario, los derechos conferidos por la patente no se extienden a:</p> <p>b) Los actos realizados con fines experimentales que se refieran al objeto de la invención patentada.</p>

		<p>c) Los actos realizados exclusivamente con fines de enseñanza o de investigación científica o académica respecto del objeto de la invención patentada.</p>
Cote d'Ivoire	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	<p>Article 8(1): The rights deriving from the patent shall not extend:</p> <p>(c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;</p>
Croatia	Patent Law, No. NN 78/99	<p>Article (5) The patent owner's exclusive right of exploitation of the invention shall not apply to:</p> <ol style="list-style-type: none"> 1. acts in which the invention is exploited for private and non-commercial purposes, 2. acts done for the purposes of the research and development of the subject matter of the protected invention, in particular: making, using, offering for sale, importation, or exportation of the protected product, where such acts are reasonably connected with the experiments and tests necessary for the registration of the human and veterinary medicines, medical and veterinary products or preparations for

		the protection of plants,.
Cuba	Decree Law No. 68, May 1983.	<p>Article 54: No se reconocen como violaciones del derecho exclusivo de una invención protegida:</p> <p>3) La utilización de la misma con fines de investigación científica.</p>
Cyprus	Patent Law of 1998	<p>Article 27(3) Notwithstanding paragraphs (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:</p> <p>(ii) where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the proprietor of the patent;</p> <p>(iii) where the act consists of making or using for purely experimental purposes or for scientific research;</p>
Democratic People's Republic of Korea	Law on Inventions and Innovations, June 1986. updated 13. May 1998, updated 11. March 1999	Not available.

Democratic Republic of the Congo LDC	Law No. 82-001, January 1982 (Inventions: arts. 1 to 105). Ordinance No. 89-173, August 1989, implementing Law No. 82-001.	Not available.
Djibouti (LDC)	No Patent legislation	
Dominica	Patents Act No. 8, 1999.	Article 33(4) The rights under the patent shall not extend to c) acts done only for experimental purposes relating to the patented invention
Dominican Republic	Law No. 20-00 on Industrial Property, April 2000.	Article 30: La patente no da el derecho de impedir: b) Actos realizados exclusivamente con fines de experimentación con respecto a la invención patentada; c) Actos realizados exclusivamente con fines de enseñanza o de investigación científica o académica; g) Aquellos usos necesarios para obtener la aprobación sanitaria y para comercializar un producto después de la expiración de la patente que lo proteja.
Ecuador	Intellectual Property, Law, 08/05/1998, No. 83. See also Decision 486 of December 2000, in Colombia above.	Article 150. The owner of a patent may not exercise the right provided for in the foregoing Article in any of

		<p>the following circumstances:</p> <p>(a) where the use takes place in a private circle and on a non-commercial scale;</p> <p>(b) where the use takes place for non-profit-making purposes at an exclusively experimental, academic or scientific level;</p>
Egypt	Intellectual Property Law 82 of 2002	<p>Article 10: the Following shall not be considered as infringements of that right when carried out by third parties</p> <p>1) Activities carried out for scientific research purposes.</p> <p>5) 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.</p> <p>6) Any other acts by third parties, provided that they shall not unreasonably hamper the normal exploitation of the patent, and shall not be unreasonably prejudicial to the legitimate interests of the patent owner, taking into consideration the</p>

		legitimate interests of others.
El Salvador	Legislative Decree No. 604 of 15 July 1993 on the Promotion and Protection of Intellectual Property Rights	Article 116: The effects of the patent shall not extend: b) to a third party who, privately and on a non-commercial scale, or for non-profit making purposes, performs acts in relation to the patented invention c) to a third party who, without gainful intent, engages in the manufacture or use of the subject matter of the patented invention either for experimental purposes or for the purpose of scientific, academic or educational research;
Equatorial Guinea	Decreto-Ley No. 7/1987, por el que se crea el Consejo de Investigaciones Científicas y Tecnológicas, August 1987. Decreto No. 56/1990, por el que se aprueba el Reglamento Orgánico del Consejo de Investigaciones Científicas y Tecnológicas (CICTE), September 1990. Decreto No. 38/1991, por el que se crean los Institutos Especializados del Consejo de Investigaciones Científicas y Tecnológicas (CICTE), May 1991.	Not available.
Eritrea	No Patent Law	
Ethiopia	Proclamation concerning Inventions, Minor Inventions and Industrial Designs, No. 123 of 1995.	Not available.
Fiji	The Fiji Patent Act	No experimental use

		exception
Gabon	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Gambia (LDC)	Industrial Property Act of 1989, published in 1990 (not yet in force): Part II: Patents (sections 3-15).	Not available.
Ghana	The Patent Law, 1992, PNDCL, No. 305A	Text not available in electronic format.
Grenada	Industrial Property Act 2002	Article 12(4)(a): The rights under the patent do not extend: iii) to acts done only for experimental purposes relating to a patented invention;
Guatemala	Ley de Propiedad Industrial, Decreto No. 57-2000, Industrial Property Law, Decree No. 57-2000, issued in August 2000, entered into force in November 2000,	Article 130: La patente no dará el derecho a su titular de impedir: a) Actos realizados en el ámbito privado y con fines no comerciales; b) Actos realizados exclusivamente con fines de experimentación respecto al objeto de la invención patentada; c) Actos realizados exclusivamente con fines

		de enseñanza o investigación científica o académica, sin propósitos comerciales, respecto al objeto de la investigación patentada;
Guinea	Bangui Agreement, March 1977 (Annex I), as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Guinea-Bissau (LDC)	Decreto lei No. 6/96, Capitulo I, February 1997.	Not available.
Guyana	Patents and Designs Act Chapter 90:03 (last amended by Act no. 4 of 1972)	No exception.
Haiti (LDC)	Patents, Designs and Utility Models Act, December 1922, amended by Act of July 1924.	Not available.
Honduras	<i>Ley de Propiedad Industrial, Decreto No. 12-99-E.</i> Law on Industrial Property, Decree No. 12-99-E, January 2000.	Article 18: Los Derechos conferidos por la patente solo podran hacerse valer contra actos realizados por tercero con fines industriales o comerciales. En particular, tales derechos no podran hacerse valer contra actos realizados exclusivamente en el ambito privado y con fines no comerciales, o con fines de experimentacion, investigacion cientifica or ensenanza relativos al objeto de la invencion patentada

India	Patent Act 1970 Patents (Amendment) Act 1999 <u>Patents (Amendment) Act 2002,</u> <u>dated 25th June, 2002</u>	Article 47: The grant of a patent under this Act shall be subject to the condition that: 3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils;
Indonesia	Patent Law No. 6 of 1989 as amended by Law No. 13 of 1997, and last amended by Law No. 14 of 2001.	Article 16(3): 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, experiment, or analysis, as long as it does not harm the normal interest of the patent holder. (not official translation)
Iran	Patent and Trademark Registration Law, July 1931.	Not available.
Iraq	No law as yet	
Jamaica	Patents and Designs Act 2001	Article 79(1) An Act which would, apart from this section, constitute an infringement of a patent, shall not do so if that act: b) is done for experimental purposes relating to the subject matter of the invention

Jordan	Patents of Invention Law No. 32 for the Year 1999 Official Gazette No. 4389 dated 1.11.1999 and its amendment by: Temporary Law No. 71 for the Year 2001 Official Gazette No. 4520 dated 2.12.2001	Article 21C: Notwithstanding any conflicting provision in this law or any other law, all types of scientific research and development and filing applications for obtaining marketing permits carried out before the elapse of the patent protection period shall not be regarded as infringement neither civil nor criminal.
Kazakhstan	Patent Law No. 427-3PK, July 1999.	Article 12: The following shall not constitute acts infringing the exclusive right of the patent owner: - the use of the subject matter incorporating the protected industrial property subject matter for scientific research and experimental purposes; - the use of the subject matter incorporating the protected industrial property subject matter for private and non-commercial purposes;
Kenya	Industrial Property Act of July 2001,	Article 58(1): 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.
Kuwait	Patents, Designs and Industrial Models Law No. 4 of 1962. Patent Law No. 3 of 2001.	No experimental use exception.

		Not available.
Kyrgyzstan	Patent Law, February 1998.	Article 13: The following shall not be deemed to infringe the exclusive right of a patent owner: ii. the use of a device incorporating industrial property subject matter for the purposes of research or scientific experimentation;
Lao People's Democratic Republic	Decree of the Prime Minister on Patents, Industrial Designs and Utility Models, January 2002; Implementing Regulations of the Decree on Patents, Industrial Designs and Utility Models, February 2003.	Not available.
Lebanon	Law No. 240 of August 2000.	Article 42: - A person infringing the rights of a basically published patent while being aware of such action, shall be penalized by a fine ranging from five to fifty million Lebanese Liras and imprisonment from three months up to three years or by either of the penalties hereinbefore mentioned. - Exploiting the invention on non-commercial, non-industrial personal aims or for scientific research reasons shall not be considered counterfeit according to the provisions of the Article herein.
Lesotho (LDC)	Industrial Property Amendment Act of 1995.	
Liberia	An Act Adopting a New Patent, Copyright and Trademark Law, Title 24, approved	Not available.

	May 1972: Chapter 1. Patents (F) IP/PI, November 1977.	
Libya	Law No. 8 of 1959.	No experimental or research exception
Madagascar (LDC)	Décret No 92-993 de décembre 1992 portant application de l'ordonnance No 89-019 de juillet 1989 instituant un régime pour la protection de la propriété industrielle à Madagascar. Ordonnance No 89-019 instituant un régime pour la protection de la propriété industrielle en République démocratique de Madagascar, de juillet 1989 (Titre I)(Art 3 à 54) (JO d'août 1989).	Not available.
Malawi (LDC)	Patents Act No. 13, cap. 49:02, April 1958 (F). Statute Law (Miscellaneous Amendments) Act No. 9, April 1985; Section 10A: Patents granted under the ARIPO Harare Protocol, amending the Patents Act cap. 49:02.	Not available.
Malaysia	Patents Act No. 291 of 1983, as amended by Act No. A648, by Patents Regulations (Amendment) of 1986, by Patents (Amendment) Act No. A863 of 1993 by Patents (Amendment) Regulations of 1993 (in force since August 1995) and by Patents (Amendment) Act 2000.	Article 37(1): 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.
Maldives	Not available.	Not available.
Mali (LDC)	Bangui Agreement of March 2, 1977 (Annex I), since September 1984, as last amended in February 1999.	Article 8: The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are

		carried out for experimental purposes in the course of scientific and technical research;
Mauritania (LDC)	Bangui Agreement, March 2, 1977 (Annex I), since February 1982, as last amended in February 1999.	Article 8: The rights deriving from the patent shall not extend: (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Mauritius	Patents, Industrial Designs and Trademarks Act of 2002	Article 21(4)(d): Any right under the patent shall not extend – d) to acts done only for research and experimental purposes relating to a patented invention;
Mexico	Ley de la Propiedad Industrial publicada por decreto de Agosto de 1994, reformada de Diciembre de 1997 y de Mayo de 1999. Industrial Property Law, published by decree in August 1994, amended in December 1997 and in May 1999.	Article 22(I): a third party who, in the private or academic sphere, and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or process, identical to the one patented.
Moldova	<u>Law on Patents for Invention nr. 461/1995</u>	Article 24(1): The use of an invention protected by a patent shall not constitute an infringement of the patent owner's exclusive right: b) for the performance of research work or scientific experimentation for assessing the application of the subject matter of the invention or for non-

		commercial purposes; e) for private purposes without gain.
Mongolia	Patent Law of Mongolia, June 1993, covering inventions, industrial designs, innovation certificates and utility models, as last amended in April 1995 and in February 1997.	Article 18(2)(2): The performances of the following acts of using patented inventions or industrial designs shall not constitute an infringement of the exclusive rights of patent owners: 2) use for scientific research or experimental purposes in Mongolia.
Morocco	Industrial Property Law No. 17-97, 1997. DAHIR N° 1-00-19 DU 9 Kaada 1420 (15 Février 2000) portant promulgation de la loi n°17-97 relative à la protection de la propriété industrielle.	Article 55 a) aux actes accomplis dans un cadre privé et à des fins non commerciales; b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;
Mozambique (LDC)	By Decree-Law No. 18/99 of May 4, 1999 from the Mozambican Cabinet, an Industrial Property Code has been enacted, and entered into force on July 5, 1999.	Not available.
Myanmar (LDC)	The Myanmar Patents and Designs (Emergency Provisions) Act of 1946.	Not available.
Namibia	Unified Bill on Intellectual Property Rights 2000-2001 (draft law)	Article 17(3) The rights under the patent shall not extend: c) to acts done for scientific research
Nepal (LDC)	Patent, Design and Trademark Act. Act No.15, August 1965.	No experimental or research exception

Nicaragua	Law No. 354, on Patents, Utility Models and Industrial Design.	<p>Article 46: A patent shall not confer the right to prohibit the following acts:</p> <p>a) those conducted in a private circle and for non-commercial purposes, and also those conducted solely for the purposes of experimentation in relation to the subject matter of the patented invention;</p> <p>b) those performed exclusively for teaching or scientific or academic research purposes in relation to the subject matter of the patented invention, and those referred to in Article 5^{ter} of the Paris Convention for the Protection of Industrial Property;</p>
Niger (LDC)	Bangui Agreement, March 1977 (Annex I), since February 1982, as last amended in February 1999.	<p>Article 8(1): The rights deriving from the patent shall not extend:</p> <p>(c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;</p>
Nigeria	Patents and Designs Decree No. 60 of 1970, (F) IP 1973, 147; PI 1973, 151.	<p>Article 3: The rights under a patent:</p> <p>a) shall extend only to acts done for industrial or commercial purposes;</p>

Oman	Royal Decree No. 82/2000, Patent Law.	No research exception
Pakistan	Patents Ordinance of 2000. (As amended by Patents (Amendment) Ordinance, 2002)	Article 30(5): The rights under the patent shall not extend to: c) Acts done only for experimental purposes relating to a patented invention f) Acts done for teaching purposes in educational or research institutions.
Panama	Ley de Propiedad Industrial No. 35. Law on Industrial Property No. 35, May 1996.	Article 19: The right conferred by a patent shall have no effect whatever against: 1) a third party who, in the private sphere and on a non-commercial scale, or for a noncommercial purpose, engages in acts involving the patented invention; 2) an industry or enterprise in the general sense, or an educational or scientific body, that engages in acts of manufacture or use of the invention for experimental purposes relating to the subject matter there or for the purposes of scientific or educational research;
Papua New Guinea	Patent and Industrial Act 2000, in force since January 2001.	Article 29(4) The rights of an owner of a patent shall not extend to: c) acts done only for experimental purposes relating to a patented

		invention;
Paraguay	Law on Patents for Invention No. 1630, November 2000.	<p>Article 34: la patente no dara el derecho de impedir:</p> <p>a) los actos realizados exclusavimente con fines de expeimentacion y sin fines comerciales respecto al objeto de la invencion patentada</p> <p>b) los actos realizados exclusavimente con fines de ensenanza o de investigacion cientifica o academica</p>
Peru	Decision No. 486, Andean Community Common Regime on Industrial Property, December 2000.	<p>Article 53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:</p> <p>(a) acts performed in a private circle for non-profit-making purposes;</p> <p>(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;</p> <p>(c) acts performed solely for the purposes of teaching or scientific or academic research;</p> <p>(d) acts referred to in Article 5^{ter} of the Paris Convention for the Protection of Industrial Property;</p> <p>(e) where the patent protects biological material, that can be reproduced,</p>

		other than plants, using that material as the basis with which to obtain viable new material, except where to do so requires repeated use of the patented subject matter
Philippines	Republic Act No. 8293, the Intellectual Property Rights Code of the Philippines, adopted in June 1997, and in force in January 1998.	Section 72: The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances: 2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: Provided, that it does not significantly prejudice the economic interests of the owner of the patent; 3. Where the act consists of making or using exclusively for the purpose of experiments that relate to the subject matter of the patented invention;
Qatar	Patent Regulation of the GCC (approved by the Supreme Council of the Cooperation Council for the Arab States of the Gulf) of 1992.	Article 14: The rights under the patent shall not extend to: 1) Acts done particularly for experimental purposes.
Rwanda (LDC)	Arrêté ministériel no 5/10/67 de mai 1967 portant mesures d'exécution de la Loi du 25 février 1963 sur les brevets. Loi de février 1963, relative aux brevets.	Not available.
St. Kitts and Nevis	United Kingdom Designs (Protection) Act of 1930, chap.	Not available.

	193, as last amended in 1956.	
St. Lucia	Patents Act, 2001	Article 62(2) An act, which apart from this subsection would constitute an infringement of a patent for an invention shall not do so if- a) it is done for experimental purposes relating to the subject matter of the invention
St. Vincent and the Grenadines	Registration of United Kingdom Patent Act, Chap. 112, Revised Laws, September 1990. United Kingdom Designs (Protection) Act, Chap. 116, Revised Laws, September 1990.	Not available.
Samoa	Patents Act of 1972.	No experimental exception
Sao Tome et Principe	No legislation	
Saudi Arabia	Law No. M/38, May 1989.	Article (24): The rights under a patent shall be confined to acts undertaken in respect of industrial or commercial purposes and they shall not extent in particular to acts performed for scientific purposes.
Senegal LDC	Bangui Agreement, March 1977 (Annex I), since February 1982, as last amended in February 1999.	Article 8(1): The rights deriving from the patent shall not extend (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Serbia and Montenegro	Patent Law, April 1995.	<i>2.7.1. Exceptions</i> The patent rights do not

		affect: 1) the use in personal, non-commercial purposes; 2) the use for conducting research, and 3) the preparation of a single pharmaceutical item by pharmacists in drugstores, upon the prescription of a doctor.
Seychelles	The Patent Act, Cap. 253, Ordinance Nos. 5/1901, 4/1925, 9/1933, 13/1958, 10/1960, 34/1967, as amended by the Constitution (Adaptation and Modification of Existing Law) Order No. 2 of 1976.	<i>Not available.</i>
Sierra Leone LDC	Patents Act No. 21, Chapter 247, of 1924, 10 of 1932, 31 of 1932, 9 of 1957, as amended by the Laws (Adaptation) Act No. 29 of 1972.	<i>Not available.</i>
Singapore	Singapore Patents Act No. 221, November 1994, as amended by the Patents Amendment Act of 1996, the Patents Amendment Act of 2001 (which took effect in January 2002), and the Patents Amendment Act (Commencement) Notification of 2002.	Article 66(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if— a) it is done privately and for purposes which are not commercial; b) it is done for experimental purposes relating to the subject-matter of the invention;
Solomon Islands	Not available.	Not available.

(LDC)		
Somalia	Not available.	
South Africa	Patents Act No. 57 of 1978 (as last amended by Act No. 38 of 1997)	No experimental exception
Sri Lanka	Code of Intellectual Property Act No 52 as last amended by Act No 40 of 2000	Section 82: The provisions of section 81 (rights of a patent owner) 1) extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research
Sudan	Law No. 58 of 1971.	Article 23. (1) The rights under a patent shall only extend to acts done for industrial or commercial purposes.
Suriname	Draft Intellectual Property Act 2000	Article 10(4)(a) the rights under the patent shall not extend: iii) to acts done only for experimental purposes relating to a patented invention
Swaziland	Patents, Utility Models and Industrial Designs Act No. 6 of 1997,	Article 12(4): The rights under the patent shall not extend to: (c) acts done for experimental purposes related to a patented invention.
Syria	Legislative Decree No. 47, October 1946, modified by Law No. 28, April 1980.	No experimental exception
Tajikistan	Provisional Regulations of Inventions, Utility Models and Industrial Designs, February 1994.	Not available.
Tanzania (LDC)	Not available.	Not available.

Thailand	Patent Act No.2, B.E.2535, September 1992, as last amended by Patent Act No. 3, B.E. 2542, March 1999, in force since September 1999.	Section 36: The preceding paragraph shall not apply to: (1) any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner; (not an official translation)
Togo (LDC)	Bangui Agreement, March 1977 (Annex I), as last amended in (WTO No. 6) February 1999.	Article 8(1): The rights deriving from the patent shall not extend (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;
Tonga	Industrial Property Act, 1994.	Article 13(4) (4) The rights under the patent shall not extend: (c) to acts done only for experimental purposes relating to a patented invention;
Trinidad and Tobago	Patent Act No. 21, August 1996. as amended by Intellectual Property (Miscellaneous Amendment) Act No. 18, June 2000.	Article 42: The rights conferred by a patent shall not extend to: a) acts done privately and for non-commercial purposes; b) acts done for experimental purposes relating to the subject matter of the relevant patented invention;

Tunisia	Law on Patents No. 2000-84 of August 2000,	Article 47 Les droits conférés par le brevet ne s'étendent pas: a) aux actes accomplis dans un cadre privé et à des fins non commerciales; b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;
Turkmenistan	Patent Law No. 867-XII, October 1993.	Article 14: Actions being not violation of exclusive rights of patent holder. The following cases: carrying out scientific research or experiment on facilities which includes object of industrial properties;
Uganda (LDC)	Schedule to the Patents Act: The Patents Rules No. 22, December 1993. The Patents Statute No. 10, December 1991.	Not available.
United Arab Emirates	A Decree of the Federal Law No. 17 for the year 2002, amending the Federal Law No. 44 for the year 1992 pertaining to the Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs	Article 15(2): The rights afforded by the letters patent or by the utility certificate as referred to hereinbefore in (1) of article 15 shall be restricted only to those activities adopted to industrial / commercial purposes, and shall not extend to other associated activities with the protection of the product following its sale.
United Republic of Tanzania	Tanzania: The Patents Act No. 1 of 1987 as amended by Acts Nos. 13 and 18 of 1991. Zanzibar: Patents Decree, cap.	Tanzania: Article 37: 1) The rights under the patent shall extend only to acts done

	157 (11 of 1930, cap. 90, 1934, 27 of 1935, s.5, 11 of 1958) (in The Laws of Zanzibar).	for industrial or commercial purposes and in particular not to acts done for scientific research.
Uruguay	Law No. 17.164 regulating Rights and Obligations relating to Patents, Utility Models and Industrial Designs, September 1999.	<p>Article 39: The rights conferred by patents shall not cover the following acts:</p> <p>a) acts carried out in private for non-industrial or non-commercial purposes, provided that they do not cause economic prejudice to the owner of the patent;</p> <p>c) acts carried out solely for experimental purposes, including acts anticipating future commercial exploitation, carried out during the year prior to expiry of the patent;</p> <p>d) acts carried out for teaching, scientific or academic research purposes;</p>
Uzbekistan	Law on Inventions, Utility Models and Industrial Designs No. 1068-XII, May 1994.	<p>Article 12: The following shall not be recognized as an infringement of a patent owner's exclusive right:</p> <p>- the conduct of scientific research or an experiment on means containing industrial property subject matter protected by patents;</p> <p>- the use of means containing industrial property subject matter protected by patents, for personal reasons without an income being obtained;</p>
Venezuela	Decision No. 486, Andean	Article 53. The owner of the

	<p>Community Common Regime on Industrial Property, December 2000.</p>	<p>patent may not exercise the right referred to in the foregoing Article in relation to the following acts:</p> <p>(a) acts performed in a private circle for non-profit-making purposes;</p> <p>(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;</p> <p>(c) acts performed solely for the purposes of teaching or scientific or academic research;</p> <p>(d) acts referred to in Article 5^{ter} of the Paris Convention for the Protection of Industrial Property;</p> <p>(e) where the patent protects biological material, that can be reproduced, other than plants, using that material as the basis with which to obtain viable new material, except where to do so requires repeated use of the patented subject matter</p>
<p>Vietnam</p>	<p>The Civil Code of the Socialist Republic of Vietnam passed by the National Assembly in October 1995 and effective from July 1996 (Part Six “Intellectual Property and Technology Transfer”; Chapter II “Industrial Property”).</p>	<p>Article 12(2) The following acts shall not be considered to amount to infringement of the rights of an owner of a protected title:</p> <p>a) The utilization of the object of industrial property for non-commercial purposes.</p>

Yemen	Law No. 19 of 1994.	No experimentation exception
Zambia (LDC)	The Patents Act, Cap. 692, Federal Acts Nos. 13 of 1957, 12 of 1959, 36 of 1960, 1 of 1962, Government Notices Nos. 185 of 1964, 497 of 1964, Statutory Instrument No. 175 of 1965, as amended by The Patents (Amendment) Acts Nos. 18 of 1980 and 26 of 1987.	Not available.
Zimbabwe	The Patents Act Chapter 26:03, February 1972, Patents Amendment Bill, 2001, before Parliament for debate.	No experimental exception.

LDC: Least Developed Country