

5. Patent Exceptions and Limitations in the Health Context by Coenraad Visser

Table of Contents

1	Human Rights Framework	1
2	Patent Exceptions and Limitations.....	3
2.1	Compulsory licences	3
2.2	Individual Prescriptions	24
2.3	Parallel imports	24
2.4	Regulatory Exception.....	26

Patent Exceptions and Limitations in the Health Context

1 Human Rights Framework

A fundamental distinction in human rights law is between the so-called civil and political rights (“first generation” rights), on the one hand, and socio-economic rights (“second generation” rights), on the other. The former are “negative” rights that curb state power by imposing a duty on it not to act in certain ways; the latter are “positive rights” that impose obligations on the state to secure for its citizens a basic set of social goods - education, health care, food, water, shelter, and access to land and housing.

The most important international instrument on socio-economic rights is the International Covenant on Economic, Social and Cultural Rights (ICESCR)¹ of 1966, which has been ratified by some 130 states.

One of the substantive rights recognized by the Covenant is “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.² In particular, parties are obliged to take steps necessary for “the prevention, treatment and control of epidemic, endemic, occupational and other diseases”,³ and “the creation of conditions which would assure to all medical service and medical attention in the event of sickness”.⁴

The overarching obligation imposed by the Covenant is “to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures”.⁵ It is important to note that the obligation is not absolute⁶ - states have to move “progressively” towards the full realization of the right, and they have to do so within their available resources.

Many constitutional democracies incorporate socio-economic rights along the lines of the Covenant. Some do so in the form of directly enforceable rights,⁷ while the majority

1 GA res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 49, UN Doc. A/6316 (1966); 993 U.N.T.S. 3; 6 I.L.M. 368 (1967) [hereinafter “ICESCR”]. It entered into force on 3 January 1976, in accordance with Article 27.

2 ICESCR, Art. 12(1).

3 ICESCR, Art. 12(2)(c).

4 ICESCR, Art. 12(2)(d).

5 ICESCR, Art. 2(1).

6 Compare Art. 2(1) of the International Covenant on Civil and Political Rights, GA res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 52, UN Doc. A/6316 (1966); 999 U.N.T.S. 171; 6 I.L.M. 368 (1967): : “Each State Party ... undertakes to respect and ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant.”

7 For example, Hungary (Constitution of the Republic of Hungary, 1949, as amended, Art. 70/D), Lithuania (Constitution of the Republic of Lithuania, 1992, Art. 53), Portugal (Constitution of the Portuguese Republic, 1976, Art. 64), and South Africa (Constitution of the Republic of South Africa, 1996, Art. 27).

prefer to do so in the guise of “directive principles of state policy”.⁸ Such principles are not directly justiciable but may affect the interpretation of other rights by being ‘read into’ those rights, or may be relevant in the interpretation of legislation. For example, under Article 37 of the Indian Constitution, the directive principles “shall not be enforceable by any court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws”.

Where the socio-economic rights are at their strongest - where they are directly enforceable - they are not absolute but subject to reasonable limitation,⁹ and often clash with property rights.¹⁰

The primary responsibility for the enforcement of the Covenant lies with the Committee on Economic, Social and Cultural Rights, established in 1987 to monitor compliance with the Covenant.

The Committee realizes, generally, that two forms of state action are required.¹¹ In the first instance, a state must “adopt ... legislative measures” - create a legal framework within which individuals can pursue their rights. Secondly, the state has to implement other measures and programmes designed to assist individuals in realizing their rights.

Again, the obligation on states is not absolute but qualified in two respects.

In the first instance, a state must take appropriate steps towards achieving progressively the full realization of the right. The reference to progressive achievement does not hide the obligation that the state must take those steps that are within its power immediately and other steps as soon as possible. In *Soobramoney v. Minister of Health (Kwa-Zulu-Natal)*,¹² for example, the South African Constitutional Court held that while the state has a discretion in determining which measures it will implement and how it will utilize its resources, it must show that it is exercising its discretion rationally and in good faith. The margin of discretion is considerable.¹³

Secondly, resource scarcity does not relieve a state of its “core minimum obligation” - “to ensure the satisfaction of, at the very least, minimum essential levels of each of the

8 For example, Brazil (Constitution of the Federative Republic of Brazil, 1988, as amended, Art. 6), India (Constitution of India, as amended, Art. 47), Ireland (Constitution of Ireland, 1937, as amended, Art. 45), and Namibia (Constitution of the Republic of Namibia, 1990, as amended, Art. 95).

9 For example, in South Africa, section 36(1) of the Constitution of the Republic of South Africa, 1996, states that “[t]he rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including - (a) the nature of the right; (b) the importance of the purpose of the limitation; (c) the nature and extent of the limitation; (d) the relation between the limitation and its purpose; and (e) less restrictive means to achieve the purpose.

10 For example, Hungary (Constitution of the Republic of Hungary, 1949, as amended, Art. 30), Lithuania (Constitution of the Republic of Lithuania, 1992, Art. 23), Portugal (Constitution of the Portuguese Republic, 1976, Art. 62), and South Africa (Constitution of the Republic of South Africa, 1996, Art. 25).

11 UN Committee on Economic, Social and Cultural Rights, General Comment 3 (1990), “The Nature of States Parties’ Obligations” UN Doc HR1/Gen 1/Rev 1, para.4.

12 1998 (1) SA 765 (CC), paras 29-39.

13 UN Committee on Economic, Social and Cultural Rights, General Comment 3 (1990), “The Nature of States Parties’ Obligations” UN Doc HR1/Gen 1/Rev 1, para.4.

rights”.¹⁴ Such core minimum obligation is lifted only when the state can show that its resources are “demonstrably inadequate” to allow it to fulfill its duties. And even when resources are demonstrably inadequate, the obligation remains on a state to strive to ensure the widest possible enjoyment of the relevant rights under the prevailing circumstances.¹⁵

What is the significance of the human rights framework in the present context?

In the first instance, it provides an organisational matrix for the diverse pro-health provisions in patent laws. In so doing, it also motivates the adoption of these provisions in countries where they do not exist in patent laws.

Secondly, it brings to the fore the competing claims of patentees and consumers. For example, in 1998, the South African Pharmaceutical Manufacturers Association and 40¹⁶ mostly multinational pharmaceutical manufacturers instituted action against the South African government. They alleged that the Medicines and Related Substances Control Amendment Act¹⁷ their property right as entrenched in the South African constitution.¹⁸ The Amendment Act introduced a legal framework to increase the availability of affordable medicines in South Africa by generic substitution of off-patent medicines, transparent pricing, and the parallel importation of patented medicines. Had the case proceeded to judgment, it would have been interesting to see how the court would have weighed the property right of the patentees against the right to health care services,¹⁹ especially given the constitutional obligation of the State to “take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of” this right.²⁰ However, this point is still moot, given that the case was withdrawn before it could proceed to judgment.

2 Patent Exceptions and Limitations

In the health context, four of these will be surveyed here: compulsory licences, individual prescriptions, parallel imports, and the regulatory exception.

2.1 Compulsory licences

2.1.1 Introduction

“The provision of compulsory licenses is a crucial element in a health-sensitive patent law. Such licenses may constitute an important tool to promote competition and

14 UN Committee on Economic, Social and Cultural Rights, General Comment 3 (1990), “The Nature of States Parties’ Obligations” UN Doc HR1/Gen 1/Rev 1, para.10.

15 UN Committee on Economic, Social and Cultural Rights, General Comment 3 (1990), “The Nature of States Parties’ Obligations” UN Doc HR1/Gen 1/Rev 1, para.11.

16 Later 39, as a result of a merger.

17 Act No. 90 of 1997.

18 Constitution of the Republic of South Africa, 1996, s. 25(1): “No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.”

19 Constitution of the Republic of South Africa, 1996, s. 27(1)(a).

20 Constitution of the Republic of South Africa, 1996, s. 27(2).

increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.”²¹

At the same, their importance may sometimes be overstated in developing and, especially least developed countries in the health context. In the first instance, the vast majority of products on the essential medicines list issued by the World Health Organisation is off patent. Secondly, the frequency of patenting in a country is largely explained by its market size - an inventor’s incentive to patent is greatest where there are more consumers having more disposable income.²² In very poor, low-income developing countries, predominantly in Africa, annual per capita medicine spending is negligible, so that many pharmaceutical manufacturers decide to forgo patent protection in these countries. Instead, patenting is commonplace only in large, middle-income countries (such as Brazil, China, South Africa, and Mexico). So while these low-income countries may “benefit” from the absence of drug patents in that they can manufacture these drugs themselves, they do not have the manufacturing capacity to do so. Their interest in compulsory licences, therefore, is of a special kind - in the ability of countries with manufacturing capacity to manufacture medicines under compulsory licence there to supply at affordable prices to the low-income countries.

2.1.2 International Context

Under the Paris Convention for the Protection of Industrial Property, a country of the Union may provide for compulsory licences “to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”.²³ An applicant may not apply for a compulsory license for failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application, or three years from the date of the grant of the patent, whichever period expires last.²⁴ The application must be refused if the patentee justifies his inaction by legitimate reasons.²⁵ Such a compulsory license must be non-exclusive and not-transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.²⁶

The restrictions on compulsory licences were restated and increased by Article 31 of the TRIPS Agreement,²⁷ headed “Other use without authorization of the right holder”. It allows a Member to provide for the use of the subject matter of a patent without the authorization of the right holder, including use by the government, or third parties authorized by the government.

²¹ Carlos Correa Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre: Geneva 2000 p. 94.

²² Amir Attaran, “How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?”, 23 Health Affairs (2004) 155, 158.

²³ Paris Convention, Art. 5A(2).

²⁴ Paris Convention, Art. 5A(4).

²⁵ Ibid.

²⁶ Ibid.

²⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: the Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter “TRIPS Agreement”].

There are certain common requirements: (a) the authorization of such use must be considered on its individual merits; (b) such use may be permitted only if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions, which efforts have not been successful within a reasonable time; (c) the scope and duration of such use must be limited to the purpose for which it was authorized, (d) such use must be non-exclusive; (e) such use must be non-assignable, except with that part of the enterprise or goodwill which enjoys such use; (f) any such use must be authorized predominantly for the supply of the domestic market of the Member authorizing such use; (g) authorization for such use must be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority must have the authority to review, upon motivated request, the continued existence of these circumstances; (h) the right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; (i) the legal validity of any decision relating to the authorization of such use must be subject to judicial review, or other independent review by a distinct higher authority in that Member; and any decision relating to the remuneration provided in respect of such use must be subject to judicial review, or other independent review by a distinct higher authority in that Member.

Requirement (b) may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use. In these situations the right holder must still be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or third-party contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder must be informed promptly.

Requirements (b) and (f) need not be met where such use is permitted to remedy an anti-competitive practice, determined by judicial or administrative process. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities may refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

Any decision relating to the remuneration provided in respect of such use is subject to judicial review, or other independent review by a distinct higher authority in that Member.

Where such use is authorized to permit the exploitation of a patent (“the second patent”) that cannot be exploited without infringing another patent (“the first patent”), the following additional conditions apply: (i) the invention claimed in the second patent must 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 must be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and (iii) the use authorized in respect of the first patent must be non-assignable except with the assignment of the second patent.

From this it appears that compulsory licences fall broadly into four main categories - licences to correct an abuse of rights, licences to address a national emergency or a situation of extreme urgency, and dependant patents.

In the context of public health, the first two categories are significant.

From the perspective of developing countries, Article 31(f) of TRIPS presented a significant obstacle to their providing treatment for HIV/AIDS, tuberculosis, and malaria, for example, diseases affecting citizens of developing countries disproportionately: by requiring that medicines produced under compulsory licence be predominantly for the domestic market, Article 31(f) renders compulsory licences under Article 31 cold comfort to countries that are unable to manufacture the patented medicines themselves.

At the Fourth Ministerial Conference in Doha, in November 2001, delegates agreed that “that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”.²⁸ They affirmed that the agreement “... can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all WTO members”.²⁹ The delegates added that “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”.³⁰ Of special importance, the delegates recognized that “... WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”.³¹ They were unable to decide how this difficulty should be allayed and so instructed the Council for TRIPS to find a solution.

Subsequently, the African group of countries, among others, submitted to the Council for TRIPS that, inter alia, that the reference to “domestic market” be read to refer to the markets of all parties to a regional trade agreement,³² and that the solution is intended to be part of a permanent or long-term solution to the problem of lack of or insufficiency of manufacturing capacity, while at the same time the solution responds to the short-term or immediate needs of developing countries with such capacity problems.³³ It was also proposed that Article 31(f) of TRIPS be amended by the addition of the following sentence: “This restriction to supply predominantly for the domestic market shall not apply to laws and measures adopted to address public health problems.”³⁴

On 30 August 2003, the General Council of the WTO adopted a decision to waive the obligations of an exporting Member under Article 31(f) in respect of the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product and its export to an eligible importing Member.³⁵ For the purposes of the Waiver Decision, the term “pharmaceutical product” connotes “any patented product, or product

28 WTO, Declaration on the TRIPS Agreement and Public Health (20 Nov. 2001) WT/MIN(01)/DEC/2, para. 4.

29 Ibid.

30 WTO, Declaration on the TRIPS Agreement and Public Health (20 Nov. 2001) WT/MIN(01)/DEC/2, para. 5(c).

31 WTO, Declaration on the TRIPS Agreement and Public Health (20 Nov. 2001) WT/MIN(01)/DEC/2, para. 6.

32 WTO, Council for TRIPS, Elements of a Paragraph 6 Solution: Communication From Kenya, the Coordinator of the African Group (14 Nov. 2002) IP/C/W/389, paras 14(c) and 16(c).

33 WTO, Council for TRIPS, Elements of a Paragraph 6 Solution: Communication From Kenya, the Coordinator of the African Group (14 Nov. 2002) IP/C/W/389, para. 6(a).

34 WTO, Council for TRIPS, Elements of a Paragraph 6 Solution: Communication From Kenya, the Coordinator of the African Group (14 Nov. 2002) IP/C/W/389, para. 18(a).

35 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and (30 August 2003), Doc. WT/L/540 (1 September 2003) para. 2 [hereinafter “Waiver Decision”].

manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration”;³⁶ the definition includes active ingredients necessary for its manufacture and diagnostic kits needed for its use. The term “eligible importing member”, in turn, connotes “any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use”.³⁷

Certain conditions attach to utilizing the waiver.

In the first instance, an eligible importing Member must lodge a notification with the Council for TRIPS, which (a) specifies the names and expected quantities of the product(s) needed; (b) confirms that the Member in question, other than a least developed country Member, has established that it has no or insufficient manufacturing capacity in the pharmaceutical sector for the product(s) in question; and (c) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the Waiver Decision.³⁸ Least-developed country Members are deemed to have no or insufficient manufacturing capacity in the pharmaceutical sector.³⁹ For other eligible importing Members no or insufficient manufacturing capacity for the product in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity in this sector, it has examined such capacity and found that, excluding any capacity owned or controlled by the patentee, it is currently insufficient to meet its needs.⁴⁰

Secondly, the compulsory licence issued by the exporting Member must contain the following conditions: (a) only the amount necessary to meet the needs of the eligible importing Member may be manufactured under the licence, and the entire production must be exported to the Member which has notified its needs to the Council for TRIPS; (b) products produced under the licence must be clearly identified as being produced under the Waiver Decision through specific labeling or marking. Suppliers must distinguish such products through special packaging and/or special colouring or shaping of the products themselves, provided that such distinction is feasible and does not have a significant price impact; and (c) before the products are shipped, the licensee must post on a web site certain information (the quantities being supplied to each destination, and the distinguishing features of the product(s)).⁴¹

Thirdly, the exporting Member must notify the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁴²

36 Waiver Decision, para. 1(a).

37 Waiver Decision, para. 1(b).

38 Waiver Decision, para 2(a).

39 Waiver Decision, Annex.

40 Waiver Decision, Annex.

41 Waiver Decision, para. 2(b).

42 Waiver Decision, para. 2(c).

Fourthly, where a compulsory licence is granted by an exporting Member under the Waiver Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement must be paid in that Member, taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member.⁴³ This provision avoids the possibility of remuneration having to be paid twice, in both the importing and exporting Members, as both issue compulsory licences.

Fifthly, to ensure that the products imported under the Waiver Decision are used for the public health purposes underlying their importation, eligible importing Members must take “reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion” to prevent re-exportation of the products that have actually been imported into their territories under the Waiver Decision.⁴⁴

Sixthly, Members must ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the Waiver Decision and diverted to their markets inconsistently with its provisions. Members need not establish mechanisms for this purpose over and beyond those already required to be available under the TRIPS Agreement.⁴⁵ “Implicit in this scheme is an understanding that medicines produced under the relevant compulsory licenses should not be treated as ‘lawful parallel imports’ after having initially been placed on the market.”⁴⁶

In order to harness economies of scale for the purposes of enhancing purchasing power for, and facilitate the local production of, pharmaceutical products, where a developing or least-developed country WTO Member is a party to a regional trade agreement, at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries,⁴⁷ the obligation of that Member under Article 31(f) of the TRIPS Agreement is waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.⁴⁸

Canada was the first country to pass legislation to implement Waiver Decision, through An Act to Amend the Patent Act and the Food and Drugs Act - The Jean Chretien Pledge to Africa, which came into force on 14 May 2005. This regime allows Canadian producers to acquire compulsory licenses in order to produce patented drugs for countries requesting these drugs. The compulsory licenses are issued by the Canadian Intellectual Property Office.⁴⁹

43 Waiver Decision, para. 3.

44 Waiver Decision, para. 4.

45 Waiver Decision, para. 5.

46 Frederick M. Abbott & Jerome H. Reichman, “The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions”, 10 J. Of Int’l Econ. L (2007) 921, 944.

47 Compiled by the United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing Countries, and available at <<http://www.unohrrls.org/en/ldc/related/62/>> [accessed 30 June 2010].

48 Waiver Decision, para. 6(i).

49 They are available at <<http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00682.html>> [accessed on 30 June 2010].

Only Rwanda as least developing country has availed itself of this facility as importing Member.⁵⁰ The related exporting Member is Canada.⁵¹

Some have argued that the decision will do little to make compulsory licencing a viable vehicle for access to medicines for the poor in least developed and developing countries:

“After years of debate, the WTO enacted a mitigating policy in August 2003, which allows patent rights to be forcibly overridden using a legal procedure called ‘compulsory licensing’, so that generic medicines can be manufactured and exported to poor countries that cannot manufacture their own. It is extremely doubtful that this use of compulsory licensing, although much celebrated, can be made practicable. Indeed, compulsory licensing is so disused that even where a country’s own citizens might benefit from it - never mind foreigners in poor countries - zero generic medicines have been manufactured this way in the past decade, treating zero patients in any country worldwide. Threats of compulsory licensing might be useful when rattling sabers with drug companies to lower medicine prices, but only a single (and unusually powerful) developing country, Brazil, has ever succeeded in so doing. As such, compulsory licensing or the threat of it has seldom had any practical effect for public health.”⁵²

This decision did improve, though, export opportunities also for the generic pharmaceutical sectors in emerging economies such as Brazil, China, and India.⁵³

The Fifth Ministerial Conference in Cancun, in September 2003, ended in deadlock as to the next phase of the Doha process.

In December 2005, the WTO General Council decided that the flexibility inherent in the Waiver Decision should become a permanent part of TRIPS. It adopted a Protocol amending the TRIPS Agreement by inserting a new Article 31*bis*. The amendment will take effect when two thirds of WTO members have accepted the change.⁵⁴ The deadline for acceptance is now 31 December 2011.⁵⁵ Once two thirds of the members have formally accepted it, the amendment will take effect in those members and will replace the Waiver Decision for them. For the remaining members, the waiver will continue to apply until that member accepts the amendment and it takes effect.

50 WTO, Council for TRIPS, Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Rwanda (19 July 2007) IP/N/9/RWA/1.

51 WTO, Council for TRIPS, Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Canada (8 October 2007) IP/N/10/CAN/1.

52 Amir Attaran, “How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?”, 23 *Health Affairs* (2004) 155, 161.

53 Frederick M. Abbott & Jerome H. Reichman, “The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions”, 10 *J. Of Int’l Econ. L.* (2007) 921, 929.

54 WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization, 15 Apr. 1994, *The Legal Texts: the Results of the Uruguay Round of Multilateral Trade Negotiations* 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994), Art. X, para. 3 [hereinafter “WTO Agreement”].

55 WTO, General Council, Amendment of the TRIPS Agreement - Second Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (17 December 2009), WT/L/785 (18 December 2009).

The new Article 31*bis* and the Annex to be inserted after Article 73 of the TRIPS Agreement repeats the provisions of the Waiver Decision. The amendment confirms that, subject to certain conditions set out in the Annex, the obligations of an exporting Member under Article 31(f) do not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of the production of a pharmaceutical product and its export to an eligible importing Member. Adequate remuneration pursuant to Article 31(h) must be paid taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. To harness economies of scale for the purposes of enhancing purchasing power for, and facilitate the local production of, pharmaceutical products, where a developing or least developed country WTO Member is a party to a regional trade agreement, at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) does not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.

It has been noted that as Rwanda was the only member to trigger the mechanism of the Waiver Decision, “there is neither a strong experiential basis for recommending acceptance of the Amendment, nor of declining to accept it. The question is largely political...”⁵⁶

As of 16 March 2010, the following countries have accepted the amendment: the United States of America (17 December 2005); Switzerland (13 September 2006); El Salvador (19 September 2006); the Republic of Korea (24 January 2007); Norway (5 February 2007); India (26 March 2007); Philippines (30 March 2007); Israel (10 August 2007); Japan (31 August 2007); Australia (12 September 2007); Singapore (28 September 2007); Hong Kong, China (27 November 2007); China (28 November 2007); the European Union (30 November 2007); Mauritius (16 April 2008); Egypt (18 April 2008); Mexico (23 May 2008); Jordan (6 August 2008); Brazil (13 November 2008); Morocco (2 December 2008); Albania (28 January 2009); Macau, China (16 June 2009); Canada (16 June 2009); Bahrain (4 August 2009); Colombia (7 August 2009); Zambia (10 August 2009); Nicaragua (25 January 2010); Pakistan (8 February 2010); and the Former Yugoslav Republic of Macedonia (16 March 2010).

2.1.3 Typology

The term “compulsory licence” is often used as an umbrella term for many types of non-voluntary authorizations to exercise a patentee’s rights without his or her authorisation, such as ex officio licenses, government use, crown (or government) use, licences to remedy anti-competitive practices, mandatory licenses, and statutory licenses.

Procedurally, the requirements are pretty standard in all patent laws, as dictated by the TRIPS Agreement:

- a compulsory licence is case and fact specific;
- a compulsory licence may not be exclusive;

⁵⁶ Frederick M. Abbott & Jerome H. Reichman, “The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions”, 10 J. Of Int’l Econ. L (2007) 921, 933.

- a compulsory licence may not be assigned except to a person who also takes assignment of the part of the enterprise that uses the patented invention, or of the goodwill that belongs to that part;
- a compulsory licence is predominantly for the supply of the local market;
- a compulsory licence must be limited in scope and duration to the purpose for which it is granted; and
- a compulsory licence must provide for adequate remuneration to be paid to the patentee, taking into account the economic value of the licence.

The burden is on the applicant for a compulsory licence to prove the grounds for issuing the licence.

Substantively, in the health context, Carlos Correa has argued that a health-sensitive patent law may specifically provide for several grounds for compulsory licenses:

- lack or insufficiency of working;
- refusal to deal;
- anti-competitive practices;
- emergency;
- government use; and
- public interest.⁵⁷

These grounds also suggest appropriate clusters of the diverse compulsory licensing provisions found in national laws.

2.1.3.1 Lack or insufficiency of working

This ground is expressed in a number of ways. For example:

- the invention has not been worked, or only partially implemented by the patentee;
- the demand for a patented product is not being met to an adequate extent and on reasonable terms;
- the reasonable requirements of the public with respect to the patented product have not been satisfied;
- the patented product is not available to the public at a reasonable price; or
- the quality of the patented product available to the public is not acceptable (poor).

The lack or insufficiency of working is often evaluated after a stated period has elapsed, such as four years since the date of the patent application, or three years since the grant of the patent.

National laws also state criteria to determine sufficient (or, negatively, inadequate) working. These include -

- whether any existing trade or industry, or the establishment of any new trade or industry in the compulsory licence issuing country is unfairly prejudiced;
- the market for the export of the patented article manufactured in the compulsory licence issuing country is not being supplied or developed;

⁵⁷ Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre, Geneva (2000), pp. 97-98.

- the establishment or development of commercial activities in the compulsory licence issuing country is prejudiced;
- by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire, or use of the patented article or process, the manufacture, use or sale of materials *not* protected by the patent, or the establishment or development of any trade or industry in the compulsory licence issuing country is prejudiced; or
- the working of the patented invention in the compulsory licence issuing country is being prevented or hindered by the importation of the patented article.

It is still an area of contention whether or not domestic demand should be met through local working (manufacture in the country) only, or whether meeting domestic demand would be sufficient. Some countries explicitly require local manufacture, while others leave the matter open in their national laws; a few state explicitly that importation constitutes working.

In 2001, the United States Trade Representative (USTR) questioned with the WTO whether Article 68 of the Brazilian Patent Law violated Articles 27 and 28 of the TRIPS Agreement. The contentious provision allows for compulsory licenses to be issued in situations where the patentee does not locally work the patent. In particular, the USTR argued that the definition of failure to be worked as connoting a failure to manufacture or incomplete manufacture of the product, or a failure to make full use of the patented process.⁵⁸ The parties subsequently reached a settlement, and the United States of America withdrew the complaint.⁵⁹

These countries, for example, provide for compulsory licences on this ground: Algeria,⁶⁰ Argentina,⁶¹ Bahrain,⁶² Bangladesh,⁶³ Brazil,⁶⁴ Canada,⁶⁵ Egypt,⁶⁶ Ethiopia,⁶⁷ Ghana,⁶⁸ India,⁶⁹ Indonesia,⁷⁰ Jordan,⁷¹ Kenya,⁷² Lebanon,⁷³ Malaysia,⁷⁴ Mexico,⁷⁵

⁵⁸ Brazil - Measures Affecting Patent Protection - Request for Consultations by the United States, WT/DS199/1, G/L/385, IP/D/23 (8 June 2000).

⁵⁹ Brazil - Measures Affecting Patent Protection - Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1 (19 July 2001).

⁶⁰ Ordonnance n° 03-07 du 19 Jomada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention, Art. 38.

⁶¹ Ley de Patentes de Invención y Modelos de Utilidad, N° 24.481, modificada por la Ley N° 24.572, Art. 43.

⁶² Law No. 14 for the year 2006 Amending Some Provisions of Law Number 1 of the Year 2004 in Respect of Patents and Utility Models, Art. 24(b).

⁶³ Patents and Designs Act, 1911, s. 22.

⁶⁴ Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 68(1).

⁶⁵ Patent Act, R.S.C. 1985, c. P-4, ss. 65-71.

⁶⁶ Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 23(4).

⁶⁷ Proclamation No. 123/1995 Concerning Inventions, Minor Inventions and Industrial Designs, Art. 29(3).

⁶⁸ Patent Law, 1992, PNDCL, No. 305A, s. 45.

⁶⁹ Patents Act, 1970, s. 84(1).

⁷⁰ Law No. 14 of 1 August 2001 Regarding Patents, Art. 75(2).

⁷¹ Patents of Invention Law No. 32 of 1999 and its Amendment by Temporary Law No. 71 of 2001, Art. 22B.

⁷² Industrial Property Act, 2001, s. 72.

⁷³ Patents Law No. 240 of 7 August 2000, Art. 32.

⁷⁴ Patents Act No. 291 of 1983, as amended, s. 49(1)(a).

⁷⁵ Ley de la Propiedad Industrial del 25 de junio de 1991 con las últimas enmiendas del 17 de mayo de 1999, Arts. 70-74.

Morocco,⁷⁶ Mozambique,⁷⁷ Nigeria,⁷⁸ Philippines,⁷⁹ Qatar,⁸⁰ Saudi Arabia,⁸¹ South Africa,⁸² Tanzania,⁸³ Thailand,⁸⁴ Tunisia,⁸⁵ Uruguay,⁸⁶ Zambia,⁸⁷ Zimbabwe.⁸⁸

This cluster would, arguably, also include government rights such as the march-in rights in terms of the Bayh-Dole Act⁸⁹ in the United States of America. These rights enable the Federal funding agency, on its own initiative or at the request of a third party, effectively to override the exclusivity of a patent obtained under the Act and grant additional licenses to other “reasonable applicants”. This right is strictly circumscribed and can be exercised only if the agency determines, after an investigation, that, inter alia, the contractor had failed to take “effective steps to achieve practical application of the subject invention”.

2.1.3.2 Refusal to Deal

This ground relates to a situation where patentee refuses to grant a voluntary license when requested to do so on reasonable commercial terms. The refusal to deal is often linked to other factors, such as that the availability of the patented product is negatively affected by such refusal, or the development of a commercial activity jeopardized by such refusal.

Examples of refusal to deal provisions can be found in the legislation of, amongst others, Argentina,⁹⁰ China,⁹¹ Egypt,⁹² Indonesia,⁹³ Pakistan,⁹⁴ Philippines,⁹⁵ Qatar,⁹⁶ Saudi Arabia,⁹⁷ South Africa,⁹⁸ and Uruguay.⁹⁹

76 Loi n° 13-99 portant création de l'Office marocain de la propriété industrielle et commerciale (Dahir n° 1-00-71 du 9 kaada 1420 (15 février 2000)), Art. 60.

77 Industrial Property Code (Approved by Decree No. 04/2006 of 12th April 2006), Art. 83.

78 Patents and Designs Act, Chapter 344, 1990, Schedule 1, paras. 1-14.

79 Intellectual Property Code, s. 93(5) (states expressly that importation constitutes working or using the patent).

80 Patents Law, as enacted by Decree Law No. 30 for the Year 2006 to Issue Patents' Law, Art. 15(a)-(b).

81 Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs, 2004, Art. 24(a)(1).

82 Patents Act No. 57 of 1978, s. 56(2).

83 Patents Act No. 1 of 1987, s. 52.

84 Patent Act B.E. 2522 (1979), s. 46.

85 Loi n° 2000-84 du 24 août 2000, relative aux brevets d'invention, Art. 69.

86 Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 54.

87 Patents Act, Chapter 400 of the Laws of Zambia, s. 37.

88 Patents Act (Chapter 26:03) (as last amended by Act 20/1994 (S.7)), s. 31.

89 35 U.S.C. § 203.

90 Ley de Patentes de Invención y Modelos de Utilidad, N° 24.481, modificada por la Ley N° 24.572, Art. 42. Carlos María Correa, “Licencias Obligatorias”, in” Derecho de Patentes, Buenos Aires (1996) 174 states that this provision is compatible with the TRIPS Agreement on the basis of competition concerns. Cf CABANELLAS, op. Cit., vol. II, p. 433, who denies such compatibility.

91 Patents Law, 2000, Art. 48.

92 Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 23(3).

93 Law No. 14 of 1 August 2001 Regarding Patents, Art. 76(3).

94 Patents Ordinance No. LXI of 2 December 2000, Art. 58(4).

95 Intellectual Property Code, s. 95(1).

96 Patents Law, as enacted by Decree Law No. 30 for the Year 2006 to Issue Patents' Law, Art. 15(c).

97 Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs, 2004, Art. 24(a)(2).

98 Patents Act No. 57 of 1978, s. 56(2).

99 Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 66.

2.1.3.3 Anti-competitive Practices

This ground can either be stated as a general proscription of anti-competitive behaviour, or as a catalogue of factors to be considered by the compulsory licence issuing authority. These factors include:

- excessive (exorbitant) pricing;¹⁰⁰
- preferential treatment as regards prices and conditions of sale;
- failure to supply the domestic market with the patented product, or supplying it on prohibitive terms;
- stopping production of the patented product, given the production capacity and market demand; or
- exercising of the rights conferred by the this Law in a manner that adversely affects the transfer of technology.

If anti-competitive behaviour has been determined by judicial or administrative process, certain of the TRIPS Agreement limitations fall away: it is no longer required that the patentee be approached first to conclude a voluntary licence on reasonable commercial terms and conditions,¹⁰¹ and, perhaps more importantly, the licensed used need not be restricted predominantly to the domestic market of the compulsory licence issuing country.¹⁰²

Examples of countries with providing for this ground in their patent laws include Argentina,¹⁰³ Bahrain,¹⁰⁴ Brazil,¹⁰⁵ Canada,¹⁰⁶ Chile,¹⁰⁷ Egypt,¹⁰⁸ Jordan,¹⁰⁹ Pakistan,¹¹⁰ Philippines,¹¹¹ Saudi Arabia,¹¹² and Uruguay.¹¹³

The Andean Community, too, national authorities may grant compulsory licenses where practices are determined by national competition authorities to be detrimental to the exercise of free competition, especially where they constitute an abuse by the patent owner of a dominant position in the market.¹¹⁴

100 In Canada, in a system that replaces that the compulsory licensing regime that Canada had in place prior to 1987 that kept pharmaceutical product prices low, the Patent Act provides for review of pharmaceutical prices by the Patented Medicines Price Review Board based on the price charged for similar products in Canada or an average of prices charged in seven comparator countries: R.S.C. 1985, c. P-4, ss. 79-101.

101 TRIPS Agreement, Art. 31(k), with reference to Art. 31(b).

102 TRIPS Agreement, Art. 31(k), with reference to Art. 31(f).

103 Ley de Patentes de Invención y Modelos de Utilidad, N°24.481, modificada por la Ley N°24.572, Art. 44.

104 Law No. 14 for the year 2006 Amending Some Provisions of Law Number 1 of the Year 2004 in Respect of Patents and Utility Models Art. 24(d).

105 Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 68.

106 Patent Act, R.S.C. 1985, c. P-4, ss. 65 (where trade is blocked).

107 Texto refundido Ley de Propiedad Industrial, 2005, Art. 51.

108 Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 23(5).

109 Patents of Invention Law No. 32 of 1999 and its Amendment by Temporary Law No. 71 of 2001, Art. 22C.

110 Patents Ordinance No. LXI of 2 December 2000, Art. 58(1)(ii).

111 Intellectual Property Code, s. 93(3).

112 Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs, 2004, Art. 24(a)(3).

113 Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 57.

114 Decisión N° 486 del 14 de septiembre de 2000, de la Comisión de la Comunidad Andina - Régimen Común sobre Propiedad Industrial, Art. 66.

2.1.3.4 Emergency

It almost goes without saying that countries should be allowed to issue compulsory licences in situations of national emergency, or extreme urgency, such as when urgent public health needs arise as a result of a natural catastrophe, war, or epidemics. Again the requirement in the TRIPS Agreement that the patentee be approached first to conclude a voluntary licence on reasonable commercial terms and conditions falls away.¹¹⁵ All that is required is that the patentee be notified as soon as is reasonably practicable.

Bahrain,¹¹⁶ Brazil,¹¹⁷ Chile,¹¹⁸ China,¹¹⁹ Egypt,¹²⁰ Malaysia,¹²¹ Philippines,¹²² Saudi Arabia,¹²³ and Zambia¹²⁴ are among those countries which expressly state this ground in their patent laws.

2.1.3.5 Government Use

The patents laws in many countries contain elaborate provisions relating to government use, generally, or with reference to health care needs, such as the production of specified medicines, specifically.

Examples of express provision for government use can be found in the patents laws of, for example, Canada,¹²⁵ India,¹²⁶ Kenya,¹²⁷ Lebanon,¹²⁸ Mexico,¹²⁹ Nigeria,¹³⁰ Tanzania,¹³¹ Tunisia,¹³² United Kingdom,¹³³ United States of America,¹³⁴ Zambia,¹³⁵ and Zimbabwe.¹³⁶

2.1.3.6 Public Interest

The term “public interest” can either be referred to generally, or it can be stated to relate explicitly to national security, health, or the development of vital sectors of the

115 TRIPS Agreement, Art. 31(b).

116 Law No. 14 for the year 2006 Amending Some Provisions of Law Number 1 of the Year 2004 in Respect of Patents and Utility Models, Art. 24(a).

117 Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 71.

118 Texto refundido Ley de Propiedad Industrial, 2005, Art. 51.

119 Patents Law, 2000, Art. 49.

120 Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 23(1).

121 Patents Act No. 291 of 1983, as amended, s. 84(1).

122 Intellectual Property Code, s. 95(3).

123 Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs, 2004, Art. 24(a)(2).

124 Patents Act, Chapter 400 of the Laws of Zambia, s. 41.

125 Patent Act, R.S.C. 1985, c. P-4, ss. 2.1, 19 & 19.1.

126 Patents Act, 1970, ss. 99-103.

127 Industrial Property Act, 2001, s. 80.

128 Patents Law No. 240 of 7 August 2000, Art. 36.

129 Ley de la Propiedad Industrial del 25 de junio de 1991 con las últimas enmiendas del 17 de mayo de 1999, Art. 77.

130 Patents and Designs Act, Chapter 344, 1990, Schedule 1, paras. 15-23.

131 Patents Act No. 1 of 1987, s. 61.

132 Loi n°2000-84 du 24 août 2000, relative aux brevets d'invention, Art. 78.

133 Patents Act 1977, ss. 55-59.

134 28 U.S.C. § 1498 (Federal government); 35 U.S.C. § 296 (a) (state governments). Federal law that imposed liability for state use of a patent is invalid unless the state has waived its immunity: *Florida Prepaid Postsecondary Education Expense Board v College Savings Bank* 527 U.S. 627 (1999).

135 Patents Act, Chapter 400 of the Laws of Zambia, s. 40.

136 Patents Act (Chapter 26:03) (as last amended by Act 20/1994 (S.7)), s. 34.

economy. This ground can also be stated defensively - the relevant patent has been implemented by the patentee in a form and manner that contravenes the public interest

Examples can be found in the patent laws of Algeria,¹³⁷ Argentina,¹³⁸ Brazil,¹³⁹ Chile,¹⁴⁰ China,¹⁴¹ Egypt,¹⁴² Ghana,¹⁴³ Japan,¹⁴⁴ Jordan,¹⁴⁵ Malaysia,¹⁴⁶ Morocco,¹⁴⁷ Mozambique,¹⁴⁸ Pakistan,¹⁴⁹ Philippines,¹⁵⁰ Saudi Arabia,¹⁵¹ South Africa,¹⁵² Tanzania,¹⁵³ and Uruguay.¹⁵⁴

This cluster would, arguably, also include government rights such as the march-in rights in terms of the Bayh-Dole Act¹⁵⁵ in the United States of America. These rights enable the Federal funding agency, on its own initiative or at the request of a third party, effectively to override the exclusivity of a patent obtained under the Act and grant additional licenses to other “reasonable applicants”. This right is strictly circumscribed and can be exercised only if the agency determines, after an investigation, that, inter alia, the contractor had failed to satisfy the “health and safety needs” of consumers.

2.1.4 Selected Case Studies of Countries Where Compulsory Licences Have Been Granted for Pharmaceuticals

2.1.4.1 Brazil

Pre-TRIPS Agreement

In 1969, three compulsory licenses were granted concerning Patent No. PI 76.767, held by the National Research Development Corporation, covering a process for a viral culture, used in the production of a vaccine against aftose fever.

137 Ordonnance n°03-07 du 19 Joumada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention, Arts 49-50.

138 Ley de Patentes de Invención y Modelos de Utilidad, N°24.481, modificada por la Ley N°24.572, Art. 45.

139 Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 71.

140 Texto refundido Ley de Propiedad Industrial, 2005, Art. 51.

141 Patents Law, 2000, Art. 49.

142 Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 23(1) (preservation of national security, health, environment and food safety; support of national efforts in vital sectors for economic, social, and technological development).

143 Patent Law, 1992, PNDCL, No. 305A, s. 47 (vital importance to defence, economic, or public health interests).

144 Patent Law No. 121 of 13 April 1959, as amended, s. 93.

145 Patents of Invention Law No. 32 of 1999 and its Amendment by Temporary Law No. 71 of 2001, Art. 22A.

146 Patents Act No. 291 of 1983, as amended, s. 84(1).

147 Loi n° 13-99 portant création de l'Office marocain de la propriété industrielle et commerciale (Dahir n° 1-00-71 du 9 kaada 1420 (15 février 2000)), Art. 67.

148 Industrial Property Code (Approved by Decree No. 04/2006 of 12th April 2006), Art. 85 (fundamental importance to public health, national defence, and economic and technological development).

149 Patents Ordinance No. LXI of 2 December 2000, Art. 58(1)(i).

150 Intellectual Property Code, s. 93(2),

151 Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs, 2004, Art. 24(a)(2) (especially security, health, nutrition or the development other vital sectors of the national economy).

152 Patents Act No. 57 of 1978, s. 56(2).

153 Patents Act No. 1 of 1987, s. 54.

154 Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 55.

155 35 U.S.C. § 203.

In 1984, the mechanism of compulsory licenses of patents by lack of use by the patentee was used in the first and only case of compulsory licensing for lack of working in Brazil.¹⁵⁶ As the licence concerned an important chemical product, the episode immediately attracted international attention.¹⁵⁷

Post TRIPS Agreement

In early 2001, Brazil announced that it was considering compulsory licenses for patents on nelfinavir and efavirenz. On 8 January 2001, the USTR questioned with the WTO whether Article 68 of the Brazilian Patent Law violated Articles 27 and 28 of the TRIPS Agreement. This provision allows compulsory licenses to be issued in situations where the patentee does not locally work the patent. In particular, the USTR argued that the definition of failure to be worked as connoting a failure to manufacture or incomplete manufacture of the product, or a failure to make full use of the patented process.¹⁵⁸ In March 2001, the Brazil government reached a settlement with Merck, the patentee, for price discounts on efavirenz, in exchange for not issuing a compulsory license. The United States withdrew the complaint on 25 June 2001. Brazil agreed to provide the United States with advance notice if a license is issued under Article 68, and disputes would be discussed through a bilateral Consultative Mechanism.¹⁵⁹

On 22 August 2001, the Health Minister announced that the Brazilian government would issue a compulsory license for the manufacture of nelfinavir (sold under the brand name VIRACEPT by Roche) to Far Manguinhos, a local pharmaceutical producer. On 31 August, the government and Roche agreed that Roche will sell the drug in Brazil at an additional 40 per cent discount. In return, the government will not grant a compulsory licence.

Post Doha

In 2003, just after the above episode, and following the Doha Declaration on compulsory licenses, the Federal Ministry of Health initiated a series of exercises targeting HIV/AIDS drugs needed to supply the full Federal-funded coverage of such infections. On 5 September 2003, the Brazilian government issued a decree that would allow it to produce or import generic anti-AIDS drugs without the consent of companies holding the patent on those medications. The Minister of Health made it clear that the decree was meant to apply to antiretroviral drugs - specifically lopinavir (Abbott), efavirenz (Merck), ritonavir (Abbott), and nelfinavir (Gilead). The ministry said in a statement that it had negotiated with the name-brand companies in August seeking a reduction of more than 40 per cent, but was offered a maximum discount of only 6.7 per cent. Brazil and Merck reached an agreement in November.

¹⁵⁶ Compulsory License of PI7107076 by Nortox Agro-Química S/A.

¹⁵⁷ See P. Ash, "Notes on Compulsory Licensing of Patents in Brazil: The Nortox v. Monsanto Case", in: Patents in Brazil, Daniel & Companhia, available at <<http://denisbarbosa.addr.com/daniel.doc>> [accessed 30 June 2010].

¹⁵⁸ Brazil - Measures Affecting Patent Protection - Request for Consultations by the United States, WT/DS199/1, G/L/385, IP/D/23 (8 June 2000).

¹⁵⁹ Brazil - Measures Affecting Patent Protection - Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1 (19 July 2001).

In 2005, Minister of Health Humberto Costa signed a decree declaring the patent of KALETRA (lopinavir + ritonavir) in the public interest and appropriate for compulsory licensing. A subsequent settlement with Abbott reduced the price of by 46 percent.

In the same year, the government declared that it was considering issuing compulsory licenses to permit the manufacture of VIREAD. After discussions, Gilead agreed to reduce the price of VIREAD in Brazil by about 50 per cent.

On 25 April 2007, the Minister of Health, José Gomes Temporão, signed Decree 866, declaring efavirenz to be in the public interest. This led to a compulsory licence on this drug being issued on 4 May 2007.

The Brazil action on efavirenz followed a similar decision by Thailand. As the Thai compulsory license authorized competition from generic suppliers, Merck was forced to offer efavirenz at a much lower price in Thailand. The Brazil government was unable to obtain similar price concessions from Merck, and issued the compulsory licenses.

2.1.4.2 Chile

Chilean law provides for a number of specific compulsory license grounds, such as anti-competitive practices - where the patentee has engaged in conduct or practice declared contrary to free competition, in direct connection with the use or exploitation of the patent in question, according to final decision rendered by the competition.¹⁶⁰

In December 2004, Essential Inventions requested a compulsory license to supply Chile with GLEEVEC (Imatinib Mesylate), a medication for certain rare cancers, notably chronic myeloid leukemia, and gastrointestinal stromal tumors.¹⁶¹ The request sought to persuade Chile to avail itself of the flexibility under the Waiver Decision.

2.1.4.3 Ecuador

Although the regulation of the Andean Community applies in Ecuador, its domestic patent law contains detailed provisions relating to compulsory licences. By means of a Presidential declaration of public interest, compulsory licences for national security emergencies or in the public interest may be issued.¹⁶²

A general declaration of public interest, the Presidential Decree 118 of 23 October 2009, focused on access to “medicines used to treat diseases that affect the Ecuadorian population and that are a priority for public health”.¹⁶³ On 15 January 2010, the Ecuadorian Intellectual Property Institute (IEPI) issued a Resolution (10-04),¹⁶⁴ in terms of which public non-commercial use and commercial use initiatives will be entertained under different requirements. Despite the fact that those licences were in appearance standard Andean Pact

¹⁶⁰ Texto refundido Ley de Propiedad Industrial, 2005, Art. 51.

¹⁶¹ For the text of the request, see <<http://www.essentialinventions.org/drug/imatinibmesylate/ei12172004.pdf>> [accessed 30 June 2010].

¹⁶² Ley de Propiedad Intelectual (Codificación N° 2006-013), Art. 154.

¹⁶³ Available at <http://www.iepi.gov.ec/Files/Leyes/Decreto_118.pdf> [accessed 30 June 2010].

¹⁶⁴ Available at <<http://www.iepi.gov.ec/Files/LicenciasObligatorias/InstructivoLicenciasFarmacias.pdf>> [accessed 30 June 2010].

Decision 486 specimens, a further requirement is actually added - the granting of such licenses are conditional upon a specific declaration from the health authority that the product in question is a priority for human health.

Two licence requests were received.¹⁶⁵

The first compulsory licence was granted on 22 April 2010 for the anti-retroviral drug ritonavir.¹⁶⁶ It was granted to Eskegroup SA, the local distributor for Cipla, an Indian generic pharmaceutical producer, according to Andrés Ycaza Mantilla, head of the IEPI. The owner of the patent is Abbott Laboratories, a United States pharmaceutical manufacturer. Eskegroup will pay royalties to Abbott according to the terms of the compulsory licence. The compulsory licence has been granted for the time that was left on patent, until 30 November 2014.

Previously, in 2003, petitions by local manufacturer Acromax for a compulsory license for COMBIVIR (Lamivudine + AZT) were refused, appealed, and refused again.

2.1.4.4 Ghana

Section 47(1) of the Patent Law, 1992, states that “[t]he Secretary may by legislative instrument direct that, for patented inventions concerning certain kinds of products, or processes for the manufacture of such products declared to be of vital importance to the defence, economic or public health interests of Ghana, compulsory licences may be granted”.

In October 2005, the Minister of Health declared an emergency situation with regard to HIV/AIDS and issued compulsory licenses for importation into Ghana of Indian generic HIV/AIDS medicines for government use only.¹⁶⁷

2.1.4.5 Mozambique

On 5 April 2004, the Deputy Minister of Industry and Commerce issued a compulsory license for patent rights to lamivudine, stavudine and nevirapine. The license was granted to Pharco Moçambique Lda, a local producer for the manufacture of the ARVs as a fixed-dose combination. Royalties are not to exceed 2 per cent of sales.¹⁶⁸

Article 83 of the Industrial Property Code¹⁶⁹ now states that a compulsory licence may be granted where a patent has not been worked within three years after the date on which the patent was granted, or within four years after the application was filed, whichever period is longer. Such licence will be granted only when “... the potential user has made efforts to obtain the patent proprietor’s agreement on reasonable conditions and the negotiations have not been successful”.

¹⁶⁵ See <<http://www.abreui.com/Noticias.html>> [accessed 30 June 2010].

¹⁶⁶ Available at <<http://structurallymaladjusted.blogspot.com/2010/04/ecuador-grants-first-compulsory-license.html>> [accessed 30 June 2010].

¹⁶⁷ The text of the licence is available at <<http://www.cptech.org/ip/health/cl/Ghana.png>> [accessed 30 June 2010].

¹⁶⁸ The text of Compulsory License no. 01/MIC/04 is available at <<http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>> [accessed 30 June 2010]. The licence was granted under Art. 70(6) of Decree no. 18/99.

¹⁶⁹ Decree Nr. 04/2006 of 12 April 2006.

Article 85 states that an invention may be worked under authorization given by the responsible Ministry, without the consent of the patent proprietor, for reasons of public interest. An invention is of public interest if it is of fundamental importance to public health, national defence, and economic and technological development. Again, the applicant has to show that it sought a contractual licence from the proprietor of the patent but did not obtain one on reasonable commercial conditions and within a reasonable time. (This does not apply to cases of national emergency or other circumstances of extreme urgency.) The patent proprietor must be paid adequate remuneration, adjusted according to each particular case, taking into account the economic value of the patent. The extent and duration of the use must be limited to the purposes for which it was authorized. The licence may not be exclusive and cannot be assigned. The use provided for under the licence may be transferred only together with the enterprise or the goodwill of the enterprise that works the patented invention. The working of the invention by a third party or a legal entity designated by the Government must be aimed predominantly at supplying the market in Mozambique.

2.1.4.6 South Africa

Although there is no reference to compulsory licences for anti-competitive practices in the Patents Act 57 of 1978, Section 8 of the Competition Act 89 of 1998 prohibits a dominant firm from (a) charging an excessive price to the detriment of consumers; (b) refusing to give a competitor access to an essential facility when it is economically feasible to do so; and (c) engage in an exclusionary act, if its anti-competitive effect outweighs its technological, efficiency, or other pro-competitive gain. The term “excessive price”, in turn, connotes “a price for a good or service which – (aa) bears no reasonable relation to the economic value of that good or service; and (bb) is higher than the value referred to in subparagraph (aa).”¹⁷⁰ There are a number of reasons for pursuing public health objectives under competition law.¹⁷¹

In the first instance, as competition regulators usually have broad powers of investigation, competition authorities are able to conduct independent investigations into drug pricing. As part of such an investigation, competition authorities usually deal with the actual costs of research and development in its determination of whether the prices charged for pharmaceuticals bear a “reasonable relation” to their “economic value”, particularly in respect of those drugs that were developed using public funds.

Secondly, competition legislation is not primarily concerned with the individual parties to a dispute, but rather with the broader social and economic implications of the alleged prohibited conduct.

Thirdly, a significant part of the regulatory flexibility afforded by the TRIPS Agreement depends upon whether a particular practice is determined to be anti-competitive. Article 31 waives the requirement that the use of a compulsory license be “predominantly” for the supply of the domestic market when the license is issued to remedy an anti-competitive practice.

¹⁷⁰ Competition Act, Section 1(1)(x).

¹⁷¹ Jonathan Michael Berger, “Litigation Strategies to Gain Access to Treatment for HIV/AIDS: the Case of South Africa’s Treatment Action Campaign”, *Wis. Int’l LJ* 596 (2002), 608-609.

On 7 March 2001, the Indian pharmaceutical manufacturer Cipla formally requested the Department of Trade and Industry issue compulsory licenses to patents on the following HIV/AIDS drugs: nevirapine, lamivudine, zidovudine, stavudine, didanosine, efavirenz, indinavir, and abacavir.

On 19 September 2002, Hazel Tau and twelve other complainants, working with the Treatment Action Campaign (TAC), filed a complaint with the Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI). They charged GSK and BI with excessive pricing in respect of ritonavir, lamivudine, ritonavir, lamivudine, and nevirapine.

On 16 October 2003, after an extended investigation, the South Africa Competition Commission found that GSK and BI have abused their dominant positions in their respective ARV markets. In particular, the Commission found the firms have engaged in the following restrictive practices: denying a competitor access to an essential facility; excessive pricing; and engaging in an exclusionary act.

Menzi Simelane, Commissioner at the Competition Commission, said:

“We will request the [Competition] Tribunal to make an order authorizing any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty. In addition, we will recommend a penalty of 10% of the annual turnover of the respondents’ ARVs in South Africa for each year that they are found to have violated the Act.”¹⁷²

On 10 December 2003, the Commission announced it had reached a settlement agreement with GSK.¹⁷³ The settlement required GSK -

- to extend a voluntary licence granted to Aspen Pharmacare (a South African pharmaceutical company) in October 2001 in respect of the public sector to include the private sector;
- grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare;
- permit the licensees to export the ARVs to sub-Saharan African countries;
- permit the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa;
- permit licensees to combine the relevant ARV with other ARVs;
- and charge royalties of no more than 5 per cent of the net sales of the relevant ARVs.

A similar settlement agreement was reached with BI.

¹⁷² Press statement of 16 October 2003, available at <<http://www.cptech.org/ip/health/sa/cc10162003.html>> [accessed 30 June 2010].

¹⁷³ For the text of the settlement agreement, see <<http://www.cptech.org/ip/health/sa/settlement12092003.pdf>> [accessed 30 June 2010].

2.1.4.7 Thailand

At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows, in that that the patented product has not been produced, or the patented process has not been applied in the country, without any legitimate reason; or no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices, or does not meet the public demand, without any legitimate reason.¹⁷⁴ Where such a compulsory license is awarded, the patentee shall be entitled to remuneration.¹⁷⁵

On 29 November 2006, the Ministry of Health announced a government use compulsory license to import (from India) and locally produce efavirenz until 2011.¹⁷⁶ The proposed royalty was 0.5 per cent of the price of the generic product, subject to negotiation with the patentee.

On 25 January 2007, the government announced two additional government use compulsory licenses on patents for the AIDS drug KALETRA (LPV+RTV),¹⁷⁷ and the heart disease drug Plavix (clopidogrel bisulfate),¹⁷⁸ also with a proposed royalty of 0.5 per cent.

On 29 January 2007, the Minister of Public Health's Department of Disease Control, issued a decree regarding the exploitation of patents on drugs and medical supplies by the government on the combination drug lopinavir & ritonavir, marketed under the trade name KALETRA by Abbott.

2.1.4.8 Zambia

Any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, after the expiration of a period of three years subsequent to the date on which that patent was sealed, or four years subsequent to the date on which the application in respect of it was lodged, whichever period is the longer, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention in question have not been, or will not be, satisfied.¹⁷⁹ The reasonable requirements of the public are deemed not to have been satisfied in any of the following circumstances: (a) if the patented invention, being an invention capable of being worked in Zambia, is not being worked there on a commercial scale and there is no satisfactory reason for such non-working; (b) if the working of the invention within Zambia on a commercial scale is being prevented or hindered by the importation of the patented article by the patentee or persons claiming under him, or by

¹⁷⁴ Patent Act B.E. 2522 (1979), s. 46.

¹⁷⁵ Patent Act B.E. 2522 (1979), s. 48.

¹⁷⁶ A translated text of the actual license is available at <<http://www.cptech.org/ip/health/c/thailand/thaicl4efavirenz.html>> [accessed 30 June 2010].

¹⁷⁷ A translated text of the actual license is available at: <http://www.cptech.org/ip/health/c/thailand/thaicl-kaletra_en.pdf> [accessed 30 June 2010].

¹⁷⁸ A translated text of the actual license is available at <http://www.cptech.org/ip/health/c/thailand/thaicl-clopidogrel_en.pdf> [accessed 30 June 2010].

¹⁷⁹ Patents Act, Chapter 400 of the Laws of Zambia, s. 37.

persons directly or indirectly purchasing from him or by persons against whom the patentee is not taking or has not taken proceedings for infringement; (c) if the demand for the patented article in Zambia is not being met to an adequate extent and on reasonable terms; (d) if by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry of Zambia or the trade of any person or class of persons trading in Zambia, or the establishment of any new trade or industry in Zambia, is being prejudiced, and it is in the public interest that a licence or licences should be granted; (e) if any trade or industry in Zambia, or any person or class of persons engaged therein, is being prejudiced by unfair conditions attached by the patentee, whether before or after the commencement of this Act, to the purchase, hire, licence or use of the patented article, or the using or working of the patented process; (f) if any condition which under the provisions of section 49¹⁸⁰ is null and void as being in restraint of trade and contrary to public policy, has been inserted in any contract made in relation to the sale or lease of or any licence to use or work any article or process protected by the patent.

To determine whether there has been any abuse of the monopoly rights under a patent, due regard shall be had to the fact that patents are granted not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Zambia without undue delay. The High Court may order the grant of a licence on such terms as it may think expedient, including a term precluding the licensee from importing into Zambia any goods the importation of which by persons other than the patentee or persons claiming under him, would be an infringement of the patent.

On 21 September 2004, the Minister of Commerce, Trade and Industry issued a compulsory license for lamivudine, stavudine, and nevirapine to Pharco Ltd, a local pharmaceutical producer, to produce a triple fixed-dose combination. A maximum royalty rate of 2.5 per cent of total annual turnover applies.¹⁸¹

2.1.4.9 Zimbabwe

Any department of the State, or any person authorized in writing by the Minister of Justice, Legal and Parliamentary Affairs, may make, use, or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the state.¹⁸²

During any period of emergency, the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under Section 34 include the power to make, use, exercise, and vend the invention for any purpose which appears to the Minister necessary or expedient (a) for the efficient prosecution of any war in which Zimbabwe may be engaged; (b) for the maintenance of supplies and services essential to the life of the community; (c) for securing a sufficiency of supplies and services essential to the well-being of the community; (d) for promoting the productivity of industry, commerce or agriculture; (e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade; (f) generally, for ensuring that the whole resources of the community are available for use, and are used, in a

¹⁸⁰ Section 49 prohibits the insertion of certain restrictive conditions in contracts.

¹⁸¹ The text of Compulsory Licence No 1/2004 is available at <<http://www.cptech.org/ip/health/c/zambia/zcl.html>> [accessed 30 June 2010].

¹⁸² Patents Act (Ch. 26:03 Consolidation), s. 34.

manner best calculated to serve the interests of the community; or(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in grave distress as the result of war.¹⁸³

On 24 May 2002, the Minister declared a period of emergency in order to enable the state, or a person authorised by the Minister, to make or use any patented drug, including any ARV, used in the treatment of persons with HIV/AIDS or HIV/AIDS related conditions, and to import any generic drug used in the treatment of persons with HIV/AIDS or HIV/AIDS-related conditions.¹⁸⁴ In 2003, the period of emergency was extended by five years (until 31 December 2008).

2.2 Individual Prescriptions

Some patent laws exclude from the ambit of the patentee's rights, medicines prepared for an individual case in a pharmacy or by a medical professional.

The following countries, amongst others, have made provision to this effect in their patent laws: Albania, Andorra, Argentina,¹⁸⁵ Armenia, Belarus, Belgium, Bosnia and Herzegovina, Brazil,¹⁸⁶ Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Moldova, Morocco,¹⁸⁷ Netherlands, Norway, Philippines, Poland, Portugal, Republic of Korea, Russian Federation, Santa Lucia, Serbia, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Syrian Arab Republic, Thailand, Former Yugoslav Republic of Macedonia, Trinidad and Tobago, Tunisia,¹⁸⁸ Turkey, United Kingdom, Uruguay,¹⁸⁹ and Uzbekistan.

2.3 Parallel imports¹⁹⁰

Parallel imports are imports of a patented or trademarked product from a country where it is already marketed. For example, in Mozambique, Bayer sells 100 units of its ciprofloxacin (500mg) for US\$740, but in India Bayer sells the same drug for US\$15 (owing to local generic competition).¹⁹¹ In terms of the doctrine of parallel imports, Mozambique can import the product from India without Bayer's consent.

According to the theory of exhaustion, the exclusive right of the patentee to import the protected product is exhausted when the product is first launched on the market. When a state

¹⁸³ Patents Act (Ch. 26:03 Consolidation), s. 35.

¹⁸⁴ General Notice 204 of 2002. The text of the notice is available at <http://www.cptech.org/ip/health/c/zimbabwe/zim05242002.html> [accessed 30 June 2010].

¹⁸⁵ Decreto N° 260/96; Texto Ordenado de la Ley N° 24.481 del 30 de Marzo de 1995 modificada por la ley N° 24.572 del 28 de Setiembre de 1995, Art. 36.

¹⁸⁶ Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 43.III.

¹⁸⁷ Loi n° 13-99 portant création de l'Office marocain de la propriété industrielle et commerciale (Dahir n° 1-00-71 du 9 kaada 1420 (15 février 2000)), Art. 55(c).

¹⁸⁸ Loi n° 2000-84 du 24 août 2000, relative aux brevets d'invention, Art. 47(c).

¹⁸⁹ Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 39.B and C.

¹⁹⁰ Also, exhaustion, and implied licences.

¹⁹¹ World Health Organisation, Trade, foreign policy, diplomacy and health: Parallel Imports, <http://www.who.int/trade/glossary/story070/en/index.html> [accessed 30 June 2010].

does not recognize this principle, only the patentee has the right to import the protected product. The theory may be applied at the national level,¹⁹² at the regional level,¹⁹³ or at the international level. From the perspective of developing country access to medicines, exhaustion at international level is preferable, of course.

Parallel imports often takes occurs when there is differential pricing of the same product - either brand-name or generic drugs - in different markets (usually because of local manufacturing costs or market conditions), as in the above example. In the public health context, the importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the product. At the same time, the patentee is not prevented from receiving the remuneration for the patented invention in the country where the product was first sold.

Parallel imports can reduce the price of pharmaceuticals by introducing competition. But they can also affect the negotiation of tiered pricing regimes with pharmaceutical companies. If a private pharmaceutical company agrees to sell a product at a lower price in poor country markets, it will want some assurance that the cheaper product will not be imported back into its rich country markets, so undercutting its profits.

The TRIPS Agreement explicitly states that this practice cannot be challenged under the WTO dispute settlement system,¹⁹⁴ and so it is a matter of national discretion.

A large number of countries have adopted provisions along the lines of exhaustion of patent rights, implied licences to use, or parallel importation. Examples are: Albania, Algeria,¹⁹⁵ Andorra, Argentina, Armenia, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia and Herzegovina, Brazil,¹⁹⁶ Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, Egypt,¹⁹⁷ El Salvador, Estonia, Ethiopia,¹⁹⁸ Finland, France, Georgia, Ghana,¹⁹⁹ Guatemala, Hungary, Iceland, India,²⁰⁰

192 The patentee's rights are deemed to be exhausted domestically only, so that the commercialization in foreign countries is not deemed to have exhausted the patentee's rights. In Brazil, for example, exhaustion is national (except in the case of certain biological material), subject to the special provision of Art. 68(4), whereby whenever a patentee exploits its patent by importing the products related, international exhaustion then applies. There is no recorded case where this provision was actually utilized.

193 For example, the Treaty Establishing the European Community, Arts 28 and 30.

194 Article 6: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

195 Ordonnance n°03-07 du 19 Jomada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention, Art. 12(2).

196 Where a compulsory license is granted on the ground of the abuse of economic power, the licensee who proposes local manufacture is given a limited period within which to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent (Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 68(3)). In the case of importation to exploit a patent, and in the case of importation under paragraph (3), third parties must also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent (Art. 68(4)).

197 Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 10.

198 Proclamation No. 123/1995 Concerning Inventions, Minor Inventions and Industrial Designs, Art. 25(1)(c).

199 Patent Law, 1992, PNDCL, No. 305A, s. 30(b).

200 Patents Act, 1970, s. 107A (b). It states that importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as an infringement of patent rights. Consequently a patentee cannot assert its patent rights to prevent a third party from importing the patented product into India if such product was sold or distributed by the patentee overseas, with the patentee's consent, or by a person duly authorized under the law. The Act gives no guidelines to define 'consent' or 'duly authorized'. It could, therefore, be interpreted to include even the importation of articles manufactured by a third party with no relation to the

Indonesia,²⁰¹ Ireland, Kenya,²⁰² Kyrgyz Republic, Latvia, Luxembourg, Malaysia, Malta, Mauritius, Mexico,²⁰³ Mongolia, Morocco,²⁰⁴ Mozambique,²⁰⁵ Netherlands, Nicaragua, Nigeria,²⁰⁶ Norway, Oman, Pakistan,²⁰⁷ Panama, Papua New Guinea, Peru, Philippines,²⁰⁸ Poland, Romania, Russian Federation, Santa Lucia, Serbia, Singapore, South Africa,²⁰⁹ Spain, Sweden, Thailand, Trinidad and Tobago, Tunisia,²¹⁰ Turkey, Uganda,²¹¹ Ukraine, United Kingdom, Uruguay,²¹² Uzbekistan.

The *Accord de Bangui* likewise provides for parallel imports for the members of the OAPI.²¹³

2.4 Regulatory Exception

This exception, also known as the *Bolar* exception,²¹⁴ is primarily, but not exclusively, aimed at assisting the generic pharmaceutical industry to obtain regulatory approval for the eventual sale of patented medicine. Generally, it allows a third party to undertake, without the authorisation of the patentee, acts in respect of a patented product necessary for the purpose of obtaining regulatory approval for a product. As generic competition almost invariably lowers prices, this exception promotes the affordability of off-patent medicines.

In a WTO ruling, this exception has been upheld as conforming with the Articles 27.1 and 28.1 of the TRIPS Agreement in a WTO.²¹⁵ In issue was, inter alia, a provision in the Canadian Patents Act: “It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.” Canada argued that this exception had been enacted because of the potential delaying effect of regulatory review on the ability of would-be competitors (here, generic drug manufacturers) to enter the market as soon after patent expiry as possible, as was particularly the case in the regulatory regime for pharmaceutical products, which involved long delays before new drugs (innovator and generic) could be placed on the market. These delays arose, it was argued, because, independent of the time it may take to invent, or to discover a method to replicate, a

patentee in a foreign country, provided that such manufacture is legal in such foreign country (for example, the product is not patented in the said foreign country).

201 Law No. 14 of 1 August 2001 Regarding Patents, Art. 135(a).

202 Industrial Property Act, 2001, s. 58(2).

203 Ley de la Propiedad Industrial del 25 de junio de 1991 con las ultimas enmiendas del 17 de mayo de 1999, Art. 22.II.

204 Loi n° 13-99 portant création de l'office marocain de la propriété industrielle et commerciale (Dahir n° 1-00-71 du 9 kaada 1420 (15 février 2000)), Art. 55(d).

205 Industrial Property Code (Approved by Decree No. 04/2006 of 12th April 2006), Art. 68(b).

206 Patents and Designs Act, Chapter 344, 1990, s. 6(3)(b).

207 Patents Ordinance, 2000, Art. 30(1).

208 Intellectual Property Code, s. 93(5), Art. 76.

209 Medicines and Related Substances Control Act No. 101 of 1965, s. 15C.

210 Loi n° 2000-84 du 24 août 2000, relative aux brevets d'invention, Art. 47(d).

211 Patents Act, 1993, s. 28(b).

212 Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 40.

213 Accord portant revision de l'accord de Bangui du 02 mars 1977 instituant une organisation africaine de la propriete intellectuelle, Annexe I: Des brevets d'invention, Art. 8(1)(a).

214 Taking its name from Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984).

215 Canada - Patent Protection of Pharmaceutical Products, WT/DS114 /R (17 March 2000), p. 174.

new drug, the time required to develop the information needed to demonstrate the safety and effectiveness of a new drug (innovator and generic) was considerable and variable. Likewise, the time that the regulatory authorities took to review and assess the adequacy of the materials submitted in support of an application for marketing authorization was considerable. Finally, it was stated that it was not uncommon for the product development, application preparation, and regulatory review process to take, in the case of an innovative drug, eight to twelve years, and, in the case of a generic drug, three to six-and-a-half years.²¹⁶

Countries that have adopted this exception include: Australia,²¹⁷ Bahrain,²¹⁸ Brazil,²¹⁹ Canada,²²⁰ Costa Rica,²²¹ Croatia,²²² Czech Republic, Egypt,²²³ France, Germany, Hungary, India,²²⁴ Israel, Jordan,²²⁵ Kenya,²²⁶ Malaysia,²²⁷ New Zealand, Oman, Pakistan,²²⁸ Paraguay,²²⁹ Poland, Serbia, South Africa,²³⁰ Switzerland, Syrian Arab Republic, Thailand,²³¹ Former Yugoslav Republic of Macedonia, Tunisia,²³² Turkey, Uruguay,²³³ and the United States of America.²³⁴

216 Canada - Patent Protection of Pharmaceutical Products, WT/DS114 /R (17 March 2000), p. 39.

217 Patents Act No. 83 of 1990 as amended, s. 119A.

218 Law No. 14 for the year 2006 Amending Some Provisions of Law Number 1 of the Year 2004 in Respect of Patents and Utility Models, Art. 13(e).

219 Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial, Art. 43.VII.

220 R.S.C. 1985, c. P-4, s. 55.2 (1). This provision exempts from patent infringement, any use of an invention to file information to any federal, provincial or foreign regulator in respect of the sale of any product. It is "... unrestricted as to subject matter of the patent, it applies to medicines, bicycles and anything patented, and unrestricted as to any country not just Canada or the province in which regulatory approval may be sought" (Apotex Inc. v. Merck & Co. Inc., 2008 FC 1185 at para. 21). This exception is thus broader than that in the United States as interpreted in Merck KG v. Integra Lifesciences Ltd., 545 US 1 (2005). "That United States statute is more restrictive as it speaks only of requirements under United States law and is limited to drugs" (Merck & Co. Inc. v. Apotex Inc. 2006 FC 524 at para. 154).

This exemption applies to both pre-market and post-market activities undertaken to comply with regulation (Merck & Co. v. Apotex Inc., [2007] 3 F.C.R. 588 at para. 100). Further, the provision does not exempt only activity that actually results in submitted information: "Any samples which are reasonably related to the development and submission of information under legislation or regulations are exempt by the provision. It does not limit the exemption to information actually submitted" (Merck & Co. v. Apotex Inc., [2007] 3 F.C.R. 588 at para. 103).

Section 55.2(1) is "not an exemption from the purpose of the Act, but is an integral part thereof by seeking to balance the rights of patentees with those of the public" (Merck & Co. v. Apotex Inc., [2007] 3 F.C.R. 588 at para. 102). The section should not, therefore, be given a narrow interpretation but should be interpreted in the same way as provisions granting the patent itself.

221 Ley N° 6867 de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad, Art. 16(2)(e).

222 Patent Act and Amending Patent Act and the Act on Amendments to the Patent Act (OG No. 173/2003 of 31 October 2003, OG No. 87/2005 of 18 July 2005, OG No 76/2008 of 23 July 2007), Zagreb September 2007, Art. 63(2).

223 Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002, Art. 10(5).

224 Patents Act, 1970, s. 107A(a). This provision is expressly not limited to obtaining regulatory approval in India.

225 Patents of Invention Law No. 32 of 1999 and its Amendment by Temporary Law No. 71 of 2001, Art. 21C.

226 Industrial Property Act, 2001, s. 54(2).

227 Act 291 of 1983 as amended by Act A1196 of 2003, s. 37.

228 Patents Ordinance, 2000, Art. 35.

229 Ley N° 1630 de 29 de noviembre de 2000 sobre Patentes de Invenciones, Art. 34.

230 Patents Act No. 57 of 1978, s. 69A.

231 Patent Act B.E. 2522 (1979), s. 36(2).

232 Loi n° 2000-84 du 24 août 2000, relative aux brevets d'invention, Art. 47(e).

233 Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invención, los modelos de utilidad y los diseños industriales (1.827*R), Art. 39.

234 35 U.S.C. § 271 (e)(1). Research that may result in information being filed under Federal food and drug laws does not constitute patent infringement. To qualify, the researcher need only have the intention of eventually filing an application. The research need not be mandated by federal authorities. The provision was interpreted broadly by the Supreme Court as allowing any research where there is a legitimate belief that a filing will be made (Merck KGaA v. Integra Lifesciences Ltd., 545 U.S. 193 (2005)).

The Andean Community likewise adopted this exception.²³⁵

[Annex VI follows]

²³⁵ Decisión N° 486 del 14 de septiembre de 2000, de la Comisión de la Comunidad Andina - Régimen Común sobre Propiedad Industrial, Art. 54.