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UNCTAD/ICTSD Capacity Building Project on
*Intellectual Property Rights and
Sustainable Development*

Non-voluntary Licensing of Patented Inventions:

**Historical Perspective,
Legal Framework under TRIPS, and an Overview
of the Practice in Canada and
the United States of America**

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Explanatory Note

This case study by Prof. J. H. Reichman with C. Hasenzahl, J.D. on non-voluntary licensing of patented inventions has been prepared in the context of the Project on TRIPS and Development Capacity Building sponsored by the Department of International Development (DFID UK). The Project is being implemented by the secretariat of the United Nations Conference on Trade and Development (UNCTAD) (Project Number INT/OT/1BH) and the International Centre for Trade and Sustainable Development (ICTSD). The broad aim is to improve the understanding of TRIPS-related issues among developing countries and to assist them in building their capacity for ongoing as well as future negotiations on intellectual property rights (IPRs).

The Project produces a series of documents through a participatory process involving trade negotiators, national policy makers, as well as eminent experts in the field, NGOs, international organizations, and institutions in the North and the South dealing with IPRs and development. The published outputs are not intended to be academic exercises, but instruments that, in their final forms, will be the result of a thorough process of consultation. This will be achieved by rapid development of working drafts and circulation of these to experts and to the intended audiences for their comments. These documents include:

- **A Policy Discussion Paper** intended to be a clear, jargon-free synthesis of the main issues to help policy makers, stakeholders and the public in developing and developed countries to understand the varying perspectives surrounding different IPRs, their known or possible impact on sustainable livelihoods and development, and different policy positions over TRIPS. (A preliminary draft of the Paper was issued on 20 Nov. 2001)
- **The Resource Book on TRIPS and Development** conceived as a guide that will provide background and technical information on the main issues under discussion in TRIPS.
- **Case studies** on various IPRs issues to supplement the Resource Book and the Discussion Paper. This will allow concrete evidence to emerge and shed light on the impact and relevance of IPRs in developing countries. Including non-voluntary licensing, these studies cover other issues such as geographical indications (available as of June 2002), technology transfer (forthcoming), nutrition (forthcoming).

In addition, the Project produces background material on Indicators of the Relative Importance of IPRs in Developing Countries (see draft of November 2001) and a Review of Activities being carried out by other organizations and institutions on TRIPS related questions and a Review of Literature (both available in the website). For details on the activities of the Project and available material, see <<http://www.ictsd.org/unctad-ictsd>>.

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The Case Study on Non-voluntary Licensing

The case study on compulsory licensing consists of three parts. They are being published separately in order to facilitate their dissemination and to receive feedback from interested people and institutions. In their revised version, they will be part of an integrated and consolidated publication.

Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America

After introducing non-voluntary licensing in its historical context, the paper explains in general terms the approach taken under the TRIPS Agreement and highlights the main issues. It then provides a brief, comparative overview of non-voluntary licensing in the legal systems of Canada and the United States. The purpose of this paper is to give a first insight, in an historical perspective, into the wide range of possible uses of compulsory licenses as authorized by the TRIPS Agreement.

The Canadian Experience

This survey contains a detailed analysis of the Canadian practice with respect to non-voluntary licensing. It presents both the former and the current legal approaches and illustrates them through case law. The purpose is to provide concrete examples of the approach taken by Canada, including possible problems in the implementation of non-voluntary licensing in the context of the TRIPS Agreement.

Non-Voluntary Licensing of Patented Inventions in the United States

Like the survey on the Canadian experience, this part analyses in detail the US case law. Again, the purpose is to draw lessons from the experience made by a developed country in the use of policy instruments such as non-voluntary licensing over time and at various stages of its own economic progress

1. Introduction

This study begins with an historical overview of the treatment of non-voluntary licensing of patented inventions in international intellectual property conventions. It briefly traces the evolution of international minimum standards regulating this legal institution from their origins in the Paris Convention for the Protection of Industrial Property of 1883¹ ("Paris Convention") to their fullest elaboration in the Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994² ("TRIPS Agreement"). The study also considers the potential impact that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of November 2001³ may have on the use of non-voluntary licensing to secure access to patented medicines. These materials will provide a foundation for understanding the technical complexity of non-voluntary licensing and the pressures that are brought to bear on its regulation in actual practice. However, no effort is made here to provide an in-depth legal analysis of the applicable minimum standards, as this task has been accomplished in another study to be published within the framework of the UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development (hereinafter: UNCTAD/ICTSD Project)⁴ Finally, the study highlights the different approaches to non-voluntary licensing of patented inventions that have been taken by Canada and the United States, respectively. In this context, the reader is provided with a general overview of the past and current handling of non-voluntary licensing under the domestic laws of those two countries.

¹ See Paris Convention for the Protection of Industrial Property, 20 March 1883, as last revised at Stockholm, 14 July 1967 [hereinafter Paris Convention], 25 Stat. 1372, 828 U.N.T.S. 305.

² See Marrakech Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994 [hereinafter TRIPS Agreement], 33 I.L.M. 81 (1994).

³ See Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha [Qatar], 9-14 Nov. 2001, WT/MIN(01)/DEC/2, 14 Nov. 2001 [hereinafter Doha Declaration on Public Health].

⁴ See the UNCTAD/ICTSD Project, The Resource Book, chapter 2.5.8 "Non-voluntary Uses (Compulsory Licenses, Art. 31)".

2. An Historical Perspective

The term "non-voluntary" or "compulsory" licensing refers to the practice by a government to authorize itself or third parties to use the subject matter of a patent without the authorization of the right holder for reasons of public policy. In other words, the patentee is forced to tolerate, against his will, the exploitation of his invention by a third person or by the government itself. In these cases, the public interest in broader access to the patented invention is considered more important than the private interest of the right holder to fully exploit his exclusive rights.⁵

Historically, non-voluntary licensing arose to ameliorate the patentee's risks of forfeiture that derived from numerous restrictions on the use of patented inventions in early domestic and international laws. The first major improvement of the patentee's status in this regard was the abolition of forfeiture for merely importing patented articles into countries that practiced this restriction.⁶ France, indeed, did not abolish the prohibition of imports until 1953.⁷ Once the risk of forfeiture for imports had been attenuated, the most important obligation that the laws of many countries imposed on patentees was the duty to work or exploit the invention in the countries granting patents. As *Stephen Ladas* portrays it, the history of the stipulations concerning this issue in the Paris Convention "is, in a sense, the history of the [Paris] Union" itself.⁸

2.1. Avoiding Forfeiture: Compulsory Licensing to Correct Abuses of the Patentee's Exclusive Rights

Initially, and for a considerable period that lasted at least until 1925, the only breaks on forfeiture for nonworking of patents under the Paris Convention were a three-year grace period and the ability of the patentee to justify his failure to work under conditions set by local law. The 1883 Convention did not define what the term "working" meant, and each member country "could give it the meaning of its own law."⁹ Moreover, the policies behind the working requirement have always been controversial, especially with regard to foreign patentees. They could be required not only to work the patent as such, within a specified period of time, but to "work the patent locally" as well, which entailed manufacturing or organizing the industrial use of the patented invention in the country that issued the patent.¹⁰ (See the Annex for an historical overview of the evolution of Article 5 A of the Paris Convention).

Obliging foreign patentees to work each and every patent locally is often economically inefficient for a number of reasons.¹¹ Nevertheless, most countries opted for a local working requirement out of psychological and political concerns to favor domestic development and the protection of national industries. Writing in 1975, *Ladas* thus reached the following conclusion:

⁵ See the introductory clause in Art. 31, TRIPS Agreement, supra note 2. See also the UNCTAD/ICTSD Project, The Resource Book, chapter 2.5.8 "Non-voluntary Uses (Compulsory Licenses, Art. 31)", in the introduction.

⁶ See Paris Convention, supra note 1, Article 5A(1), 1883 text (embodying a provision that was first adopted at the Paris Conference of 1880); 1 Stephen P. Ladas, *Patents, Trademarks, and Related Rights - National and International Protection* [hereinafter *S. Ladas*] 516 (1975).

⁷ See 1 *S. Ladas*, supra note 6, at 516.

⁸ *Id.* at 519-520 (citing text of Washington Conference of 1911, article 5). See also Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, South Centre (1999), [hereinafter *Correa, Compulsory Licenses*], available at <<http://www.southcentre.org/publication/pubindex.htm#working>>; at 3 (stating that the "granting of compulsory licenses appeared as a means to mitigate that drastic measure of direct forfeiture," and tracing the first such provision to section 22 of the United Kingdom's Patent Act of 1883).

⁹ See 1 *S. Ladas*, supra note 6, at 524.

¹⁰ See, e.g., Correa, *Compulsory Licenses*, supra note 8, at 3 n.7.

¹¹ See, e.g., 1 *S. Ladas*, supra note 6, at 522-23; Friedrich-Karl Beier, *Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law*, 30 *Int'l Rev. Indus. Prop. & Copyright Law (I.I.C.)* 251, 263 (1999), (stressing loss of comparative advantages and division of labor in a globalized economy).

"Most countries felt that they should not be tributary to foreign industry and must encourage the development of national industry by requiring a foreign patentee to work his invention directly or through a licensee. The result then today [1975] is that a patentee is required, generally, to work his invention in nearly every country in which he obtains a patent."¹²

However, forfeiture of patents as the sanction for nonworking often generated still other social costs, especially when investment or know-how was insufficient to enable competitors to produce the disclosed invention by their own means. For these and other reasons, states gradually adopted a system of compulsory licensing as the primary sanction for nonworking in lieu of forfeiture.¹³

This reform was consistent with the purposes of the Paris Union, which gave patentees priority rights in all member countries even though it was impossible for the inventor to work the patent in them all.¹⁴ Serious efforts to replace forfeiture for nonworking with the milder sanction of compulsory licensing were accordingly undertaken at the Conference of The Hague in 1925.¹⁵ The compromise principle adopted at this Conference was to allow states to "take the necessary legislative measures to prevent the abuses" of the patentee's exclusive rights, as exemplified by "failure to work."¹⁶

The tail end of this provision was first put forward during the discussion of article 5 in the Plenary Committee, when the Canadian delegation "proposed that it be made clear that failure to work the invention is such an abuse of the exercise of the patentee's exclusive rights."¹⁷ According to *Ladas*, it was to satisfy this desire that the last words of the second paragraph of article 5 were inserted, viz. "for example, failure of working."¹⁸

The crux of the 1925 reform was that forfeiture as a remedy for "abuse" was not allowed unless the grant of a compulsory license had failed to prevent such abuse. In any case, neither sanction could apply for a period of at least three years from the date the patent issued or if the patentee proved the existence of "legitimate excuses."¹⁹

The importance of this provision was, reportedly, to shift attention to abuses of the patentee's exclusive rights and away from the obligation to work patents as such.²⁰ Thus, as *Ladas* interprets it, the patentee's failure to work the patent becomes actionable if it amounts to an abuse, which could depend on such ancillary factors as the willingness of the patentee to grant licenses on reasonable terms and the extent to which the market for the patented article was adequately supplied.²¹ In practice, the evidence that *Ladas* himself cites shows that failure to work was at least prima facie evidence of abuse in many or most industrialized countries;²² while *Bodenhausen* appears to accept the view that insufficient working was a per se abuse, even if states remained free to define what they meant by failure to work and the extent to which the patent must be worked locally or not.²³

¹² 1 S. Ladas, supra note 6, at 523. See also A. Samuel Oddi, TRIPS -- Natural Rights and a "Polite Form of Imperialism", 29 Vand. J. Transnat'l L. 415 (1996); A. Samuel Oddi, The International Patent System and Third World Development: Myth or Reality?, 1987 Duke L.J. 831.

¹³ See 1 S. Ladas, supra note 6, at 523-24.

¹⁴ See Paris Convention, supra note 1, art. 4A(1).

¹⁵ See 1 S. Ladas, supra note 6, at 526.

¹⁶ Paris Convention, supra note 1, Hague text of 1925, art. 5 (quoted in 1 S. Ladas, supra note 6, at 527).

¹⁷ 1 S. Ladas, supra note 6, at 528 (citing authorities).

¹⁸ See id. Many examples of the Canadian practice implementing this provision are provided in the part/section/chapter on the Canadian experience (forthcoming). For a list of countries that required local working as of 1988, see Michael D. Scott, Compulsory Licensing of Intellectual Property in International Transactions, 11 E. I. P. R. 319, 323 - 25 (1988).

¹⁹ See supra note 16.

²⁰ See 1 S. Ladas, supra note 6, at 528.

²¹ See id.

²² See 1 S. Ladas, supra note 6, at 528-29.

²³ See G. H. C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property (as Revised at Stockholm in 1967) 71 (1968).

If one effect of the 1925 reforms was clearly to discredit the use of forfeiture as a remedy for abuse,²⁴ another equally clear if unintended consequence was to legitimate the use of compulsory licenses to remedy a wide variety of abuses, including a failure to work the patent locally. As *Ladas* himself somewhat ruefully admits, the result of the revision of article 5 of the Paris Convention in 1925 "was to stimulate the adoption of a compulsory license system in the patent law of most countries which theretofore had no such provision."²⁵

While the reform of 1925 also allowed the patentee, in principle, to avoid a charge of abuse by proving "the existence of legitimate excuses,"²⁶ the notion of legitimacy was contingent on local law, and this did not necessarily make it easy to justify a failure to work the patent locally. For example, "importation of the product ... and putting such product on sale on reasonable terms was not, in itself, a legitimate excuse."²⁷

At the London Revision Conference of 1934, it was further provided that Paris Union members could not institute proceedings for forfeiture on grounds of abuse before the expiration of two years from the grant of the first compulsory license.²⁸ The net result was to ensure that any demonstrable claim of abuse had first to elicit a compulsory license, while the availability of forfeiture as the ultimate sanction had been already further limited, in 1925, by a provision that it not be prescribed "except in cases where the grant of compulsory licenses would not have been sufficient to prevent such abuses."²⁹

2.2. Compulsory Licensing to Promote the Public Interest

As states familiarized themselves with the remedy of compulsory licensing used to limit forfeiture in cases of abuse, and especially in cases of nonworking, another unintended consequence of the entire exercise was that they increasingly resorted to this same remedy in order to restrict the powers of the patentee even in the absence of abuse. They did this for a variety of reasons that were generally supposed to promote the "public interest"³⁰. Not surprisingly, compulsory licensing was of particular interest to countries seeking to regulate patents covering medicinal products and food products.³¹ Although some observers attempted to argue that the limitations applicable to instances of "abuse" under article 5A of the Paris Convention, as amended in 1934, also applied to limit a state's ability to issue compulsory licenses on other grounds, these arguments had no basis in the text of the treaty. They were authoritatively rejected by the House of Lords in a famous decision of 1954,³² and more recently by the German Federal Supreme Court in 1995.³³

In preparing for the Lisbon Conference of 1958, the International Bureau administering the Paris Convention at this period duly sought to clarify the wishes of the member countries concerning the possible application of article 5A to cases where no abuse of the patent monopoly was at issue. They learned that some fifteen countries (including some ten or eleven developed countries) "reserved the right in case of public interest to grant a compulsory license at any time without awaiting the lapse of the ... period" set out in articles 5A(3) and (4).³⁴ They also learned that the Members essentially

²⁴ See, e.g., 1 S. Ladas, *supra* note 6, at 529.

²⁵ *Id.* at 530. Conversely, countries that did not enact legislation permitting compulsory licenses often continued to forfeit patents that had not been worked for three years. See *id.* at 530-37.

²⁶ *Id.* at 532.

²⁷ *Id.*

²⁸ *Id.*

²⁹ Paris Convention (1967), *supra* note 1, art 5A(3); 1 S. Ladas, *supra* note 6, at 532.

³⁰ See 1 S. Ladas, *supra* note 6, at 532-37.

³¹ See *id.* at 533.

³² See *Parke-Davis Co. v. Comptroller of Patents, Designs and Trade Marks*, [1954] 71 R.P.C. 169; 1 S. Ladas, *supra* note 6, at 533.

³³ See *Case Nasser*, NJW 49,1953 (5 Dec. 1995); see also Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* 319-21 (2002) [hereinafter J. Watal], at 319.

³⁴ 1 S. Ladas, *supra* note 6, at 534-35. These countries included Belgium, Canada, Denmark, Finland, France,

agreed that compulsory licenses should always be granted on a nonexclusive basis,³⁵ hence, a limited provision to this effect was added to article 5A(4) of the 1958 text.³⁶ However, the United States blocked a consensual drive to require remuneration in all cases where compulsory licenses were authorized, ostensibly because this obligation was inconsistent with the judicial treatment of antitrust violations in that country,³⁷ and no provision to this effect was adopted prior to article 31 of the TRIPS Agreement in 1994.³⁸

The International Bureau's efforts to clarify the application of article 5A to cases in which no abuse was at issue then produced another of those unintended consequences that seem to have characterized the entire history of the provisions regulating compulsory licenses in international conventions. By the end of the Lisbon Conference to revise the Paris Convention in 1958, the delegates had decided that a member state's freedom to issue compulsory licenses on grounds of public interest without any mandatory period of delay should also extend to all cases of abuse, except that of nonworking. As a result, article 5A(4) was revised downwards so that, from 1958 on, it required a mandatory period of delay (i.e., four years from the date of filing or three years from the date the patent issues, "whichever period expires last") only for compulsory licenses made available "on the ground of failure to work or insufficient working!"³⁹

In other words, the conditions governing the issuance of compulsory licenses on general grounds of abuse were liberalized and harmonized with the more permissive rules (or lack of rules) governing compulsory licenses issued on public interest grounds. Even a patentee who worked the patent locally thus became vulnerable to the imposition of such a license at any time if, for example, he sold the patented products at "unreasonably high prices," or if, having licensed the product for local manufacture, he surfeited the market with imported (but patented) products from abroad "at a price with which the locally manufactured product cannot compete."⁴⁰

Subsequent efforts to stipulate and restrict conditions under which a compulsory license might be granted for reasons other than abuse were promoted at international meetings of patent attorneys during the period 1960-1966,⁴¹ but none of these proposals entered the Stockholm Revision of 1967. Indeed, those who had feared that efforts to restrict such licenses to cases of "imperative" or "exceptional" requirements of public interest might tend "to encourage member countries which do not have provision for such measures to legislate about such restrictions" saw their worst fears realized over time.⁴² In the European Union, for example, all member countries have provisions allowing the imposition of compulsory licenses on public interest grounds.⁴³ While these provisions reportedly "encounter few legal and economic policy reservations," interpretations of the term "public interest" varied too much in the European Union Member States to permit harmonization even by the end of the twentieth century.⁴⁴ It was nonetheless generally understood that such licenses could be invoked to meet national defense, environmental concerns, to increase energy supplies, to enhance workers' safety, or to combat new diseases "if the patent owner does not take sufficient account of the needs of the general public."⁴⁵

Germany, Israel, Japan, Norway, The Netherlands, Rhodesia, Romania, South Africa, Sweden, and Yugoslavia.

³⁵ See 1 S. Ladas, *supra* note 6, at 535.

³⁶ See Paris Convention (Lisbon text of 1958), *supra* note 1, art. 5A(4) (compulsory licenses granted for failure to work shall be nonexclusive), which remained unchanged in the Stockholm revision of 1967.

³⁷ See 1 Ladas, *supra* note 6, at 535. However, other reports suggested that the U.S. objection was also rooted in national security concerns, especially those bearing on atomic energy.

³⁸ See TRIPS Agreement, *supra* note 2, art. 31(h). Even today, art. 31(k) states that the "need to correct anti-competitive practices may be taken into account in determining the amount of remuneration."

³⁹ 1 S. Ladas, *supra* note 6, at 535-36; see also Paris Convention (1967 text), *supra* note 1, art. 5A(4).

⁴⁰ 1 S. Ladas, *supra* note 6, at 536.

⁴¹ See *id.* at 536-38.

⁴² *Id.* at 536.

⁴³ See Beier, *supra* note 11, at 261.

⁴⁴ *Id.*

⁴⁵ *Id.*

From a worldwide perspective, about one hundred countries had reportedly recognized some form of non-voluntary licensing in their domestic patent laws by the early 1990s.⁴⁶ While the grounds for imposing such licenses varied from country to country, the following rubrics had all been invoked at different times and places: refusal to deal; nonworking or inadequate supply of the market; public interest; abusive and/or anticompetitive practices; government use; dependent or "blocking" patents (on improvements to prior inventions); special product regimes, e.g., pharmaceuticals and food; licenses of right.⁴⁷

Against this background, tensions generated by the emphasis that spokesmen for developing countries increasingly gave to non-voluntary licensing of patents came to a head during the Conference to Revise the Paris Convention that dragged on from 1979 to 1985. In this period, the developing countries were as intent on lowering the international minimum standards of patent protection as the developed countries were resolved to elevate these same standards.⁴⁸ Especially controversial were proposals to strengthen the capacity of member countries to impose non-voluntary licenses generally, and even to restrict the ability of affected patentees to remain in the market with the designated licensees.⁴⁹ In the end, such proposals led to the collapse of the Paris Revision Conference, and they were instrumental in the decision to remove efforts to reform international industrial property law from the exclusive jurisdiction of WIPO and to bring them within the legislative and judicial jurisdiction of the GATT and its successor institution, the WTO.

⁴⁶ See Correa, *Compulsory Licenses*, supra note 8, at 4. See also Beier, supra note 11, at 259-260 (finding majority of patent laws in developed countries to permit compulsory licenses, but stressing that actual grants of such licenses remain rare); Scott, supra note 18.

⁴⁷ Correa, *Compulsory Licenses*, supra note 8, at 10-21. With specific regard to patented inventions, the United Kingdom adopted a license of right in 1977, when it expanded the duration of protection from 16 to 20 years. In the final few years of patents benefiting from this provision, nonexclusive licenses of right "became available if the patentee had been importing the bulk of the product into the United Kingdom, subject to certain restrictions." See, e.g., *id.* at 20-21.

⁴⁸ See generally J. H. Reichman, *Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection*, 22 *Vand. J. Transnat'l L.* 747, 754-67 (1989) [hereinafter Reichman, *GATT Connection*].

⁴⁹ See, e.g., Beier, supra note 11, at 260, 260 n.31 (citing authorities). For proposals to institute a preferential regime for developing countries within the framework of the Paris Convention that were debated but not adopted at the Conference to Revise the Paris Convention, 1979-1986, see WIPO Synoptic Tables Concerning Articles 1, 5A, and 5Quater of the Paris Convention for the Protection of Industrial Property, WIPO Doc. No. PR/DC/INF/51 (1984); see also Peter Kunz-Hallstein, *The Revision of the International System of Patent Protection in the Interest of Developing Countries*, 10 *Int'l Rev. Indus. Prop. & Copyright Law (I.I.C.)* 649, 658-64 (1979); Gail E. Evans, *Intellectual Property as a Trade Issue: The Making of the Agreement on Trade Related Aspects of Intellectual Property Rights*, 1994 *World Competition L. & Econ. Rev.* 137 (Dec. 1994).

2.3. A Comprehensive Legal Framework: Non-voluntary Licenses under the TRIPS Agreement

The outcome of this initiative, undertaken within the framework of the Uruguay Round of Multilateral Trade Negotiations was, of course, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of 1994.⁵⁰ The TRIPS Agreement blocked further efforts to negotiate differential and more favorable treatment for developing countries under the patent provisions of the Paris Convention, and it greatly elevated the international minimum standards of patent protection that would apply to all WTO member countries in the future.⁵¹ The impact of this "revolutionary" change in international patent law⁵² on developing and least-developed countries remains even more controversial today than at the time the TRIPS Agreement was adopted.⁵³

Nevertheless, when it came to determining the rules applicable to non-voluntary licensing of patented inventions under the TRIPS Agreement, the delegates found it no easier to reach a consensus concerning agreed limitations on this institution than it had been during the failed negotiations to revise the Paris Convention. This lack of consensus persisted notwithstanding the fact that the issue of non-voluntary licenses engendered "some of the most intensely negotiated provisions" of the TRIPS Agreement.⁵⁴

2.3.1. Framework of the TRIPS Approach

The exclusive rights conferred by article 28.1 of the TRIPS Agreement empower patent owners to prevent others from making, using, offering for sale, selling, or importing a patented article or process without their permission.⁵⁵ Exclusivity ensures that the patent holder may fully exploit the invention and obtain a "reasonable reward" for the creative endeavor. The potential reward is meant to stimulate risk taking and especially investment in research and development, and the limited monopoly effected by the grant of exclusive rights for a specified term protects the returns from that investment.⁵⁶

Article 28.2 further provides that patent owners shall have the right to assign or transfer the exclusive patent rights, or to enter into voluntary licensing arrangements. The terms of licensing agreements are open to negotiation among the parties, subject to domestic laws governing abuse and other anticompetitive practices.⁵⁷

The principal limitations on a patentee's exclusive rights are the relatively narrow set of exceptions covered by article 30⁵⁸ and the rather broad possibilities for imposing non-voluntary licenses under

⁵⁰ See supra note 2.

⁵¹ See, e.g., Joseph Straus, Implications of the TRIPS Agreement in the Field of Patent Law, in *From GATT to TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights* 160 (F.K. Beier & G. Schricker, eds., 1996), at 100 et seq.; J. H. Reichman, Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement, in *Intellectual Property and International Trade: The TRIPS Agreement* 21 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998) [hereinafter C. Correa & A. Yusuf].

⁵² Straus, supra note 51.

⁵³ See generally Keith Maskus, *Intellectual Property Rights in the Global Economy* (2000) [hereinafter K. Maskus]; Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, study prepared for the United Kingdom Commission on Intellectual Property Rights, Feb. 2002 [hereinafter Drahos, *Developing Countries*].

⁵⁴ J. Watal, supra note 33, at 317.

⁵⁵ TRIPS Agreement, supra note 2, art. 28.1.

⁵⁶ See generally Beier, supra note 11, at 255-56.

⁵⁷ See TRIPS Agreement, supra note 2, arts. 8.2, 28.2, 40.

⁵⁸ See TRIPS Agreement, supra note 2, arts. 30-31. For a discussion of the limitations on the application of article 30, see Canada -- Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R (17 Mar. 2000) [hereinafter *Canadian Pharmaceutical Products Decision*].

article 31.⁵⁹ Account must also be taken of article 27.1, which requires patents to be available "and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced."⁶⁰ This non-discrimination provision lies at the center of the debate regarding the continued legitimacy of the working requirements under the TRIPS Agreement.

2.3.2. Understanding the TRIPS Approach

It is not the purpose of this survey to parse the technical language implementing the compromise that the TRIPS negotiators finally embodied in article 31.⁶¹ Rather, what follows summarily evaluates the end result in light of the questions that were raised during the failed negotiations to revise the Paris Convention.

To begin with, the continuing ability of WTO Member Countries to treat a failure to work patents locally as an abuse under article 5A of the Paris Convention remains controversial and unsettled. While article 5A has been incorporated bodily into the TRIPS Agreement,⁶² that Agreement also provides, in article 27.1, that the enjoyment of the patentee's exclusive rights must be "without discrimination as to ... whether products are imported or locally produced."⁶³ Whether this provision and its ambiguous legislative history suffice to repeal the pre-existing right of Member States to continue to treat local nonworking as an abuse, as some contend,⁶⁴ or whether this right survives as an option that states retain within the framework of their competition laws and regulations,⁶⁵ as others contend,⁶⁶ remains an open question at the time of writing.⁶⁷ A suit filed at the WTO by the United States against Brazil challenging the latter's local working requirement was withdrawn prior to adjudication.⁶⁸

Apart from questions pertaining to either the grant of a compulsory license for failure to work or the grant of such a license to prevent abuses of the patentee's exclusive rights under Paris Convention articles 5A(4) and 5A(2), respectively, strenuous efforts were made to formulate some criteria that might limit the Member States' powers to grant non-voluntary licenses on other grounds, particularly the broad and generic ground of promoting the "public interest." However, every attempt to narrow these grounds during the Uruguay Round negotiations ran afoul of the state practices of leading developed countries, including those of the United States.⁶⁹ Legislation in that country broadly authorizes the government and its contractors to make use of patented inventions without the patentee's permission and without access to injunctive relief to prevent infringement⁷⁰ and there are also a number of statutes allowing private compulsory licenses on specific public interest grounds.

⁵⁹ See, e.g., Correa, *Compulsory Licenses*, supra note 8, at 8-9; Reichman, *GATT Connection*, supra note 48, at 34-36.

⁶⁰ TRIPS Agreement, supra note 2, art. 27.1.

⁶¹ See further Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (2000) [hereinafter C. Correa, *TRIPS Agreement*]; UNCTAD/ICTSD Project, supra note 4.

⁶² See TRIPS Agreement, supra note 2, art. 2.1.

⁶³ *Id.* art. 27.1

⁶⁴ See, e.g., Straus, supra note 51; J. Watal, supra note 33, at 318.

⁶⁵ See TRIPS Agreement, supra note 2, arts. 8.2., 40.2.

⁶⁶ See, e.g., Carlos M. Correa, *Patent Rights*, in C. Correa & A. Yusuf, supra note 51, at 203.

⁶⁷ See C. Correa, *TRIPS Agreement*, supra note 61, at 90-91.

⁶⁸ See *Brazil- Measures Affecting Patent Protection, Notification of Mutually Agreed Solution*, WT/DS199/4, 19 July 2001 [hereinafter *Brazil Measures Affecting Patent Protection*].

⁶⁹ See J. Watal, supra note 33, at 319-21.

⁷⁰ See 28 U.S.C. §1498 (2002); A patentee can make a claim for "reasonable or entire compensation" when it discovers the government's "taking." For specific public interest provisions, see the forthcoming part on United States practice.

Once the United States delegation failed to persuade its negotiating partners that they could meaningfully differentiate "government use" from "compulsory licenses," an Indian proposal to combine both categories under a single set of conditions was ultimately accepted without any restrictions having been placed on the grounds for which states could grant licenses under either category.⁷¹ In other words, the long-simmering controversy over compulsory licenses, which more than any other issue had been responsible for the removal of negotiations concerning international industrial property standards from WIPO to GATT in 1986, once again gave rise to an unexpected and unintended set of consequences. The final text of article 31, while recognizing such grounds as "national emergencies," "circumstances of extreme urgency," "anti-competitive practices," "public non-commercial use," and "dependent patents,"⁷² otherwise "places no restrictions on the purposes for which such ... [a non-voluntary license] could be authorized."⁷³ It thus indirectly vindicated the public interest as a ground separate from the category of abuse, and constituted "quite a significant achievement for developing countries."⁷⁴

It is true, of course, that article 31 also codifies eleven conditions governing the issuance of non-voluntary licenses,⁷⁵ and some believe these to constitute "strict safeguards."⁷⁶ These conditions require among other things, case-by-case authorizations;⁷⁷ prior negotiations with rights holders (except for emergencies, government use, and anticompetitive practices);⁷⁸ non-exclusivity, limited scope of the licenses, and adequate remuneration based on the economic value of the license;⁷⁹ judicial review;⁸⁰ and the possibility of terminating a non-voluntary license if the circumstances justifying its initial grant "cease to exist and are unlikely to recur."⁸¹ Article 31(f) further requires that such licenses shall be authorized "predominantly for the supply of the domestic market."⁸²

Of these pre-conditions, the potentially most troublesome is the patent holder's possible claim to terminate a non-voluntary license under article 31(g) "if and when the circumstances which led to it cease to exist and are unlikely to recur." Read broadly, this provision could discourage investors from seeking compulsory licenses once a state decides to make them available.⁸³

However, the stringency of this and other pre-conditions must necessarily vary in practice with the purposes for which non-voluntary licenses were issued in the first place. Suppose, for example, that a state resorts to a non-voluntary license in connection with "some circumstances of extreme urgency" under article 31(b), even though it remains fully entitled to emit non-voluntary licenses in the absence of any such circumstances. While a temporary emergency might later subside, the specific nature of the urgent circumstances would logically influence the government's choice of instruments to address them.

⁷¹ See J. Watal, *supra* note 33, at 320-21.

⁷² TRIPS Agreement, *supra* note 2, art. 31.

⁷³ J. Watal, *supra* note 33, at 320. J. Watal, as a negotiator for India at the time, was personally involved in bringing this result to fruition.

⁷⁴ *Id.*

⁷⁵ See TRIPS Agreement, *supra* note 2, art. 31. A twelfth clause, art. 31(l) deals with compulsory licenses issued for dependent patents, but the present survey does not deal with that subject matter in detail. See J. Watal, *supra* note 33, at 326-27.

⁷⁶ See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* 165 (1998).

⁷⁷ See TRIPS Agreement, *supra* note 2, art. 31(a) (requiring authorization of use to "be considered on its individual merits").

⁷⁸ See *id.* arts. 31(b), (k) (requiring efforts to obtain voluntary license "on reasonable commercial terms and conditions...within a reasonable period of time").

⁷⁹ See *id.* arts. 31(c), (d), (h). The license can only be assigned "with that part of the enterprise or goodwill which enjoys such use." *Id.* art. 31(e).

⁸⁰ See *id.* art. 31(i).

⁸¹ See *id.* art. 31(g).

⁸² See *id.* art. 31(f).

⁸³ See *id.* art. 31(g); Correa, *Compulsory Licenses*, *supra* note 8, at 8.

In such cases, the authorities could either rely on private parties under a license granted in the "public interest" or on their own resources under a "government use" provision, or on some combination of the two approaches. In any case, if the emergency appeared chronic and likely to endure, the terms of the grant itself (or of the law authorizing the grant of a non-voluntary license) should immunize the licensee from undue risk⁸⁴ and should overtly protect its "legitimate interests."⁸⁵ If, instead, the "emergency" was a one-time event or of a likely short-term duration, the terms of the grant should enable would-be licensees to assume the risk of termination and avoid structural investments.

By the same token, the use of non-voluntary licenses to address anticompetitive practices will vary significantly with the facts and with the local legal culture. In the United States, for example, a guilty patent holder may "purge" his misuse of the statutory exclusive rights, at least in theory; but in that event, the party that had invoked "misuse" as a defense to a patent infringement action would once again become liable for his infringing uses. In contrast, consent decrees that impose some form of non-voluntary license to redress antitrust violations or to regulate contested mergers and acquisitions cannot readily be modified.

In most other cases, one would expect the grant of a non-voluntary license to be part of some medium or long-term program or project that was premised either on public interest grounds or on governmental use. For example, Canada allowed non-voluntary licensing to promote local production of pharmaceuticals and food products in the public interest until recently, while the United States allows non-voluntary licensing of patents in connection with certain major development projects to dam rivers and generate electricity. Such programs and projects normally take on a life of their own, independent of any given patentee's desire to reacquire its foregone exclusive status.

In this context, non-voluntary licenses that had been issued for similar projects or programs could seldom be terminated merely to accommodate a disgruntled patentee⁸⁶ without undermining the state's obligation to "adequate[ly] protect...the legitimate interests of the persons so authorized."⁸⁷ On the contrary, non-voluntary licenses to promote the public interest should reflect a balancing of the rights of patentees against the greater public good.⁸⁸ Once this calculus has properly been made, it is not for patentees or WTO dispute-settlement panels to second guess the state's own assessment,⁸⁹ or otherwise to undermine the interests of the designated licensees.⁹⁰

On the whole, Article 31 thus leaves considerable leeway to policymakers and administrators in both developed and developing countries to impose non-voluntary licensing of patented inventions for any legitimate purpose and without undue constraints.⁹¹ In particular, any government that seeks to bring a patentee's practices into line with its own policies, especially with regard to disciplining the prices at which the patented articles are to be locally distributed, can achieve its aims within the confines of

⁸⁴ In the United States, for example, the law allowing non-voluntary licenses for "government use" immunizes government agencies and their contractual suppliers from patent infringement suits.

⁸⁵ TRIPS Agreement, supra note 2, art. 31(g).

⁸⁶ See TRIPS Agreement, supra note 2, art. 31(g) (empowering the "competent authority to review, upon motivated request, the continued existence of ...circumstances" that led to the grant of a compulsory license).

⁸⁷ Id.

⁸⁸ See, e.g., Beier, supra note 11, at 261 (citing *Polyferon* decision, Federal Supreme Court/Germany), 28 Int'l Rev. Indus. Prop. & Copyright Law (I.I.C.) 242 (1997)).

⁸⁹ See, e.g., India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Appellate Body, WT/D550/AB/R, 19 Dec. 1997 (reversing panel's "legitimate expectation test" and declining a standard of compliance that eliminated "any reasonable doubts" because members are free to determine the appropriate method of implementing TRIPS standards under art. 1.1); see also Jerome H. Reichman, Securing Compliance with the TRIPS Agreement After U.S. v. India, 1998 J.I.E.L. 585, 592-97 (reading India Patents case as a mandate for strict construction and deference to local law). Obviously, if a state's approach improperly conflicts with international minimum standards, it will be struck down, but *India – Patents*, supra, suggests that there is still plenty of room for reasonable maneuver.

⁹⁰ See TRIPS Agreement, supra note 2, art. 31(g).

⁹¹ For detailed examples, see J. Watal, supra note 33, at 321-29.

article 31. Indeed, as recent experience in both Brazil and the United States demonstrate once again, the mere threat of a non-voluntary license may obviate the need to issue it in practice⁹² because "it usually induces the grant of contractual licenses on reasonable terms."⁹³ If so, it would mean that the real obstacles to the granting of non-voluntary licenses under article 31 of the TRIPS Agreement are usually of an economic and political nature, and do not necessarily derive from the codified international minimum standards as such.⁹⁴

A number of cautionary observations are in order, however, primarily because the flexibility embedded in article 31 of the TRIPS Agreement is not boundless, and other provisions of that Agreement may further constrain it. For example, care must be taken to work around the requirement of non-discrimination in article 27.1,⁹⁵ which seems to impede the imposition of non-voluntary licensing on unreasonably broad subject-matter categories. Thus, a government presumably could not impose compulsory licensing on medicines in general as Canada did until 1992, without some compelling justifications;⁹⁶ but it could impose such licensing on medicines reasonably deemed to be "essential" if other requirements of article 31 were satisfied.⁹⁷

Still other limitations apply. With respect to patented semiconductor technology, for example, Member States can grant non-voluntary licenses only for public non-commercial use or to remedy anticompetitive practices.⁹⁸ Similarly, the power to grant non-voluntary licenses may not override international standards that protect trade secrets,⁹⁹ or that restrict the rights of third parties to appropriate the data from clinical trials of patented pharmaceutical products.¹⁰⁰ To a still unknown extent, finally, a state's ability to grant non-voluntary licenses could eventually trigger allegations of nonvoluntary acts of nullification or impairment of bargained-for expectations under the TRIPS Agreement as a whole,¹⁰¹ if and when the latest moratorium on such claims is lifted.¹⁰²

⁹² Brazil obtained major price reductions on HIV retrovirals from Hoffman-La Roche after threatening to invoke its local working requirement. See Jennifer L. Rich, *Roche Reaches Accord on Drug with Brazil*, *New York Times*, 1 Sept. 2001. Brazil also obtained significant price discounts from Merck in March of 2001 after threatening to impose a compulsory license. See Miriam Jordan, *Merck Vows AIDS Help for Brazilians*, *Wall St. J.*, 30 Mar. 2001.

⁹³ 1 S. Ladas, *supra* note 6, at 427; see also Beier, *supra* note 11, at 260.

⁹⁴ See, e.g., Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (forthcoming 2002) [hereinafter S. Sell, *Private Power, Public Law*]; Correa, *Compulsory Licensing*, *supra* note 5, at 1 (citing authorities).

⁹⁵ See TRIPS Agreement, *supra* note 2, art. 27.1; J. Watal, *supra* note 33, at 322.

⁹⁶ See, e.g., Correa, *Compulsory Licensing*, *supra* note 8, at 19.

⁹⁷ See, e.g., *Canadian Pharmaceutical Products Decision*, *supra* note 58 (allowing exceptions geared to specific subject matter when reasonably justified by valid public policy considerations). See also *infra* text accompanying notes 103 et seq. (impact of Doha Declaration).

⁹⁸ See TRIPS Agreement, *supra* note 2, art. 31(c).

⁹⁹ See TRIPS Agreement, *supra* note 2, arts. 39.1, 39.2.

¹⁰⁰ See *id.* art. 39.3; see also Trevor C. Cook, *The Protection of Regulatory Data in Pharmaceutical and Other Sectors* (2000); Carlos M. Correa, "Integrating Public Health Concerns into Patent Legislation in Developing Countries," [hereinafter Correa, *Integrating Public Health Concerns*], Report prepared for the Rockefeller Foundation, New York (Jan. 2000), available at <http://www.southcentre.org/publication/pubindex.htm#working>.

¹⁰¹ See, e.g., TRIPS Agreement, *supra* note 2, art. 64; Rochelle Cooper Dreyfus & Andreas L. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 *Va. J. Int'l L.* 275 (1997).

¹⁰² See *Implementation-Related Issues and Concerns*, Decision of 14 Nov. 2001, Ministerial Conference, Fourth Session, Doha, WT/MIN(01)/17, par. 11 [hereinafter *Doha Ministerial Decision on Implementation Issues and Concerns*].

2.4. Impact of the Doha Declaration on Public Health

The practical ramifications of article 31 may ultimately depend on a combination of state practice at the local and regional levels and subsequent legislative or judicial action at the international level, especially with regard to controversial subject matter. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health of November 2001 is a case in point.¹⁰³ This highly political document recognizes that many developing countries are experiencing public health epidemics, and it stresses the need to reconcile the TRIPS Agreement with national and international efforts to address such crises.¹⁰⁴ It also recognizes the tension between the need for legal incentives to invest in the development of new medicines and the "effects on prices" of the resulting inventions in developing countries.¹⁰⁵

The precise legal status of the Doha Declaration on Public Health remains uncertain at the time of writing. It is not clear, for example, that the Ministerial Declarations emanating from Doha¹⁰⁶ amount to formal "decisions" of the Ministerial Conference, nor is it clear that "declarations" of this kind should carry less authority than formal "decisions."¹⁰⁷ The practical question concerns the extent to which future WTO panels and the Appellate Body will "draw guidance" from such Ministerial Declarations when deciding cases.¹⁰⁸

While this cannot be known in advance, it seems logical that the Doha Ministerial Declarations should exert no less interpretative weight than the Agreed Statements to the WIPO Copyright Treaty of 1996.¹⁰⁹ A WTO panel adjudicating a copyright dispute arising under the TRIPS Agreement¹¹⁰ viewed those Agreed Statements through the lens of article 31(3) of the Vienna Convention on the Law of Treaties.¹¹¹ As posterior, consensual agreements between essentially the same parties, they shed light on how the TRIPS Agreement should be applied and reconciled with other relevant treaties.¹¹² It is also possible to view the Doha Declarations as "part of the constitutive process of decision-making by the WTO as an organization."¹¹³

The Doha Declaration on Public Health attempts to clarify the flexibility already embodied in the TRIPS provisions concerning the use of non-voluntary licenses to address public health problems, and it may help to alleviate certain misunderstandings that previously clouded these issues.¹¹⁴ For example, the drafters "reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility ... to protect public health, and, in particular, to promote access

¹⁰³ Doha Declaration on Public Health, *supra* note 3.

¹⁰⁴ See Doha Declaration on Public Health, *supra* note 3, pars. 1-4.

¹⁰⁵ *Id.* par. 3.

¹⁰⁶ These include the Doha Ministerial Declaration [the work program], WT/MIN (01)/DEC/1, in addition to the Doha Ministerial Declaration on TRIPS and Public Health, *supra* note 3. See also the Doha Ministerial Decision on Implementation Issues and Concerns, *supra* note 102.

¹⁰⁷ See, e.g., Steve Charnovitz, *The Legal Status of the Doha Declaration*, 5 J.I.E.L. 207 (2002) (interpreting the Marrakesh Agreement Establishing the World Trade Organization, arts. (II:2, IV:1, IX:1).

¹⁰⁸ *Id.*

¹⁰⁹ See World Intellectual Property Organization: Copyright Treaty and Agreed Statements Concerning the Copyright Treaty, adopted by the Ministerial Conference, 20 Dec. 1996, Geneva, Switzerland, 36 I.L.M. 65 (1997).

¹¹⁰ United States - Section 110(5) of U.S. Copyright Act, Report of the Panel, WT/DS160/R, 15 June 2000 [hereinafter United States - Section 110(5)].

¹¹¹ See Vienna Convention on the Law of Treaties, 23 May 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679 (1980), art. 31.

¹¹² See United States - Section 110(5), *supra* note 110.

¹¹³ Charnovitz, *supra* note 107. See generally Gail E. Evans, *Lawmaking Under The Trade Constitution – A Study In Legislating By The World Trade Organization* (2000).

¹¹⁴ See generally Correa, *Compulsory Licenses*, *supra* note 8; Straus, *supra* note 51; Beier, *supra* note 11. For background, detailed analysis, and posterior developments, see most recently Frederick M. Abbott, *The Doha Declaration on The TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J.I.E.L. 469 (2002) [hereinafter Abbott, *Doha Declaration*].

to medicines for all."¹¹⁵ To this end, they expressly declare that, "[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."¹¹⁶ While this provision adds nothing to the substantive legal framework of article 31, it attempts to clarify prior misperceptions, and it supplies an authoritative and "unequivocal statement regarding the right of Members to grant compulsory licenses."¹¹⁷

The Doha text also rectifies the misguided notion that states must proclaim a full-fledged national emergency in order to grant non-voluntary licenses for patented pharmaceutical products under article 31 of the TRIPS Agreement. On the contrary, the Declaration expressly recognizes the right of each Member "to determine what constitutes a national emergency or other circumstances of extreme urgency."¹¹⁸ This characterization, when made in good faith, triggers the waiver of any duty to negotiate with the right holder under article 31(b) prior to the granting of compulsory licenses.¹¹⁹

Still more concretely, the Doha Declaration on Public Health extends the transitional provisions for least-developed countries ("LDCs") so as to exempt them from implementing, with respect to pharmaceutical products, both the patent provisions of the TRIPS Agreement and the provisions on the protection of undisclosed information until at least January 1, 2016.¹²⁰ Unfortunately, the Declaration fails to address related questions about the ability of least-developed countries to similarly defer implementing the mailbox and exclusive marketing rights provisions of the TRIPS Agreement,¹²¹ as well as any obligations to provide and enforce pharmaceutical process patents after 2006.¹²² While there is reason to believe that these additional deferments were technical oversights, which the Council for TRIPS should eliminate in due course, a failure to clarify these ambiguities might constrain the strategies that LDCs employ to enhance their access to medicines during the prolonged transitional period.¹²³

The Declaration also expressly confirms that states may allow parallel imports of patented articles under a doctrine of international exhaustion "without challenge," so long as most favored nation ("MFN") and national treatment obligations are otherwise respected.¹²⁴ In other words, patented medicines or other goods lawfully placed on the market at low prices in poor countries can be re-sold and exported to other poor countries that enact enabling legislation, notwithstanding the patentee's exclusive rights to otherwise import the patented products into the latter countries. While this provision adds nothing to the pre-existing rights of states under article 6 of the TRIPS Agreement,¹²⁵ it blocks developed countries from further asserting a contrary theory of national exhaustion, as they had previously done.

The legitimation of parallel imports under a doctrine of international exhaustion in paragraph 5(d) further complicates the price discrimination strategies of the major pharmaceutical companies. While these companies have come under intense pressure to reduce the prices of patented medicines sold in

¹¹⁵ Doha Declaration on Public Health, supra note 3, par. 4.

¹¹⁶ Id. par. 5(b).

¹¹⁷ Abbott, Doha Declaration, supra note 114.

¹¹⁸ Doha Declaration on Public Health, supra note 3, par. 5(c).

¹¹⁹ See TRIPS Agreement, supra note 2, art. 31(b). It is "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." Doha Declaration on Public Health, supra note 3, par. 5(a).

¹²⁰ See Doha Declaration on Public Health, supra note 3, par. 7. This provision is stipulated "without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in article 66.1 of the TRIPS Agreement." Id.

¹²¹ The Declaration neglects to clarify whether LDCs are also exempted from the mailbox and exclusive marketing rights provisions of TRIPS Agreement, supra note 2, arts. 70.8 and 70.9, given that the shield of art. 66 expires in this respect on January 1, 2006.

¹²² See TRIPS Agreement, supra note 3, arts. 27.1, 34, 65-66.

¹²³ For details, see Abbott, Doha Declaration, supra note 114.

¹²⁴ Doha Declaration on Public Health, supra note 3, par. 5(d).

¹²⁵ See TRIPS Agreement, supra note 2, art. 6.

poor countries, they fear that uncontrolled re-exports of such products from these countries will compromise their ability to distribute the same products at higher prices in countries that are better off.¹²⁶ This fear exerts an upward pressure on the prices of patented pharmaceutical products sold in poor countries. Higher prices, in turn, put pressure on governments in poor countries to impose price controls, to invoke the doctrine of abuse for inadequately supplying the local market, and to impose compulsory licenses in the public interest or for government use.¹²⁷ The surveys of Canadian and United States practices, undertaken in the context of this study, provide instructive examples of such countervailing strategies.

Unfortunately, the Doha Declaration on Public Health does not resolve one important question concerning the right of importing states to treat products initially sold under a compulsory license in the exporting state as parallel imports covered by paragraph 5(d). Because these patented products were initially sold without the consent of the patent owner, one line of authorities holds that the doctrine of exhaustion cannot technically apply.¹²⁸ If so, the exported goods produced under a non-voluntary license abroad could infringe the local patentee's exclusive right to import the goods in question under territorial law.¹²⁹

If it turns out that patented pharmaceuticals distributed under a compulsory license cannot be exported as "parallel goods" within paragraph 5(d) of the Doha Declaration, then they remain subject to article 31(f) of the TRIPS Agreement, which literally limits such exports to 49.9 per cent of the total supplies distributed under the compulsory license in the local market.¹³⁰ Since only a small number of developing countries can manufacture technically advanced medicines, these legal impediments hamstringing the ability of these countries to assist other poor countries that issue compulsory licenses in order to acquire essential medicines without possessing any local manufacturing capacity in this regard.¹³¹

Can developing countries with manufacturing and export capabilities impose compulsory licenses on patented medicines for the purpose of assisting other developing countries that lack manufacturing capabilities to import essential medicines under compulsory licenses of their own, without violating the patentee's rights under the TRIPS Agreement? Unfortunately, the Doha Ministerial Declaration on Public Health gave an ambiguous answer to this critical issue. While recognizing that countries "with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing," it provided no clear legal machinery for resolving this dilemma and merely "instructed the Council for TRIPS to find an expeditious solution to this problem" before the end of 2002.¹³²

As a result, the Declaration did not expressly empower states capable of manufacturing generic drugs under compulsory licenses to act as the agents of states that lack such capacity. It did not authorize the former to meet the latter's needs by imposing compulsory licenses for this purpose notwithstanding the export limitations of TRIPS article 31(f), nor did it concede that the exceptions to the patentee's

¹²⁶ See, e.g., Harvey E. Bale, Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 J.I.E.L. 637 (1998); see also Alan O. Sykes, *TRIPS, Pharmaceuticals and the Doha "Solution"*, John M. Olin Law & Economics working paper No. 140 (2d series), Univ. of Chicago working paper series (2002).

¹²⁷ See TRIPS Agreement, *supra* note 2, arts. 8.1, 8.2, 31, 40.2. See also J.H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 NYU J. Int'l L. & Pol. 11, 52-58 (1997) [hereinafter Reichman, *Free Riders to Fair Followers*].

¹²⁸ See, e.g., Abbott, *Doha Declaration*, *supra* note 114 (reviewing arguments and authorities on both sides of this issue).

¹²⁹ See TRIPS Agreement, *supra* note 2, arts. 28.1, 28.1 n.6.

¹³⁰ See TRIPS Agreement, *supra* note 2, art. 31(f).

¹³¹ See, e.g., Abbott, *Doha Declaration*, *supra* note 114 (stressing that art. 31(f) limits both the ability of importing countries thus to obtain generic import drugs under compulsory licenses and the ability of producer countries to obtain economies of scale in authorized exports of compulsory licensed drugs).

¹³² See *Doha Declaration on Public Health*, *supra* note 3, par. 6.

exclusive rights under article 30 of the TRIPS Agreement may implicitly allow the exporting state to impose compulsory licenses in order to assist other states for such purposes.¹³³ Instead, the Doha Declaration leaves these and other possible options, including a U.S. proposal for a moratorium on dispute settlement actions for violations of TRIPS standards incurred when states address public health crises,¹³⁴ to future action by the Council for TRIPS. The outcome of these consultations is unpredictable at the time of writing. Nonetheless, it seems clear that the Council for TRIPS must adopt one enabling solution or another before the end of 2002.

From a broader perspective, the most important effects of the Doha Declaration on Public Health are probably of a political rather than a strictly legal character. For example, it casts a certain aura of moral impropriety over continued efforts to use the intellectual property provisions of the TRIPS Agreement to impede developing countries from vigorously addressing at least the medical emergencies specified in the text.¹³⁵

A subtler political message underlying both the final Declaration and the negotiations that produced it is that WTO member countries have not surrendered their sovereign power to regulate public health matters under either the TRIPS Agreement or the WTO Agreement as a whole. Thus, the Ministers "agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health."¹³⁶ While maintaining their commitment to the TRIPS Agreement, the Ministers further affirm that it "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."¹³⁷

These and other provisions suggest that in the event of an unavoidable conflict between the TRIPS norms and overriding needs of public health in any given member country, the WTO Appellate Body and relevant dispute-settlement panels might find themselves obliged to defer to local measures that derogated from the former in order to regulate the latter, so long as such measures appeared objectively reasonable and necessary.¹³⁸ Indeed, a prolonged failure to resolve these tensions could undermine the credibility of the WTO and convert public health into a kind of deadly "third rail" issue as even developed country negotiators come to appreciate the potential political costs at home of surrendering too much sovereignty to the WTO in this field.

¹³³ See, e.g., Abbott, Doha Declaration, *supra* note 114. But see Canada-Protection of Pharmaceutical Products, *supra* note 58 (narrowly construing the exceptions available under TRIPS art. 30).

¹³⁴ See Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Communication from the United States, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/340, 14 Mar. 2002.

¹³⁵ See Doha Declaration on Public Health, *supra* note 3, par. 1 ("We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics"); *id.* par.4 ("we agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health").

¹³⁶ *Id.* par. 4.

¹³⁷ *Id.*; see also *id.* par. 5(a) (stressing the need to interpret TRIPS provisions in light of the Agreement's objectives and principles).

¹³⁸ See WTO Agreement, *supra* note 2, Annex 1A: Multilateral Agreements on Trade in Goods [hereinafter GATT 1994], 33 I.L.M. 28 (1994), art. XX. But see TRIPS Agreement, *supra* note 2, art. 8.1 (allowing "measures necessary to protect public health..." that "are consistent with the provisions of this Agreement").

3. A General Comparison of the Canadian and US Approaches

While much has been written about the legality of non-voluntary licensing of patented inventions after the adoption of the TRIPS Agreement in 1994,¹³⁹ a different set of questions regards the extent to which states have actually used such licenses in the recent past, the purposes for which they have used them, and the methods by which they have put them into practice. The following sections provide an overview of the practices in Canada and the US.¹⁴⁰

The main focus of recent discourse has been about how to ensure access to essential medicines and about the role that non-voluntary licensing might or might not play in this endeavour.¹⁴¹ Both of the countries surveyed in this study have manifested strong opinions about these issues in public and private forums.¹⁴²

At the same time, these countries have a rich and interesting experience in the use of non-voluntary licensing of this or other patentable subject matters. Thus, a survey of this experience might shed light on the opportunities and challenges that countries generally face in the actual use of this legal instrument. For example, Canada made extensive use of non-voluntary licensing of patented inventions in the recent past, when it still regarded itself as a not fully-fledged industrialized country. Moreover, Canada pursued this strategy vigorously with respect to two of today's most controversial subject matters, pharmaceutical and food patents, and it was instrumental in the establishment of a generic medicine industry in that country. Less well known is the fact that Canada also made long use of a local working requirement to authorize compulsory licenses in non-medical fields. However, these practices have given way in recent years to more pro-patent policies that the Canadian government adopted and codified in the broader context of the North American Free Trade Agreement (NAFTA).¹⁴³

Also of interest is Canada's reliance on statutory regulation of non-voluntary licensing, with particular regard to both abuse of patent rights and public interest objectives. In practice, however, the only type of "abuse" that consistently drew attention prior to the 1990s was a failure to work patents locally. Otherwise, non-voluntary licensing of patents in the public interest was largely confined to food and medicines under the special legal regimes that were repealed in the late 1980s and early 1990s. Even in the past, in other words, Canada largely refrained from using non-voluntary licenses to address other forms of abuse or competition law issues generally. Since the 1990s, moreover, Canada has made little use of compulsory licenses for any purpose, and it has lately advocated caution in the use of such licenses by other countries.

¹³⁹See, e.g., Correa, Compulsory Licenses, supra note 8; Straus, supra note 51; Beier, supra note 11. Non-voluntary licensing of copyrights, industrial designs, and other intellectual property rights is beyond the scope of this study. See, e.g., Correa, Compulsory Licenses, supra note 8, at 4-6.

¹⁴⁰For a detailed survey, see the forthcoming chapters/parts on Canada and the United States, respectively.

¹⁴¹See, e.g., Correa, Integrating Public Health Concerns, supra note 100; Carlos M. Correa, Public Health and Patent Legislation in Developing Countries, 3 *Tulane J. Tech. & Intell. Prop.* 1 (2001) [hereinafter Correa, Public Health]; Frederick M. Abbott, Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health, Quaker United Nations Office- Geneva, Occasional Paper 9, Feb. 2002, available at <<http://www.quno.org>>; Frederick M. Abbott, The TRIPS Agreement, Access to Medicines and the WTO Ministerial Meeting, Quaker United Nations Office - Geneva, Occasional Paper 7, Sept. 2001, available at <<http://www.quno.org>>.

¹⁴²See Draft Ministerial Declaration - Proposal from a group of developed countries (Australia, Canada, Japan, Switzerland and the United States), IP/C/W/313, submitted to the Council for TRIPS, 30 Oct. 2001.

¹⁴³North American Free Trade Agreement (NAFTA), 17 Dec. 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 612 (entered into force, 1 Jan. 1994) [hereinafter NAFTA].

Historically, the situation in the United States differed from that of Canada in nearly every respect. To begin with, the United States never adopted a general statute to regulate non-voluntary licensing of patented inventions either on grounds of misuse or on public interest grounds, despite numerous proposals to do so. On the contrary, courts and commentators frequently express pro-patent sentiments that bristle with hostility to the very concept of non-voluntary licensing.

In practice, however, the United States federal courts made aggressive use of non-voluntary licensing to regulate misuses of patent rights and antitrust violations involving the exercise of such rights until the last quarter of the twentieth century. So vigorous was the judicial intervention along these lines that in the only statute to address the issue, Congress actually attempted to restrain judicial recourse to the patent misuse doctrine in 1988. Since then, the federal appellate courts have more fully integrated the doctrine of patent misuse with evaluations of the anticompetitive effects of the conduct under consideration, and they have imposed relatively few non-voluntary licenses under either rubric. However, the Federal Trade Commission ("FTC") has made extensive use of such licenses, often in consent decrees bearing on corporate mergers and acquisitions.

The United States has also made far less use of non-voluntary licensing on public interest grounds than Canada, although limited statutory and common-law bases for issuing such licenses continue to exist in the United States. At the same time, the United States has always relied heavily on the non-voluntary licensing of patented inventions to facilitate public, non-commercial uses by the government and its agents, a practice that the Canadian authorities have less frequently emulated. The bulk of the non-voluntary licenses issued for government use pertain to national defense. Nevertheless, the United States has also used this same legal tool to reduce the costs of certain medicines and to advance both environmental and economic development goals, including major projects to dam rivers and generate electricity.

Many of the practices surveyed in this study seem highly relevant to the needs of developing countries, and readers are directed to the specific country studies on Canada and the US for details. A point worth stressing at the outset is that at least with regard to the small sample of countries chosen for this investigation, state practice varies widely, single countries often act without a high degree of consistency, and no uniform patterns emerge. The evidence gathered in this general study and especially in the specific country studies on Canada and the US would thus tend to substantiate the view of *Jayashree Watal*, who stated that article 31 of TRIPS was drafted in very broad and permissive terms precisely because state practices were themselves too broad and varied to be susceptible of narrower parameters.¹⁴⁴

3.1. Capsule Summary of the Canadian Experience

From the time of the Confederation until it adhered to the North American Free Trade Agreement ("NAFTA") in 1992,¹⁴⁵ "Canada's explicit policy was to encourage local manufacture of patented products."¹⁴⁶ Until the 1930s, the law required either local manufacture to commence or local licensing on reasonable terms to occur within a two-year period after the patent issued. The penalty for non-compliance was forfeiture.¹⁴⁷

This policy was refined in the patent revision of 1935, which treated failure to work or to license a patent as "abuses" of the patentee's exclusive rights.¹⁴⁸ If the Commissioner found a demonstrated abuse, the standard remedy became that of compulsory licensing at a reasonable royalty, and

¹⁴⁴ See J. Watal, *supra* note 33.

¹⁴⁵ NAFTA, *supra* note 143.

¹⁴⁶ David Vaver, *Intellectual Property - Copyright, Patents, Trade-Marks* 169 (1997) [hereinafter D. Vaver].

¹⁴⁷ See *Re Bell Telephone Co.* (1885), 9 O. R. 339 (S.P.).

¹⁴⁸ Patent Act, R.S.C. 1935, §§65-70.

revocation of the patent thereafter became a last resort.¹⁴⁹ The provisions that codified Canada's vigorous local working requirements persisted through the revisions of 1970 and 1985,¹⁵⁰ and they embodied a "made-in-Canada for Canada policy."¹⁵¹ However, these provisions have been deemed "only moderately successful."¹⁵² According to Professor Vaver,

*"The threat of intervention has not scared many patentees off. Proceedings have been prolonged and expensive; appeals are de rigeur; patentees, when alerted, often correct the abuse and retaliate against offending applicants."*¹⁵³

Of the 53 applicants who persisted between 1935 and 1970, 11 obtained compulsory licenses, 9 were refused, 32 applications were withdrawn or deemed abandoned, and the outcome of one is unknown.¹⁵⁴ Some 43 additional applications for compulsory licenses were filed under section 65 of the Patent Act between 1970 and June 1989. Of these, 6 resulted in compulsory licenses, 6 were refused, 25 were withdrawn or deemed abandoned, and the outcome of 6 is not known.¹⁵⁵ All granted licenses were reportedly nonexclusive in form, and there were four reported settlements among the 25 withdrawn or abandoned applications after 1970.¹⁵⁶

When Canada adhered to NAFTA in 1992, which allowed patentees to manufacture abroad and meet local demand through imports,¹⁵⁷ it repealed the "local working" component of the provisions governing abuse.¹⁵⁸ Whether NAFTA (or TRIPS) compels this retreat from the doctrine of abuse as such remains unclear, however, and should not be presumed in the absence of an authoritative judicial decision.¹⁵⁹

In addition, Canada also made use of compulsory licenses to promote the public interest, particularly by means of special provisions bearing on patents for food and medicines. With respect to medicines, a compulsory licensing scheme was used aggressively to promote the production of generic pharmaceuticals, and this scheme reportedly produced some of the lowest consumer drug prices in the industrialized world.¹⁶⁰ Between 1969 and 1992, there were 1,030 applications to import or manufacture medicines under such licenses, of which 613 licenses were granted. However, Canada largely abandoned this scheme in 1987 when a new political strategy was given legislative effect.

On the whole Canada has made relatively little use of compulsory licensing to address a patentee's anticompetitive practices. It is unclear whether this practice will change in the near future.

¹⁴⁹ See D. Vaver, *supra* note 146, at 169. For application procedures, see Roger Hughes & John Woodley, *Hughes and Woodley on Patents* §58 (2001) [hereinafter Hughes & Woodley].

¹⁵⁰ Patent Act, R.S.C. 1970, c. P-4, §§67-73; Patent Act, R.S.C. 1985, c. P-4, §§65-71.

¹⁵¹ D. Vaver, *supra* note 146, at 170.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ See *id.* See also Donald G. McFetridge, *Intellectual Property, Technology, Diffusion, and Growth in the Canadian Economy*, in *Competition Policy and Intellectual Property Rights in the Knowledge Economy* 65, 79 (Robert D. Anderson & Nancy T. Gallini, eds. 1998) [hereinafter McFetridge].

¹⁵⁵ See McFetridge, *supra* note 154, at 79.

¹⁵⁶ *Id.*

¹⁵⁷ See NAFTA, *supra* note 143, Chapter 17, art. 1709.7; D. Vaver, *supra* note 146, at 170.

¹⁵⁸ See Patent Act Amendment Act (effective 1993), R.S.C. 1992, c. P-4, §33 (3rd Supp.), R.S.C. 1992, c.1, §5 (repealing §§65(2)(a)(b) of 1985 Act).

¹⁵⁹ The United States withdrew a WTO action against Brazil that would have resolved this question for purposes of the TRIPS Agreement. See also Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, 35 *Osgoode Hall L. J.* 243 (1997).

¹⁶⁰ See Christopher Scott Harrison, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 versus the North American Free Trade Agreement and Bill C-91*, 26 *North Carolina J. Int'l. L. & Comm. Reg.* 457 (2001) [hereinafter Harrison]; McFetridge, *supra* note 154, at 82.

3.2. Capsule Summary of the Non-voluntary Licensing of Patented Inventions in the United States of America

Generally speaking, the prevailing ethos maintains that, unlike "many foreign countries, the United States takes a dim view of compulsory licensing."¹⁶¹ As evidence, it is said that the United States has no general statutory provisions for compulsory licensing of unexploited patents, no general statutory provisions for compulsory translation of foreign works of authorship, and no statute approving compulsory licensing for educational purposes.¹⁶² More to the point, the United States has never adopted a statutory regime of compulsory licenses to curb patent abuse, as still occurs in Canada, nor has Congress ever enacted a law that generally authorizes compulsory licensing of patents in the public interest, like that of Germany and many other countries.¹⁶³

In this same vein, the United States Supreme Court has observed that "compulsory licensing is a rarity in our patent system . . . [It] has never been enacted on a broad scale."¹⁶⁴ The primary reasons for this approach are said to be a strong faith in free-market principles and mistrust of government pricing.¹⁶⁵ Other reasons include a drive to maximize returns on investment in research and development¹⁶⁶ and a related commitment to efficiency at the expense of fairness in the application of present-day competition laws.¹⁶⁷

While one may concede that statutory compulsory licensing of patents in favor of third parties in the United States is "virtually non-existent,"¹⁶⁸ the truth is more complex and nuanced than would at first appear. For example, the United States government has broad powers to seize and use any invention protected by privately owned patents, subject to the payment of reasonable and entire compensation,¹⁶⁹ and it makes extensive use of this power. This threat of government use always remains available as an option to achieve ends elsewhere implemented under more specific legislation empowering grants of compulsory licenses to private parties.

Similarly, United States patent practice with respect to compulsory licenses for "abuses" differs considerably from that of many other countries, including Canada. In the United States, for example, compulsory licenses are not generally available to remedy abuses of the patentee's exclusive rights (which are termed "misuse" in domestic law), unless the alleged misuse rises to the level of a violation of the antitrust laws. However, other remedies--especially that of non-enforcement of the patentee's exclusive rights--are used to correct misuses of exclusive rights, and developing countries may learn much from this practice.

¹⁶¹ Jay Dratler, *Licensing of Intellectual Property*, §3.03[2] (2001) [hereinafter *Dratler*].

¹⁶² See *id.*

¹⁶³ See, e.g., Beier, *supra* note 11; *supra* text accompanying note 34.

¹⁶⁴ *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 & n.21 (1980).

¹⁶⁵ *Dratler*, *supra* note 161, §3.03[2]

¹⁶⁶ See U.S. Dep't of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶13,132 [hereinafter *Antitrust/IP Guidelines*].

¹⁶⁷ See, e.g., Eleanor Fox, *Trade, Competition and Intellectual Property – TRIPS and Its Antitrust Counterparts*, 29 *Vand. J. Transnat'l L.* 481 (1996).

¹⁶⁸ *Dratler*, *supra* note 161, §3.03[2][a]. "United States patent law has no general statutory provisions, like those in foreign countries, designed to displace the operation of the free market with government decision making." *Id.*

¹⁶⁹ 28 U.S.C. §1498(a) (2002).

United States courts and regulatory agencies also have the power to impose non-voluntary licenses on intellectual property rights to remedy a broad array of actual, or in the case of mergers, even potential antitrust violations. This power has often been exercised in practice,¹⁷⁰ and it, too, constitutes an implicit threat that often obviates the need for its actual use. Moreover, while it is true that the United States has never codified a general public interest doctrine of compulsory licensing, it has codified the use of such licenses for specialized public interest purposes, including even economic development projects for rural irrigation and electrification.¹⁷¹

From a broader perspective, the role of non-voluntary licensing in United States patent law cannot be detached from the attitudes of policymakers towards patents in general, which have varied significantly over time. In the 1950s, for example, a pro-competitive outlook prevailed in both Congress and the federal appellate courts, and judicial hostility to patents in this period was legendary. Not surprisingly, many of the leading cases that imposed non-voluntary licensing either to remedy misuses of the patentee's exclusive rights or to remedy exercises of those rights that constituted antitrust violations date to this period of antipathy to patents in general.¹⁷²

The pattern of relatively weak patent protection coupled with relatively strong antitrust enforcement, which lasted until the 1970s, has been replaced, especially from the 1990s on, with a regime of relatively strong patent protection and relatively weak enforcement of competition law.¹⁷³ Within such a scheme, there is concern that the broad scope of patent protection will discourage follow-on research, as well as a concern that cross-licensing that often appears to be the equivalent of patent pooling arrangements could result.¹⁷⁴ Some argue that this trend towards strong patent protection stems from the creation of the Federal Circuit in 1982, which has exclusive jurisdiction of appeals from the United States Patent and Trademark Office (USPTO) and of appeals from the federal district courts in civil actions for patent infringement.¹⁷⁵ The result has been an invigoration of the patent law, as the Federal Circuit is more likely to find a patent valid and infringed than previous jurisdictions,¹⁷⁶ and it has demonstrated a tendency to rule in favor of the patent holder in such cases, "thus enhancing the value of a patent as protection for an innovation."¹⁷⁷

¹⁷⁰ See Dratler, *supra* note 161, §3.02[a];

¹⁷¹ For details, see the forthcoming chapter/part/section on US practices. Other instances where compulsory licenses may be applied include inventions concerning atomic weapons, inventions regulated by the Clean Air Act, which deals with environmental concerns, and rules that give the federal government rights in inventions derived from federal contracts and grants promoting research and development. See Dratler, *supra* note 161, §3.03[2][a]

¹⁷² In one famous decision in this period, Supreme Court Justice Jackson declared that "the only patent that is valid patent is one which this Court has not been able to get its hands on." *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

¹⁷³ See Susan De Santi [Director of Policy Planning, Federal Trade Commission], *The Intersection of Antitrust and Intellectual Property Issues: A Report from the FTC Hearings*, remarks before the Conference on Antitrust for High-Tech Companies Business Development Associates, San Francisco, 2 Feb.1996, available at <<http://www.ftc.gov/speeches/other/desanti1.htm>> [hereinafter *Remarks of Susan De Santi*]. Prof. John Barton "suggested that fundamental changes in the PTO's issuance of patents and the Federal Circuit's enforcement of patents have led to increasingly broad patents and to certain patent claims that cover basic research tools." *Id.* (citing testimony of John Barton).

¹⁷⁴ See *Remarks of Susan De Santi*, *supra* note 173.

¹⁷⁵ See *id.* (citing testimony of John Barton).

¹⁷⁶ See *Remarks of Susan De Santi*, *supra* note 173 (citing written comments of Cecil D. Quillen, Jr. (6 Dec. 1995)); see also Jon F. Merz & Nicholas M. Pace, *Trends in Patent Litigation: The Apparent Influence of Strengthened Patents Attributable to the Court of Appeals of the Federal Circuit*, *J. Patent & Trademark Office Society* (Aug. 1994). Quillen has asserted that as of 1993, "something like two thirds or more of patents which are litigated now are found to be valid and infringed," whereas a decade before "something like two thirds...were found invalid." *Remarks of Susan De Santi*, *supra* note 173 (quoting written comments of Cecil D. Quillen, Jr.).

¹⁷⁷ *Remarks of De Santi*, *supra* note 173 (citing testimony of Max Frankel).

The Federal Circuit has also conveyed a marked antipathy toward the doctrine of misuse. With the help of some ambiguous legislation enacted in 1988,¹⁷⁸ it has tended to blur the distinction between "misuse" as a defense to patent infringement actions and "misuse" as anticompetitive conduct.¹⁷⁹

In terms of the remedies available, the tendency to favor consent judgments to remedy antitrust concerns, particularly in the context of mergers, also became pronounced in the early 1990s.¹⁸⁰ Such judgements result from voluntary agreement among the parties, which the court enforces as equally binding on the government and private parties, provided that there is no change of circumstances.¹⁸¹

Approximately 75-80% of all civil cases handled by the Antitrust Division of the Department of Justice (DOJ) are settled without engaging in litigation, which allows the defendant to avoid the cost of litigation and allows the government to secure prompt relief and to conserve resources for other matters.¹⁸² Many of today's most frequently granted non-voluntary licenses are part and parcel of these consent decrees, whether they emanate from DOJ, from the Federal Trade Commission (FTC), or from the courts. On the whole, however, the authorities today will usually seek to avoid a compulsory license, even in cases where a monopoly is alleged to exist, because of the supposed "adverse effects of such a regime on innovation."¹⁸³

Even so, there is much that developing countries can learn from the older United States cases that took a more pro-competitive approach to patents and competition law.¹⁸⁴ Developing countries have also much to gain from appreciating the judicial concerns in those cases with fairness and entry to markets, even if these concerns sometimes result in losses of efficiency.

¹⁷⁸ See Patent Misuse Reform Act, 35 U.S.C. §§271(d) (4)-(5) (1988).

¹⁷⁹ See the separate country study/part/section/chapter on the US (forthcoming).

¹⁸⁰ See Wilbur L. Fugate, *Foreign Commerce and the Antitrust Laws* §14.2 (1996, updated 2001) [hereinafter W. Fugate].

¹⁸¹ See *id.* The Supreme Court summarized the legal effect of consent judgments in *United States v. Armour Co.*: *Consent decrees are entered into by parties to a case after careful negotiation has produced agreement on their precise terms. The Parties waive their right to litigate the issues involved in the case and thus save themselves the time, expense, and inevitable risk of litigation. Naturally the agreement reached normally involves a compromise...Thus the decree itself cannot be said to have a purpose; rather the parties have purposes, generally opposed to each other, and the resultant decree embodies as much of those opposing purposes as the respective parties have the bargaining power and skill to achieve. For these reasons, the scope of a consent decree must be discerned within its four corners, and not by reference to what might satisfy the purposes of one of the parties to it.* See *U.S. v. Armour Co.*, 402 U.S. 673, 681-682 (1971).

¹⁸² See W. Fugate, *supra* note 180, at §14.2. The 1974 Antitrust Procedures and Penalties Act established a public interest criterion for approval of consent decrees by the court, requiring publication of all proposed decrees in the Federal Register sixty days prior to the judgment with the opportunity for public comment. See Act of 21 Dec. 1974, P.L. 93-528, §2 88 Stat. 1706 (codified as amended at 15 U.S.C. §16 (2002)); see also W. Fugate, *supra* note 180, §14.2.

¹⁸³ Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *IP and Antitrust, An Analysis of Antitrust Principles Applied to Intellectual Property Law* [hereinafter IP and Antitrust] (2002).

¹⁸⁴ See Reichman, *Free Riders to Fair Followers*, *supra* note 127, at 26 ("A Procompetitive Strategy for Compliance with TRIPS").

4. Final Observations: Non-voluntary Licensing is a Two-Edged Sword

Apart from the previous observations concerning access to essential medicines under the Doha Declaration,¹⁸⁵ there are many other legal and policy considerations that developing countries should take into account when evaluating the prospects for non-voluntary licensing of patented inventions. Some of these are briefly summarized below.

Policymakers should bear in mind that the issuance of a non-voluntary license cannot normally impede a patent holder from entering the market in competition with the licensee. So long as the former complies with local competition law,¹⁸⁶ he may possess the economic and technical power to make life difficult for the latter. The patentee's rights to enter or remain in the market follow from article 31(d) of the TRIPS Agreement, which ensures that non-voluntary licenses "shall be nonexclusive."¹⁸⁷ Moreover, so long as domestic competition laws do not impede it, the foreign patent holder can purchase or merge with his local competitor, in which case all strategy conflicts will soon vanish.

A state's ability to use local competition laws to regulate intellectual property rights otherwise protected under the TRIPS Agreement¹⁸⁸ could eventually be called into question now that the Ministerial Declaration inaugurating the Doha Round of Multilateral Trade Negotiations has put the intersection between trade and competition policy on the future Working Agenda.¹⁸⁹ While this Declaration formally recognizes the need to build the developing countries' capacities in this field,¹⁹⁰ these countries must remain vigilant in order to preserve the autonomy they need to curb the excesses of overly protectionist intellectual property policies.¹⁹¹

Other variables must also be taken into account. One is the continued extra-legal pressures that may be exerted against those who resort to non-voluntary licenses.¹⁹² Such pressures may be more or less legal, as when voluntary preferences or concessions not regulated by MFN conditions are made available or withdrawn in response to a given state's treatment of foreign patents. Other forms of extra-legal pressure may instead violate both WTO and non-WTO international obligations.¹⁹³ Developing countries that wish to retain their autonomous powers to exploit the flexibility inherent in the TRIPS standards will sooner or later have to devise appropriate national and regional strategies for sustaining and enhancing this autonomy.¹⁹⁴

¹⁸⁵ See *supra*, under II D., Impact of the Doha Declaration on Public Health.

¹⁸⁶ See TRIPS Agreement, *supra* note 2, arts. 8.2, 31(d), 40.

¹⁸⁷ See, e.g., J. Watal, *supra* note 33, at 324 (noting the conflict over this issue as a major cause of the breakdown of negotiations to revise the Paris Convention).

¹⁸⁸ See further Reichman, *Free Riders to Fair Followers*, *supra* note 127.

¹⁸⁹ See Ministerial Declaration, Ministerial Conference (4th Session), Doha, 9-14 Nov. 2001, WT/MIN(01)/DEC/W/1, 14 Nov. 2001, pars. 23-25 [hereinafter Doha Ministerial Declaration].

¹⁹⁰ See *id.* par. 24.

¹⁹¹ See further Reichman, *Free Riders to Fair Followers*, *supra* note 127, at 88-89.

¹⁹² See, e.g., Sell, *Private Power, Public Law*, *supra* note 94.

¹⁹³ See, e.g., WTO Agreement, *supra* note 2, Annex 2: Understanding on Rules and Procedures Governing the Settlement of Disputes [hereinafter *Settlement of Disputes*], 33 I.L.M. 112 (1994), art 23; Vienna Convention on the Law of Treaties, *supra* note 111 (breach provision, art. 60, "Termination or Suspension of the Operation of a Treaty as a Consequence of Its Breach").

¹⁹⁴ See J. H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 *Case Western Reserve J. Int'l L.* 441 (2000) [hereinafter Reichman, *TRIPS Agreement Comes of Age*].

Another particularly worrisome variable derives from ongoing initiatives to harmonize the substantive rules of international patent protection.¹⁹⁵ Given the controversies still raging over problems of implementing the TRIPS Agreement, and the new tensions likely to emerge from the Doha Round of Multilateral Trade Negotiations, one could hardly imagine a less propitious moment in which to stir up latent controversies surrounding international patent rights. It is worth noting, moreover, that the high-protectionist policies prevalent in developed countries have lately begun to trigger an increasingly unfavorable reaction in those countries,¹⁹⁶ and these domestic conflicts can only further complicate this endeavor.

Unless developing countries take the steps necessary to gear up for the current substantive harmonization exercise, they could find that resolutions concerning the proper regime for industrial property that emanate, for example, from a WIPO Standing Committee acquire the status of candidate international norms cognizable by WTO dispute-settlement panels.¹⁹⁷ There is, in short, a considerable risk that the flexibility residing in the TRIPS standards that now favors those developing countries which know how to exploit it¹⁹⁸ could be squeezed out by high-protectionist standards incorporated into a new International Agreement on patents.

Beyond these technical considerations, there lie deeper, unanswered questions about the relative social costs and benefits of compulsory licensing of patented inventions as an instrument of economic development. The literature on this subject tends to engage in dogmatic polemics that either extol the virtues or deprecate the harms of this instrument without any credible empirical evidence to buttress their respective positions.

Clearly, the customary assertion of some economists that the use of compulsory licensing will depress investment in needed research and development requires careful and sceptical evaluation. Many inventions emanating from the technology-exporting countries today still respond to short-term needs and incentives primarily operative in OECD markets as a whole. Their sales to developing countries may represent windfall rents, which selective compulsory licensing could reduce with little impact on foreign R&D investment decisions.

At the same time, single firms hit by unwanted compulsory licences may decide not to voluntarily make future technology available in developing-country markets, which could lessen the possibilities for growth that voluntary imports, licensing or direct foreign investment might otherwise provide.¹⁹⁹ Moreover, one propelling goal of an integrated global market is to provide incentives for investments in R&D that could benefit all participating countries. In this context, undue distortion of market forces could discourage aggregate investments in R&D, especially investment that might yield particularly big payoffs in developing countries.²⁰⁰

With these risks in mind, however, one should not assume without further investigation that the compulsory licensing of any particular patented inventions will necessarily or automatically discourage any particular investment in R&D. At least one credible economic study of this question, with particular reference to compulsory licensing as a remedy for anticompetitive behavior in the

¹⁹⁵ See Reform of the Patent Cooperation Treaty, Memorandum prepared by the Director General, International Patent Cooperation Union, WIPO Doc. No. PCT/A/30/2, 13 July 2001 and the so-called new Patent Agenda [reference to be provided]

¹⁹⁶ See, e.g., Papers presented at the Duke Conference on the Public Domain, Duke University School of Law, 9-11 Nov. 2001 (publication forthcoming 2002).

¹⁹⁷ Cf. United States - Section 110(5), *supra* note 110 (acknowledging Agreed Statements concerning WIPO Copyright Treaty of 1996 to be authoritative interpretations of interface between that Agreement, Berne Convention, and TRIPS Agreement, within the interpretative parameters set out in the Vienna Convention on the Law of Treaties).

¹⁹⁸ See generally, Reichman, *Free Riders to Fair Followers*, *supra* note 127.

¹⁹⁹ See generally, K. Maskus, *supra* note 53.

²⁰⁰ Cf. Sykes, *supra* note 126.

United States found no such adverse consequences.²⁰¹ Moreover, the United States defense industry has long been propelled by an elaborate system of compulsory licensing without dire consequences. By the same token, a statutory license governing mechanical recordings of copyrighted musical works in the United States²⁰² generates some 200,000 voluntary licenses every year because record companies bargain around the statute with positive benefits to the music industry and individual creators.²⁰³

This topic is far more complicated in practice than appears from the bulk of the literature precisely because compulsory licensing converts exclusive property rights into *de facto* liability rules,²⁰⁴ and economists know little or nothing about how liability rules operate in the intellectual property context.²⁰⁵ So long as liability rules provide innovators with truly adequate compensation - including at times lottery effects that may exceed the returns from exclusivity - they need not undermine the innovator's incentive to invest.²⁰⁶ They may also yield unexpected social gains from allowing wider and earlier access to new technologies for purposes of improvements and follow-on innovations.²⁰⁷

What seems clear is that compulsory licenses may be used more effectively in some circumstances than in others, and broad general statements obscure these factual nuances. Clearly, selected non-voluntary licenses can yield positive results when used to address emergencies or to remove specific technology supply bottlenecks. They can be used to root the production or adaptation of appropriate technologies in qualified local facilities and to prod particular foreign companies into negotiated transactions involving intellectual property rights that adequately respect local needs and conditions. But even these presumptively beneficial uses of non-voluntary licenses impose social costs of their own, and policymakers must take these costs into account.

For example, aggressive use of compulsory licenses to address emergencies, including even medical emergencies within the Doha Ministerial Declaration on TRIPS and Public Health,²⁰⁸ may obscure other possible courses of action, such as regulatory and cooperative measures, that might persuade foreign producers to invest in local production facilities with greater long-term prospects.²⁰⁹ Similarly, any short-term benefits ensuing from the use of compulsory licensing as an instrument of technology transfer must be weighed, not just against the costs of imports, but also against the possible loss of licensing agreements or direct investments that might ensure continued access to better technology over time.²¹⁰ In short, more social benefits may accrue when foreign and local interests "bargain

²⁰¹ See F.M. Scherer, *The Economic Effects of Compulsory Patent Licensing* (1977), reprinted in F.M. Scherer, *Competition Policy, Domestic and International* 327-42 (2000).

²⁰² See 17 U.S.C. §115 (2002).

²⁰³ See, e.g., Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 Cal. L. Rev. 1293 (1996).

²⁰⁴ See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 Harv. L. Rev. 1089 (1972) (defining liability rules).

²⁰⁵ For the historical dependence of intellectual property rights on ancillary regimes of liability rules, see J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 Colum. L. Rev. 2432 (1994); see also J.H. Reichman, *Charting the Collapse of the Patent - Copyright Dichotomy: Premises for a Restructured International Intellectual Property System*, 13 Cardozo Arts & Enter. L.J. 475 (1995).

²⁰⁶ See, e.g., J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 Vand. L. Rev. 1743 (2000) [hereinafter Reichman, *Green Tulips*].

²⁰⁷ See, e.g., Pamela Samuelson & Susan Scotchmer, *The Law and Economics of Reverse Engineering*, 111 Yale L.J. 1575 (2002); J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 Vand. L. Rev. 51 (1997); see also Mark Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989 (1997). These considerations are further examined in the separate country study/chapter/part/section on the United States in connection with governmental use of patented inventions in United States law and practice.

²⁰⁸ See Doha Declaration on Public Health, *supra* note 3.

²⁰⁹ See, e.g., J. H. Reichman, *Patents and Public Health in Developing Countries: Bargaining Around the TRIPS Impasse*, Paper presented to the Conference on Access to Essential Medicines, University of Wisconsin School of Law, 8-10 Mar. 2002 (proposing central regional supply centers for essential medicines in subsaharan African countries).

²¹⁰ See, e.g., K. Maskus, *supra* note 53.

around the TRIPS Agreement" to mutually satisfactory, win-win deals than when one side sticks it to the other in attempting to vindicate internationally guaranteed exclusive rights or their codified limitations.²¹¹

One important message here is that the ability to grant non-voluntary licenses does not necessarily mean such licenses should actually be granted, at least without taking stock of the social costs that may, in the end, outweigh the benefits of this action.²¹² Excessive reliance on non-voluntary licensing could also adversely affect the interests of budding domestic inventors who fall afoul of rules prohibiting discrimination or of the government's own eagerness to intervene in the domestic market place. Above all, there are very real risks that ill-considered resort to non-voluntary licensing could discourage foreign investment and the transfer of advanced technologies by making other economic environments more attractive to firms in technology-exporting countries.²¹³

On balance, policymakers should view non-voluntary licensing of patented inventions as but one item in an arsenal of tools that may be used to promote national systems of innovation. What matters is not so much the use made of any particular tool, but rather the overall coherence and effectiveness of any given system.²¹⁴ Here is where most developing countries need to concentrate their efforts in the immediate future. Absent a coherent strategy for promoting national and regional systems of innovation - including capacity building aspects -, excessive reliance on compulsory licensing of patented inventions may simply mask deeper structural problems and make them harder to solve in the long run.

²¹¹ See, e.g., J. H. Reichman & David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 *Duke J. Compar. & Int'l L.* 11 (1998).

²¹² See, e.g., J. Watal, *supra* note 33, at 328-29.

²¹³ See, e.g., K. Maskus, *supra* note 53; J. H. Reichman, *Taking the Medicine, with Angst: An Economist's View of the TRIPS Agreement*, 4 *J.I.E.L.* 795 (2001).

²¹⁴ See, e.g., *Technology, Learning & Innovation* (Linsu Kim & Richard Nelson, eds. 2000).

Annex: Historical overview of the evolution of Article 5A of the Paris Convention²¹⁵

Current text as after the Stockholm Conference (1967)

1	Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
2	Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
3	Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
4	A compulsory license may not be applied for on the ground of 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; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be 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.
5	The foregoing provisions shall be applicable, <i>mutatis mutandis</i> , to utility models.

Text as revised in Lisbon (1958)

1	The importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
2	Each country of the Union shall have the right to take legislative measures <i>providing for the grant of compulsory licenses</i> to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work.
3	Forfeiture of the patent shall not be prescribed except in cases where the grant of compulsory licenses would not have been sufficient to prevent such abuses. No proceeding for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
4	An application for a <i>compulsory license</i> may not be made on the ground of failure to work or insufficient working before the expiration of a period of <i>four years from the date of filing</i> of the patent application or three years from the date of the grant of the patent, whichever period last expires; it shall be refused if the patentee justifies his inaction by legitimate reasons. <i>Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill using such licence.</i>
5	<i>The foregoing provisions shall be applicable, mutatis mutandis, to utility models.</i>

Text as revised in London (1934)

1	The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.
2	Nevertheless, each contracting country shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work.
3	These measures shall not provide for forfeiture of the patent unless the grant of compulsory licenses is insufficient to prevent such abuses.
4	In any case, the patent may not be subjected to such measures before the expiration of at least three years from the date of grant or if the patentee proves the existence of legitimate excuses. <i>No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.</i>

²¹⁵ Starting with the current version of 1967, this table shows the textual modifications that the current Art. 5A of the Paris Convention underwent throughout several Revision Conferences. Major changes in relation to the respective earlier version are indicated in *italics*. Other minor changes (i.e. mere modification of the text) are not particularly indicated. The latter observation applies in particular to the Stockholm text of 1967, which did not introduce any *substantive* changes to the text of Art. 5A as revised in Lisbon (1958). There were, however, some slight changes in the *formulation* of the provision. Cf. *Stephen P. Ladas, Patents, Trademarks, and Related Rights. National and International Protection*, Harvard University Press 1975, p. 1913 (text as adopted at the 1958 Lisbon Conference) and pp. 1920/21 (text as adopted at the 1967 Stockholm Conference).

Text as revised in The Hague (1925)

1	The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.
2	Nevertheless, each contracting country shall have <i>the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work.</i>
3	<i>These measures shall not provide for forfeiture of the patent unless the grant of compulsory licenses is insufficient to prevent such abuses.</i>
4	In any case, the patent may not be subjected to such measures before the expiration of at least three years from the date of grant or if the patentee proves the existence of <i>legitimate excuses</i> .

Text as revised in Washington (1911)

1	The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.
2	Nevertheless, the patentee shall remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects, <i>but with the restriction that the patent may not be forfeited for non-working in one of the countries of the Union until after a period of three years from the date of filing the application in that country, and only in case the patentee cannot justify his inaction.</i> ²¹⁶

Original text as adopted in 1883

1	The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.
2	Nevertheless, the patentee shall remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects

²¹⁶ Note that this addition was already adopted in an Additional Act at the 1900 Brussels Revision Conference. However, it was only at the Washington Conference that this addition was incorporated into the text of Art. 5.

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