

Local Working Requirements and the TRIPS Agreement: Using Patent Law as a Means of Ensuring Affordable Access to Essential Medicines

A Case Study from the US-Brazil Dispute

I. EXECUTIVE SUMMARY

1. In January 2001, the United States of America launched a legal challenge against Brazilian legislation that authorises the use of compulsory licensing and parallel import permits to promote the local working of patents.¹ The US claimed that the Brazilian legislation violated certain provisions of the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement").² The US requested that the WTO's Dispute Settlement Body establish a panel to resolve the conflict. The dispute ended several months later, when the US and Brazil agreed a temporary truce, and the US complaint was withdrawn.³
2. However, the conflict underlying the US claim remains. This conflict reveals fundamental differences between WTO Members' interpretations of their rights and obligations under the TRIPS Agreement. In particular, this dispute highlights differences in the Members' perceptions of how the Agreement balances the twin objectives of intellectual property rights protection: the protection of the individual rights of the patent holder, and the promotion of a society's collective rights to have access to the benefits of technology to protect public health. Preparations for a new round of multilateral trade negotiations may provide an opportunity for WTO Members to clarify that the TRIPS should not be interpreted in a manner that prevents governments from taking measures to protect public health.⁴
3. Although the US has withdrawn its claim, it has done so without prejudice to its position and has confirmed that it will continue to "aggressively engage other countries that impose or maintain such requirements and, if appropriate, pursue WTO dispute

¹ On 9 January 2001, the US requested the WTO dispute settlement body ("DSB") to establish a panel to resolve its dispute with Brazil in *Brazil – Measures Affecting Patent Protection (DS199)*. *Brazil – Measures Affecting Patent Protection*, Request for the Establishment of a Panel by the United States, 9 January 2001, WT/DS199/3 (the "US Request"). On 1 February 2001, the DSB established a panel, however, no panel members were appointed. Cuba, the Dominican Republic, Honduras, India and Japan reserved third party rights. The US later withdrew its claim and, without prejudice to their respective positions, the US and Brazil have agreed to enter into bilateral discussions before Brazil makes use of the disputed legislative provision, Article 68 of Brazilian Law 9,279 of 14 May 1996, against a US patent holder.

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C to the Marrakesh Agreement Establishing the World Trade Organisation, 15 April 1994 (the "TRIPS Agreement").

³ *Brazil – Measures Affecting Patent Protection* Notification of Mutually Agreed Solution WT/DS199/4, G/L/454, IP/D/23/Add.1, 19 July 2001. See also Joint US-Brazil Statement, 25 June 2001.

⁴ See e.g. Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Fourth Session, Doha 9-14 November 2001, WT/MIN(01)/DEC/W/2, 14 November 2001 ("Ministerial Declaration on TRIPS").

settlement”.⁵ Until the interpretative issues surrounding the exact meaning of certain provisions of the TRIPS Agreement have been resolved, the US may continue to place bilateral pressure on other WTO Members to change their patent laws to comply with US demands.

4. The Brazilian legislation applies to patents of all kinds. However, the international interest of governments, industry and civil society in this dispute arises from efforts in Brazil and in other countries to promote affordable access to essential medicines – particularly those medicines used to combat HIV/AIDS. This analysis is limited to the use of the Brazilian patent law as a means of ensuring access to affordable essential medicines.
5. In Brazil, as well as in many other countries, the exclusive rights extended to a patent holder to manufacture, import and sell a patented product may be limited if the patent holder fails to “work” the patent within the country, by manufacturing all or substantially all of the product locally. The exclusivity of the patent holders’ rights is suspended by granting third parties the right to manufacture the patent locally through a “compulsory license” or the right to import the patented product from another country (“parallel import” permits). The public policy objective behind local working requirements is to allow the country the opportunity to develop the local capacity and “know-how” to manufacture the product once the patent expires. Local working requirements can also seek to ensure that, through local production, the costs of the product are kept as low as possible. Finally, and importantly, a country’s sovereign power to limit patent rights – whether or not this power is actually exercised – strengthens its bargaining power with pharmaceutical companies and can help to gain preferential prices for national health care systems and programmes targeted at the poor.
6. The TRIPS Agreement, like many other aspects of the WTO Agreements, purports to provide a balanced package of rights and obligations. Its stated objective is to provide for effective and adequate protection of intellectual property rights (“IPRs”) by WTO Members in a manner that promotes *both* technological innovation *and* the transfer and dissemination of technology. The protection and enforcement of IPRs under the TRIPS Agreement must be “to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare”.⁶ The US-Brazil dispute raises directly the issue of how the negotiators of the TRIPS Agreement intended this balance to be struck.
7. More concretely, the US-Brazil dispute raises the issue of whether the TRIPS negotiators intended that each country, by joining the WTO and the TRIPS Agreement, was agreeing to give up its ability to make the exclusive enjoyment of patent rights dependent upon the patent holder’s willingness to manufacture the patented product within the WTO Member’s territory.
8. The analysis that follows focuses on whether provisions of the Brazilian legislation which are available to enforce local working requirements related to access to essential medicines, violate the basic rights extended to patent holders under Articles 27 and 28 of

⁵ Office of the United States Trade Representative, Washington, Press Release 25 June 2001 “United States and Brazil agree to use newly created Consultative Mechanism to promote cooperation on HIV/AIDS and address WTO patent dispute”, www.ustr.gov.

⁶ TRIPS Agreement, Article 7.

the TRIPS Agreement. It is then considered whether the legislation could be justified under Articles 30 or 31 of the TRIPS Agreement. In particular, it examines the TRIPS consistency of compulsory licenses granted pursuant to Article 68.1(I) of the Brazilian legislation, where the patent holder has failed to manufacture the patented product or to otherwise make full use of the patented process in Brazil. It also briefly examines the issue of parallel imports by third parties under Article 68 of the Brazilian legislation.⁷

9. The analysis and conclusions presented here are preliminary in nature, and are intended to set out the strengths and weakness of arguments that could have been raised by Brazil and the US. It draws its insight from two main sources: the text of the TRIPS Agreement, and the practice of the WTO Members, primarily as represented by examples of national legislation. In particular, the text of the TRIPS Agreement is examined in accordance with the ordinary meaning of its terms in their context and in the light of the object and purpose of the TRIPS Agreement.⁸
10. The US-Brazil dispute was likely to have focused on competing interpretations of key elements of the TRIPS Agreement that have not yet been tested by the WTO dispute settlement system. The text of the TRIPS Agreement is ambiguous in a number of fundamental parts. Aspects of the Agreement require the exercise of subjective judgements, such as determinations as to what, in the view of the countries that designed and adopted the TRIPS Agreement, is “unreasonable”, “normal” and “legitimate”.
11. The interpretation of these terms must be informed by the views and practice of the WTO Members themselves. It is evident from the submissions of a number of WTO Members to the TRIPS Council, which oversees the implementation of the TRIPS Agreement, that these governments do not see the TRIPS Agreement as prohibiting them from requiring the local manufacturing of essential medicines.⁹ It is furthermore evident from a preliminary study of the IPR legislation of many of the larger WTO members that many have clear local working provisions.¹⁰ Finally, evidence from the Uruguay Round

⁷ This paper does not examine the legal issues arising out of the grant of compulsory licenses in cases of economic abuse of patent rights in a sense broader than failure to manufacture or inadequate supply under Article 68. Moreover, it should be noted that this paper is limited to a consideration of the US claims under the TRIPS Agreement. It does not deal with issues arising under other WTO agreements, such as the GATT 1994, and it does not cover broader issues of international law, such as the right to health.

⁸ Under Article 3.2 of the WTO's *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the “DSU”), a Panel and, on appeal, the WTO Appellate Body, would resolve the dispute in accordance with “customary rules of interpretation of public international law”. The *Vienna Convention on the Law of Treaties* (the “Vienna Convention”) is recognised as describing customary rules of interpretation of public international law for the purposes of the DSU. Article 31 of the Vienna Convention provides that a treaty “shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” The text of the treaty, its preamble and annexes, and any related instruments adopted in connection with the conclusion of the treaty, are considered the “context” of the treaty. See *Vienna Convention on the Law of Treaties*, 11 UNTS 331; 8 ILM 679 (1969); See *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, adopted 7 April 2000, WT/DS114/R, para 7.13 (“*Canada – Pharmaceuticals*”); *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body adopted on 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, pp.6-7 (“*Japan – Alcoholic Beverages*”); *United States – Standards for Reformulated and Conventional Gasoline*, Report of the Appellate Body adopted 20 May 1996, WT/DS2/AB/R, pp.10-11 (“*US – Gasoline*”).

⁹ Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela to the TRIPS Council, IP/C/W/296, 29 June 2001.

¹⁰ A preliminary review of patent law revealed that a significant number of countries maintain local working requirements. See e.g. patent laws and regulations in: Indonesia and Cuba (similar to Brazil); Ghana, Ireland,

negotiations reveals that several delegations active in the design of the TRIPS Agreement defended their rights to use compulsory licensing as a means of enforcing “local working” requirements, and to thereby promote the transfer of technology. It would be an unreasonable result to infer from the reading of an ambiguous text that Brazil and other WTO Members intended to forfeit this right.¹¹

12. Arguments that could have been raised to defend the Brazilian legislation might be available to other WTO Members with similar legislation should the US or others put pressure on them to change their patent laws. Although this paper has been prepared with a view to defending specific aspects of the Brazilian legislation, it should be recalled that governments and public interest organisations dedicated to promoting affordable access to essential medicines need not limit themselves to defending the Brazilian legislation as it stands. Further analysis could usefully focus on ways in which “local working” requirements more generally could meet the TRIPS requirements, or indeed offer suggestions as to how the TRIPS Agreement could be reformed to more clearly accommodate these types of measures.

II. WHAT DOES THE BRAZILIAN LEGISLATION PROVIDE?

13. Brazilian intellectual property law is codified in Law 9,279 of 14 May 1996 (the “Brazilian legislation”).¹² Article 68 of the Brazilian legislation provides for the use of compulsory licensing and permits parallel imports in circumstances where the patent holder has abused its patent rights, including by failing to manufacture the patented product in Brazil. Brazil has not yet applied Article 68, and it has not yet been interpreted by a Brazilian administrative or judicial procedure.

South Africa, Sudan and Zimbabwe (based on former United Kingdom laws); Greece and Lesotho (compulsory licensing linked to local working); Turkey, Spain and Portugal (certificate of working required); Sweden, Norway, Finland and Iceland (local working tied to reciprocity); India; Israel; Zaire; Thailand; Pakistan; Liberia.

¹¹ See, e.g., Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 2, 4 AND 5 APRIL 1990, Note by the Secretariat MTN.GNG/NG11/20 24 April 1990, at para 34; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, EXISTENCE, SCOPE AND FORM OF GENERALLY INTERNATIONALLY ACCEPTED AND APPLIED STANDARDS/NORMS FOR THE PROTECTION OF INTELLECTUAL PROPERTY, Note Prepared by the International Bureau of WIPO, MTN.GNG/NG11/W/24, 5 May 1988, page 2; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 11, 12 AND 14 DECEMBER 1989 Note by the Secretariat, MTN.GNG/NG11/17, 23 January 1990, para 41; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 11-12 MAY 1989, Note by the Secretariat, MTN.GNG/NG11/12, 13 June 1989, para 5; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 11-12 MAY 1989, Note by the Secretariat, MTN.GNG/NG11/12, 13 June 1989, para 36; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 30 OCTOBER-2 NOVEMBER 1989, Note by the Secretariat, MTN.GNG/NG11/16, 4 December 1989, para 24; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 12-14 JULY 1989 Note by the Secretariat, MTN.GNG/NG11/14, 12 September 1989, paras 75, 83. Available at www.wto.org.

¹² See Annex II. Brazil notified the TRIPS Council of the Brazilian legislation under Article 63.2 of the TRIPS Agreement on 26 January 2000. WTO Documents IP/N/1/BRA/2 and IP/N/1/BRA/I/1.

A. Compulsory licensing

14. Article 68 of the Brazilian legislation provides for some circumstances in which patent rights may be conferred on persons other than the patent holder in accordance with what are known as “compulsory” or “mandatory” licenses. In particular, Article 68.1(I) provides for the conferral of patent rights on persons other than the patent holder (“licensee”) in circumstances where the patent holder fails to or only partly manufactures the patented product, or fails to make full use of the patented process within the Brazilian territory.
15. Article 68.1(I) embodies a concept commonly referred to as a “local working” requirement. Failure to “work” a patent is recognised in international intellectual property law as a form of “abuse” for which compulsory licenses may be granted.¹³ Compulsory licensing – licences granted to third parties to exploit a patent without the patent holder’s consent – is, therefore, a “remedy” for a patent holder’s failure to “work” its patent. Historically, “work” has referred to the manufacturing of the patented product or a product derived from a patented process.¹⁴ As will be discussed, some WTO Members, including the US, argue that importation alone is a means of “working” a patent.¹⁵ Through an application of Article 68, Brazil would require some measure of local manufacturing of a patented product or process. By requiring patents to be manufactured locally, Brazil is pursuing a policy objective designed to ensure the transfer and dissemination of technology and “know-how” which will augment or create industries in Brazil that can then provide local employment and locally produced products at competitive, low-cost prices. This is particularly important with respect to affordable medicines.¹⁶
16. In order to balance the rights of the patent holder against broader public policy objectives, the Brazilian legislation is careful to narrow the circumstances in which compulsory license may be granted. To qualify for a compulsory license under Article 68.1(I), the applicant must have a “legitimate interest” in and have technical and economic capacity to effectively manufacture the object of the patent for introduction into the domestic market (Article 68.2). In addition, a compulsory license is available only after three years have elapsed since the patent was registered (Article 68.5), allowing the patent holder ample time to prepare for local manufacturing. Subsequent Articles in the Brazilian legislation set out the conditions that shall apply to compulsory licenses. For example, the application for a license shall be made on the basis of the same conditions offered to the patent holder (Article 73). Compulsory licenses shall be granted on a non-exclusive basis only, and sublicensing shall not be permitted (Article 72). Licensees shall be vested with full powers to defend the patent (Article 74.2). However, the licensee will need to demonstrate that it is fulfilling the objective of the compulsory license by working the patent. Except where the licensee has legitimate reasons for not doing so, the licensee

¹³ See Article 5(A)(2) of the Paris Convention for the Protection of Industrial Property of March 20, 1883 (“Paris Convention”), cited in full and discussed below in fn 25 and accompanying text. Note that the concept of “abuse” of patent rights is addressed in the Paris Convention and the introductory paragraph of Article 68. We understand that the Brazilian law has been interpreted by academics and practitioners as treating abuse of economic power, and abuse through the failure to work as two distinct bases for applications for compulsory licensing.

¹⁴ See Michael Halewood, “Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law”, *Osgoode Hall Law Journal* Vol.35, No.2, 1997, p.243 (“Halewood”).

¹⁵ *Ibid.* See below paragraphs 28ff.

¹⁶ See Brazilian Press Release, 25 June 2001.

must begin the exploitation of the object of the patent within a period of one year from the granting of the license and shall be permitted to suspend exploitation for no longer than one year (Article 74). Failure to comply with this requirement entitles the patent holder to apply for a cancellation of the compulsory license (Article 74.1).

17. The Brazilian legislation also sets out the circumstances in which a request from a third party for a compulsory license will be refused, and the procedure for contesting the grant of a compulsory license. Article 69 provides that a license shall not be granted if, on the date of the application, the patent holder justifies the failure to use the patent on the basis of legitimate reasons, proves that serious and effective preparations for exploitation of the patent have been undertaken or justifies the failure to manufacture or to market on legal grounds. Article 73 of the Brazilian legislation provides for notification of compulsory license applications to the patent holder and an opportunity for the patent holder to “comment” on the application. Where the application is contested by the patent holder, Article 73 provides for investigation and arbitration procedures conducted by the patent office (INPI) to determine the amount of remuneration payable to the patent holder. The INPI shall have regard to the economic value of the compulsory license in determining appropriate remuneration.

B. Parallel imports

18. Article 68 of the Brazilian legislation also permits “parallel” imports of patented products or products derived from a patented process by the licensee and third party non-patent holders in limited circumstances. Where the patent holder imports the patented products or products derived from the patented process, third parties are also permitted to import the products provided the products have already been introduced onto the international market by the patent holder or with its consent (Article 68.4).¹⁷
19. Permitting parallel imports in these circumstances can also be intended to encourage the local working of the patent. Allowing parallel imports over the objections of the patent holder relies on the doctrine of “exhaustion”¹⁸ and is a means of ensuring that products available with the patent holder’s consent at lower cost in foreign markets can be imported into the domestic market in competition with the higher priced product.

III. WHAT DOES THE TRIPS AGREEMENT PROVIDE?

A. Objective and Principles: Articles 7 and 8

20. The object and purpose of the TRIPS Agreement is identified, in part, in Articles 7 and 8.¹⁹ Article 7 reflects the Members’ desire for balance between two primary but sometimes competing goals of intellectual property protection: the promotion of innovation through the benefits of monopoly rights for the innovator, and the promotion of access to technology as a means of fostering the social and economic welfare of consumers. Article 8.1 provides that Members may adopt measures to “protect public

¹⁷ See also John Giust “Comparative Analysis of the US Patent Law and the New Industrial Property Code of Brazil” 21 *Hastings Int’l & Comp. L. Rev.* 597, Spring 1998; C. Mayer, “The Brazilian Pharmaceutical Industry Goes Walking From Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?” 12 *Temp. Int’l & Comp. L. J.* 377, Fall 1998.

¹⁸ The “exhaustion” doctrine is discussed further, below paragraphs 36ff.

¹⁹ See Annex I to this memorandum.

health” and “promote public interest in sectors of vital importance to their socio-economic and technological development.” Article 8.2 recognises that Members may need to adopt measures to prevent patent holders from abusing their intellectual property rights or to curb practices which “unreasonably restrain trade or adversely affect the international transfer of technology”.

B. Non-discrimination and exclusive patent rights: Articles 27.1 and 28.1

21. Articles 27.1 and 28.1 of the TRIPS Agreement set out the basic rights that WTO Members must extend to patent holders through their intellectual property legislation.²⁰ Article 27.1 provides that WTO Members must make patents available “for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” Furthermore, and importantly, Article 27.1 provides that “patents shall 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.”
22. Article 28 requires that the patent holder be given the exclusive right to prevent third parties from making, using, offering for sale, selling or importing the patented product or from using a patented process.

C. Provisions on compulsory licensing: Article 30 and 31

23. Articles 30 and 31 of the TRIPS Agreement govern the circumstances in which patent holder’s rights may be limited.²¹ Article 30 provides for “limited exceptions to the exclusive rights conferred by a patent” and Article 31 sets out the conditions that are to apply to “other uses” of a patent without the authorisation of the patent holder. “Other uses” are described in footnote 7 to Article 31 as uses other than those allowed by Article 30.²² Accordingly, Articles 30 and 31 are mutually exclusive and a challenged measure will fall under either one or the other of the Articles.²³ Although the provisions in Article 31 appear to be designed to deal with measures like the issuance of compulsory licensing, this analysis also tests the potential applicability of Article 30 to the Brazilian legislation.

D. Other international agreements: Article 2

24. Article 2.1 of the TRIPS Agreement requires Members to comply with Articles 1 through 12 and Article 19 of the Paris Convention.²⁴ Article 2.2 of the TRIPS Agreement provides that “[n]othing in Parts I to IV of [the TRIPS] Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.” As noted earlier, Article 5(A)(2) of the Paris Convention provides that signatories have “the right to take legislative measures providing for the grant of

²⁰ See Annex I to this memorandum.

²¹ See Annex I to this memorandum.

²² Footnote 7 to Article 31 of the TRIPS Agreement.

²³ See *Canada – Pharmaceuticals*, para 7.20.

²⁴ See Annex I to this memorandum.

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.”²⁵

IV. ARE THE BRAZILIAN LOCAL WORKING REQUIREMENTS PROHIBITED BY ARTICLE 27 AND 28 OF THE TRIPS AGREEMENT?

25. In the preliminary arguments set out in its request to establish a WTO Panel, the US asserted that Article 68 of the Brazilian legislation violates Articles 27.1 and 28.1 of the TRIPS Agreement. The US claimed that the TRIPS Agreement “prohibits discrimination regarding the availability of patents and the enjoyment of patent rights on the basis of whether products are imported or locally produced.”²⁶ To succeed, the US would need to demonstrate to a WTO panel that it was the intent of Brazil and the rest of the WTO Membership, as reflected in the text of the TRIPS Agreement, to “prohibit[] Members of the [WTO] from requiring “local working”, i.e., local production, of the patented invention as a condition for enjoying exclusive patent rights.”²⁷
26. The US Argument is based on Article 27.1 of the TRIPS Agreement, which states that “patents shall be available and patent rights enjoyable *without discrimination as to . . . whether products are imported or locally produced.*” It would presumably be argued that the use of compulsory licensing as a means of enforcing a local working requirement would amount to such a discrimination by interfering with the patent holder’s exclusive enjoyment of its patent on the grounds that the patented product was being imported rather than produced locally.²⁸

²⁵ Paris Convention, Article 5 (A) provides in full: “Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses.

(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, *mutatis mutandis*, to utility models.” Note that Brazil and the US are both parties to the Paris Convention, see www.wipo.org.

²⁶ US Request.

²⁷ *Ibid.*

²⁸ In *Canada – Pharmaceuticals*, the Panel interpreted the term “without discrimination” under Article 27.1 broadly to “extend beyond the concept of differential treatment” embodied in the national treatment and most-favoured nation provisions in Articles 3 and 4 of the TRIPS Agreement. The Panel found that that the word “discriminate” “is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment” and concluded that: ““Discrimination” is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision than the concept contains.” *Canada – Pharmaceuticals*, para 7.94.

A. Is the use of compulsory licensing to enforce local working requirements “discrimination”?

27. Arguments against local working requirements will assert that the use of a compulsory license to promote local working violates Article 27.1 because it removes a patent right in a manner that discriminates against patent holders that manufacture their products exclusively abroad. Read in this way, Article 27.1 would appear to outlaw the infringement of patent rights as a means of enforcing local working requirements.
28. However, as a matter of treaty law, Article 27.1 cannot be read in isolation. The anti-discrimination provisions in Article 27.1 are applicable only to the extent to which they protect the “rights conferred” by a patent in conformity with Article 28. As confirmed by Article 2.2 of the TRIPS Agreement which acknowledges the continuing obligations of WTO Members under other international agreements, these rights are limited, in part, by the continuing existence and operation of the Paris Convention. As noted above, the Paris Convention expressly provides that each party “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.*”²⁹ Similarly, Article 8.2 of the TRIPS Agreement recognises that Members may need to adopt measures to prevent patent holders from abusing their intellectual property rights or to curb practices which “unreasonably restrain trade or adversely affect the international transfer of technology”. From Brazil’s perspective, a failure to “work” the patented product through local manufacture has an adverse effect on the international transfer of technology and Article 68 serves to protect against the adverse effects of solely importing the patented product.³⁰
29. Opponents to local working requirements would argue that the rights conferred in Article 28.1 can be unbundled, and that, for example, a patent can be said to be “worked” through any one of the acts of making, selling or importing the product. This interpretation would claim that a patent can be fully worked through importing alone, or indeed through manufacturing alone. Under this scenario a patent holder could produce an essential medicine under a patent in Member A to take advantage of cheaper labour costs, but to then export its entire output to Member B, to take advantage of higher prices from a wealthier consumer market. This approach would remove the ability of the conferring Member to limit patent rights in circumstances where the objectives of technology transfer and dissemination were being thwarted and would be inconsistent with the objectives and principles of the TRIPS Agreement.³¹
30. Furthermore, Article 28 confers on the patent holder the exclusive right to prevent third parties from “making, using, offering for sale, selling or importing for these purposes” the patented product. However, it can be argued that Article 28 does NOT confer a right on the patent holder NOT to make, offer for sale, sell or import that product. Indeed, conferring monopoly rights on a patent holder in a manner that entitled that patent holder to block the introduction of the patented product to the market or manufacturing base of the conferring Member would defeat the object and purpose of TRIPS Agreement which seeks to promote the transfer and dissemination of technology. In other words, patents

²⁹ Art 5(A)(2) of the Paris Convention, emphasis added. See above paragraphs 24 and 28.

³⁰ See above fn 15 and accompanying text.

³¹ See above paragraph 20.

represent a balance of exclusive rights as against third parties and an enforceable obligation to “work” the patent in the territory of the conferring Member.

31. Finally, it can be argued that Article 27.1, and its prohibitions on discrimination, are simply not applicable to the act of compulsory licensing by government authorities.³² The rights conferred under Article 28.1 are applicable only to the situation in which a patent holder is seeking to protect its exclusive rights against a third party that is infringing those rights. Article 27.1 requires governments when conferring patent rights and protecting patent holders from infringement by third parties to do so in a manner that does not discriminate on the basis of whether a product is imported or locally produced. Neither Article 27.1 nor Article 28.1 refers to the specific act of a government authority in limiting patent rights through the exercise of a compulsory license. Disciplines governing the substantive and procedural basis for granting a compulsory license are dealt with in Article 31, which is discussed below.³³ An interpretation of Articles 27 and 28 that is supportive of each WTO Member’s “right to protect public health and, in particular, to promote access to medicines for all”³⁴ would warrant a conclusion that neither Article excludes the possibility that failure to work a patent locally is a legitimate ground for granting a compulsory license.
32. Interpreting Articles 27.1 and 28.1 in a manner that allows Members to enforce local working requirements does not render the anti-discrimination provisions in Article 27.1 meaningless. Article 27.1 ensures that the fact that a product is imported cannot alone be used as grounds for the denial or removal of a patent right. In other words, it stands for the principle that a government cannot, as a condition of conferring or retaining a patent, prohibit the patent holder from importing that product. Read in this manner, Article 27.1 does not act as an absolute prohibition on “local working” requirements.³⁵
33. Had the US prevailed in establishing a *prima facie* violation of Articles 28.1 and 27.1, Brazil would, in any case, have had recourse to Articles 30 or 31, which are discussed below.³⁶

B. Can the parallel import provisions be challenged under the TRIPS Agreement?

34. Article 68 of the Brazilian legislation also authorises the government to allow, in limited circumstances, a non-patent holder to import patented products or products derived from patented processes by third parties without the permission of the patent holder (parallel importing). This measure can be invoked in circumstances where the products have already been introduced onto the international market by the patent holder (Article 68.4). Brazil’s parallel import provisions could provide an incentive for the patent holder to manufacture the patented product locally rather than import it, furthering the objective of technology transfer.
35. The requirement under Article 28.1 that a patent confer exclusive rights with respect to use, sale or importation is subject to Article 6 of the TRIPS Agreement.³⁷ Article 6

³² See generally Carlos Correa et al, *DERECHO DE PATENTES*, Ciudad Argentina, Buenos Aires, 1996.

³³ See Part V below.

³⁴ Ministerial Declaration on TRIPS, para 4.

³⁵ See e.g. Halewood at p. 257.

³⁶ See Part V below.

³⁷ See footnote 6 to Article 28.1 of the TRIPS Agreement.

provides that nothing in the TRIPS Agreement “shall be used to address the issue of the exhaustion of intellectual property rights” in dispute settlement procedures.³⁸

36. The “issue of exhaustion of intellectual property rights” described in Article 6 is referring to the theory that a patent holder’s rights in a patent are “exhausted” as soon as the patented product or the product derived from a patented process is introduced onto a market either by the patent holder or with its consent. This assumes that the exclusive right to market a patented product does not survive the sale of the product. Under the theory of exhaustion, a third party that purchases a patented product or product derived from a patented process is at liberty to sell the patented product on to another jurisdiction, without infringing the patent holder’s patent rights.
37. In negotiating the TRIPS Agreement, Members failed to reach consensus on the status of the “exhaustion” doctrine. In general, developing countries supported the rule of international exhaustion which would permit parallel imports by all WTO Members, the European Union sought to preserve its practice of intra-Union exhaustion and the United States advocated a position of no exhaustion and restriction of parallel imports.³⁹ According to Abbott, Article 6 of the TRIPS Agreement represents the fact that “(1) the subject of exhaustion of [intellectual property rights] and parallel imports was not inadvertently overlooked; (2) TRIPS negotiators failed to reach a consensus on the subject; and (3) having failed to reach a consensus on the result, each WTO Member reserves the right to regulate parallel imports in the manner it considers appropriate.”⁴⁰ Submissions to a Special Session of the TRIPS Council confirm that the divergence of views on the exhaustion doctrine persist, although some developing country Members have confirmed their understanding that Article 6 operates to exclude parallel imports from the TRIPS Agreement.⁴¹ At their fourth Ministerial Conference, Members confirmed that they are free to establish their own exhaustion regimes.⁴²
38. To the extent that provision for third party imports under Article 68 appears to rely on the theory of exhaustion of intellectual property rights, Article 28.1 cannot be used to address that issue in this dispute because of Article 6 of the TRIPS Agreement. Accordingly, it might be concluded that a WTO panel has no jurisdiction to consider the US arguments with respect to third party imports under Article 68. More research into the negotiating history of Article 6 and the meaning of the “issue of exhaustion of intellectual property rights” may be desirable if this conclusion is to be relied upon with confidence.
39. To the extent that Article 68 permits third party imports, it might be argued that it discriminates as to whether the product is imported or locally produced for the purposes of Article 27.1. However, Article 6 of the TRIPS Agreement concerning “exhaustion” applies equally to Article 27 as it does to Article 28. There is no footnote to Article 27 that is similar to footnote 6 to Article 28 regarding the application of Article 6. However, it can be argued that Article 6 precedes Article 27 and, by its own terms, it applies to the

³⁸ See Annex I to this memorandum. Recently confirmed by Ministerial Declaration on TRIPS, para 5(d).

³⁹ See F.M. Abbott “First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Importation” *Journal of International Economic Law* (1998) 607 at 609.

⁴⁰ *Ibid.*

⁴¹ TRIPS Council, Special Session 20 June 2001, “TRIPS and Public Health” Submission by the Africa Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/269, paras 24-27.

⁴² See Ministerial Declaration on TRIPS, para 5(d).

TRIPS Agreement as a whole. Moreover, footnote 6 to Article 28 confirms that Article 6 is intended to apply to all provisions in the TRIPS Agreement concerning the right to import.

V. ARE THE BRAZILIAN LOCAL WORKING REQUIREMENTS PERMITTED UNDER ARTICLES 30 OR 31?

40. Although the term “compulsory licensing” does not appear in the TRIPS Agreement, it could be used to describe any government act that limits an aspect of an otherwise “exclusive” right of a patent holder and confers part of that right on a third party without the consent of the patent holder as contemplated by TRIPS Article 31. If it were accepted that compulsory licensing is not covered by Articles 27 and 28 of the TRIPS Agreement, it could be argued that Article 31 dealing with “other uses” of a patent without the patent holder’s consent is specifically designed to govern the issuance of compulsory licenses. Accordingly, Article 31 would apply to compulsory licenses under Article 68 of the Brazilian legislation. If, on the other hand, US arguments had prevailed and Article 68 had been found to violate TRIPS Articles 27 or 28, Brazil could have argued that compulsory licensing is justified under either Articles 30 or 31.

A. How do the TRIPS objectives and principles and other international agreements inform the application of Articles 30 and 31?

41. The “Objective” and “Principles” described in Articles 7 and 8, should be “borne in mind” when examining the meaning of Articles 30 and 31 in light of the object and purpose of the TRIPS Agreement.⁴³ Moreover, Members have declared that the TRIPS Agreement should be interpreted “in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”⁴⁴

42. The context in which Articles 30 and 31 are interpreted includes other international agreements governing the protection of intellectual property rights.⁴⁵ In particular, WTO Members continue to be bound by their obligations under the Paris and Berne Conventions and both agreements contain provisions that may be relevant to a consideration of Article 68 of the Brazilian legislation under TRIPS Articles 30 and 31.⁴⁶

43. As has been indicated,⁴⁷ Art 5(A)(2) of the Paris Convention provides that each party to the Convention “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*.”⁴⁸

44. Finally, it is important to read Articles 30 and 31 in the context of Article 1.1 of the TRIPS Agreement which provides that “Members shall be free to determine the

⁴³ *Canada – Pharmaceuticals*, para 7.26 “Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when [examining the words of Article 30] as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.”

⁴⁴ Ministerial Declaration on TRIPS, para 4.

⁴⁵ Vienna Convention, Article 31.2.

⁴⁶ Article 2 of the TRIPS Agreement.

⁴⁷ See above, paragraphs 24 and 28.

⁴⁸ Paris Convention, Article 5(A)(2).

appropriate method of implementing the provisions of the Agreement within their own legal system and practice.”

B. Could the Brazilian legislation have been justified under Article 31?

45. Article 31 sets out twelve sub-paragraphs (a) through (l) that must be respected when a Member confers patent rights on a third party without the authorization of the patent holder, such as through a compulsory license. It appears that the Brazilian legislation was designed to balance the rights and obligations of the patent holder and the licensee in a manner that meets the basic objectives set out in Article 31. However, as the provision has never been applied by regulators or tested by courts in Brazil, it is difficult to provide authoritative interpretations of the legislation. The twelve provisions in Article 31 are considered below on the basis of the bare provisions of the Brazilian legislation, and preliminary advice from experts in Brazilian patent law.
46. For the purposes of Article 31(a), the Brazilian legislation appears to require applications for compulsory licenses to be considered on their individual merits (see Article 68.1(I) of the Brazilian legislation). Because the legislation provides that the license will be cancelled where exploitation does not commence within a year of being granted, it could be argued that the “scope and duration” of the compulsory license is “limited to the purpose for which it was authorised” for the purpose of Article 31(c) (see Article 74 of the Brazilian legislation). Under the legislation, compulsory licenses are granted on a non-exclusive basis, and thus meet the requirements of Article 31(d) and are non-assignable within the meaning of Article 31(e) (see Articles 72 and 74.3 of the Brazilian legislation). As required by Article 31(f), the compulsory license is granted on the basis that the product shall be destined predominantly for the domestic market (see Article 68.2 of the Brazilian legislation). With respect to Article 31(h), the Brazilian legislation provides for payment of remuneration, taking into account the economic value of the compulsory license. (see Article 74 of the Brazilian legislation) . Finally, Article 31(l) concerning derivative patents, does not appear to be relevant to Article 68.
47. Other aspects of the Brazilian legislation are less clear from the provisions as written. It is not apparent, from the legislation itself, whether the licensee must demonstrate that it has made efforts to obtain authorisation from the patent holder on reasonable commercial terms (Article 31(b)). We understand, however, that in practice, such efforts have been made, and that the Brazilian government has regularly engaged in extensive negotiations with pharmaceutical companies prior to the issuance of compulsory licenses under other provisions of Brazilian law. It is also not apparent from the legislation alone, whether the authorisation of the compulsory license or any decision relating to the remuneration provided to the patent holder in compensation for the compulsory license would be “subject to judicial review or other independent review by a distinct higher authority” in Brazil as required by Article 31(i) and (j). We understand that the patent law must, however, be read in conjunction with Brazilian constitution, which guarantees access to the judiciary for claims based on the “damage or threat to a right”.⁴⁹ These due process requirements, while beyond the scope of this analysis, would be available to Brazil in defending their legislation under a TRIPS challenge.

⁴⁹ Brazilian Federal Constitution, art 5, XXXV.

C. Could the Brazilian legislation have been justified under Article 30?

48. Any exception allowed under Article 30 must meet a four part test. The exception must

- be “limited”,
- not unreasonably conflict with a normal exploitation of the patent,
- not unreasonably prejudice the legitimate interests of the patent owner, and
- take into account the legitimate interests of third parties.

49. The interpretation of each of these phrases requires the exercise of a subjective judgement on a case-by-case basis. The only guidance from the WTO’s Dispute Settlement Body is the report of the Panel in *Canada – Pharmaceuticals*, which applied the exception in a restrictive manner. In *Canada – Pharmaceuticals*, the Panel combined the third and fourth parts of Article 30 to establish a total of three conditions to be satisfied under Article 30.⁵⁰ The Panel concluded that it was not necessary, for the purposes of that case, to decide whether the legitimate interests of third parties also qualified the second condition concerning unreasonable conflict with a normal exploitation of the patent.⁵¹ The Panel confirmed that “[f]ailure to comply with any one of the three conditions results in the Article 30 exception being disallowed.”⁵²

50. It could be argued that Article 68 of the Brazilian legislation is a “limited exception” within the meaning of the first requirement in Article 30. Although each of the rights conferred under Article 28.1 would appear to be “curtailed” by the issuance of a compulsory license under Article 68, it could be argued that it would constitute only a “small diminution” of those rights.⁵³ According to the constraints built into the Brazilian legislation, the compulsory license can be issued in only specific and limited circumstances – failure to manufacture. The license will not be issued if the patent holder can justify the failure to work the patent on the basis of legitimate reasons, proves that serious and effective preparations for exploitation of the patent have been undertaken or justifies the failure to manufacture or to market on legal grounds (Article 69 of the Brazilian legislation). If the compulsory license is granted, the patent holder is entitled to monetary compensation. (Article 73 of the Brazilian legislation).

51. Given that Article 68 provides for compulsory licenses that permit manufacture of a patented product, it may be argued that such a license would “conflict” with the patent

⁵⁰ *Canada – Pharmaceuticals*, para 7.20.

⁵¹ *Ibid*, para 7.59.

⁵² *Ibid*. The Panel described the relationship between the different parts of Article 30 as follows: “The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be “limited” and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not “unreasonably conflict with normal exploitation” could nonetheless “unreasonably prejudice the legitimate interests of the patent owner.” [Footnotes omitted] para 7.21.

⁵³ See *Canada – Pharmaceuticals*, where the Panel found that: “When a treaty uses the term “limited exception”, the word “limited” must be given a meaning separate from the limitation implicit in the word “exception” itself. The term “limited exception” must therefore be read to connote a narrow exception – one which makes only a small diminution of the rights in question.” (para 7.30). The Panel concluded: “To determine whether a particular exception constitutes a limited exception, the extent to which the patent owner’s rights have been curtailed must be measured.” (para. 7.32).

holder's rights to import or to itself commence manufacturing of the product. However, we understand that, under Articles 72 and 80 of the Brazilian legislation, the grant of the license does not prevent the patent holder from exercising its rights to "normal exploitation" of the patent through import or manufacturing.⁵⁴ Moreover, it could be argued that any conflict that does exist does not do so "unreasonably". Read in the context of Articles 7 and 8 (the TRIPS Agreements' objectives and principles) and the Paris Convention,⁵⁵ to the extent that compulsory licensing under Article 68 of the Brazilian legislation facilitates technology transfer, it could not be deemed to "unreasonably" conflict with normal exploitation. If it were successfully argued that the "legitimate interests of third parties"⁵⁶ qualify the phrase "not unreasonably conflict with a normal exploitation",⁵⁷ it would strengthen the position that Article 68 does not constitute an "unreasonable conflict" for the purposes of Article 30.

52. Whether read broadly or narrowly,⁵⁸ it would be difficult to argue that patent holders in Brazil do not have an "interest" in maintaining their exclusive rights in their patent for the purposes of the third requirement in Article 30 of the TRIPS Agreement. It could be said, however, that the interest is not a "legitimate" one where the patent holder is only importing the patented product or otherwise failing to work the patent locally. Again, the recognition by the Paris Convention that failure to work constitutes a form of "abuse" would support an interpretation of "legitimate" that demands some degree of local working of the patent. Moreover, the practice of compulsory licensing is common to many WTO Members and, to the extent that the Paris Convention expressly acknowledges that failure to work a patent constitutes an abuse, Article 68 could not be deemed to "unreasonably prejudice".⁵⁹ Reading Article 30 in light of Articles 7 and 8, it could be concluded that compulsory licensing for failure to work locally does not "unreasonably prejudice the legitimate interests of the patent owner". Article 68

⁵⁴ The meaning of "normal exploitation" was considered at length in *Canada – Pharmaceuticals*. The Panel concluded that "'exploitation" refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent" and that "normal" was both "an empirical conclusion about what is common within a relevant community" and "a normative standard of entitlement". See *Canada – Pharmaceuticals*, paras 7.54-5; see also *United States – Section 110(5) of the US Copyright Act*, Report of the Panel, WT/DS160/R ("US – Section 110(5)"), para 6.166.

⁵⁵ See above paragraphs 20 and 24. See e.g. Halewood, at 269 who refers to Article 5(A) to demonstrate that compulsory licensing for failure to work does not constitute "unreasonable" prejudice.

⁵⁶ The meaning of "legitimate interests of third parties" is discussed below fn 60.

⁵⁷ See discussion above paragraph 49.

⁵⁸ In *Canada – Pharmaceuticals*, the Panel stated that: "To make sense of the term "legitimate interests" in this context, that term must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms." para 7.69. A subsequent WTO Panel has also adopted a broader meaning of "legitimate interests" in the context of Article 13 of the TRIPS Agreement and noted that economic value of exclusive rights is only one "albeit incomplete and thus conservative" means of assessing the meaning of "legitimate interests" *US – Section 110(5)* at para 6.227; In discussing the meaning of "legitimate", the Panel in *US – Section 110(5)* found that: The term "legitimate" has the meanings of "(a) conformable to, sanctioned or authorized by, law or principle; lawful; justifiable; proper; (b) normal, regular, conformable to a recognized standard type." Thus, the term relates to lawfulness from a legal positivist perspective, but it has also the connotation of legitimacy from a more normative perspective, in the context of calling for the protection of interests that are justifiable in the light of the objectives that underlie the protection of exclusive rights." *Ibid*, para 6.224.

⁵⁹ The ordinary meaning of "unreasonably prejudice" has been considered by a WTO Panel in the context of Article 13 of the TRIPS Agreement in the *US – Section 110(5)*. In its report, the Panel in that dispute stated: "In our view, prejudice to the legitimate interests of right holders reaches an unreasonable level if an exception or limitation causes or has the potential to cause an unreasonable loss of income to the copyright owner." *US – Section 110(5)* at para 6.229.

contemplates compensation to be paid to the patent holder based on the value of the compulsory license and does not generate an “unreasonable loss of income” to the patent holder.

53. An assessment of whether an exception unreasonably prejudices the legitimate interests of the patent owner, and possibly whether it unreasonably conflicts with a normal exploitation of the patent, must take account of the “legitimate interests of third parties”.
54. The meaning of “third parties” in Article 30 could be interpreted narrowly to mean applicants for compulsory licenses under Article 68 or broadly to refer to society as a whole. In *Canada – Pharmaceuticals*, the meaning of “third parties” was addressed by the parties in their arguments but the Panel reached no conclusion as to the two views. The EC and Canada in that case argued for the narrow and broad meanings of “third parties” respectively, with Canada relying “most heavily on the statements of objectives and principles in Articles 7 and 8.1 of the TRIPS Agreement”.⁶⁰ Halewood also argues that the “legitimate interests of third parties” should be informed by the policy considerations expressed in Article 8 of the TRIPS Agreement.⁶¹
55. Read with Articles 7 and 8, the meaning of “third party” interests in Article 30 must extend beyond the narrower group of third parties – applicants for compulsory licenses – to societal interests at large.⁶² Article 7 of the TRIPS Agreement refers to “promotion of technological innovation and the transfer and dissemination of technology... in a manner conducive to social and economic welfare”. Article 8 concerns “public health”, “public interest sectors of vital importance to socio-economic and technological development”, protection against unreasonable restraints on trade and protection against practices that “adversely affect the international transfer of technology”.
56. The legitimate interests of Brazilian society as a whole are the principal basis for Article 68 and must be taken into account in an assessment under Article 30 of the TRIPS Agreement. To the extent that compulsory licensing for failure to manufacture a patented product or process in Brazil promotes and facilitates the transfer and dissemination of technology, it serves the public interest in a manner contemplated by Articles 7 and 8 of the TRIPS Agreement. In the submission from some developing country Members to the Special Session of the TRIPS Council, the nexus between technology transfer and public interest was explained in the following terms:

⁶⁰ In *Canada – Pharmaceuticals*, the meaning of “third parties” was addressed by the parties in their arguments but the Panel reached no conclusion as to whether it should be interpreted narrowly to mean applicants for compulsory licenses under Article 68 or broadly to refer to society as a whole. The EC and Canada in that case argued for the narrow and broad meanings of “third parties” respectively, with Canada relying “most heavily on the statements of objectives and principles in Articles 7 and 8.1 of the TRIPS Agreement” *Canada – Pharmaceuticals* at para 7.67. Halewood also argues that the “legitimate interests of third parties” should be informed by the policy considerations expressed in Article 8 of the TRIPS Agreement. See Halewood, p.265.

⁶¹ See Halewood, p.265.

⁶² In *Canada – Pharmaceuticals*, the meaning of “third parties” was addressed by the parties in their arguments but the Panel reached no conclusion as to whether it should be interpreted narrowly to mean applicants for compulsory licenses under Article 68 or broadly to refer to society as a whole. The EC and Canada in that case argued for the narrow and broad meanings of “third parties” respectively, with Canada relying “most heavily on the statements of objectives and principles in Articles 7 and 8.1 of the TRIPS Agreement” *Canada – Pharmaceuticals* at para 7.67. Halewood also argues that the “legitimate interests of third parties” should be informed by the policy considerations expressed in Article 8 of the TRIPS Agreement. See Halewood, p.265.

The objective of the promotion of technological innovation and the transfer and dissemination of technology places the protection and enforcement of IPRs in the context of the interests of society. Such an objective is essential for the promotion of health policies, as it encourages the development of domestic production of pharmaceutical products. Whenever economically feasible, local production of pharmaceutical products is extremely important to ensure that medications are more readily available in the market, and at more affordable prices. Local manufacturing of pharmaceutical products also encourages sustainable access to medications by insulating the price of patented medicines against currency devaluations, as well as supporting the development of local expertise, which is vital in addressing local needs. As mentioned above, these objectives can be obtained by the normal exercise of patent rights. Where the patent holder fails to meet the objectives of the TRIPs Agreement and of public health policies, however, Members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals⁶³

57. To the extent that a determination as to the meaning of “third party interests” would require a panel “to decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate,”⁶⁴ a panel could determine that it is beyond its jurisdiction to reach a finding on this issue. Giving Brazil the full benefit of its power to decide how to apply the TRIPs Agreement, a panel should not second guess the policy determinations of a WTO Member.⁶⁵

VI. CONCLUSION

58. The stated object and purpose of the TRIPs Agreement reflects the Members’ desire for balance between two primary but sometimes competing goals of intellectual property protection: the promotion of innovation through the benefits of monopoly rights for the innovator, and the promotion of access to technology as a means of fostering the social and economic welfare of consumers. In particular the TRIPs Agreement provides that Members may adopt measures to “protect public health” and “promote public interest in sectors of vital importance to their socio-economic and technological development.” Moreover, the Members affirmed at their fourth Ministerial Conference that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of

⁶³ TRIPs Council, Special Session 20 June 2001, “TRIPs and Public Health” Submission by the Africa Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/269, para 20.

⁶⁴ *Canada – Pharmaceuticals*, para 7.82.

⁶⁵ It should be noted, however, that there is negative “precedent” to suggest that the non-discrimination requirement in Article 27.1 carries over into Article 30 such that an exception allowed under Article 30 cannot discriminate as to whether the products are imported or locally produced. Discussing the issue in the context of discrimination as to the field of technology, the Panel in *Canada – Pharmaceutical* disagreed with arguments advanced on behalf of Canada and concluded that “the anti-discrimination rule of Article 27.1 does apply to exceptions of the kind authorized by Article 30.” *Canada – Pharmaceuticals*, para 7.93. If followed, the Panel’s reasoning in *Canada – Pharmaceuticals* could result in Article 68 failing to meet the requirements of Article 30. Panel’s are not required to follow the conclusions of prior WTO panels although they generally refer to the conclusions in prior disputes as guidance for their own conclusions. Nevertheless, legal and policy arguments can be made that demonstrate that the Panel was wrong in this instance or that its analysis should be distinguished from the circumstances of this dispute. For example, it could be argued that in concluding that the anti-discrimination provisions in Article 27.1 (the primary rule) apply to the provisions of Article 30, (the exceptions) the Panel in *Canada-Pharmaceuticals* made a fundamental error in treaty interpretation. The Panel formulated a general principle from an interpretation of a substantive provision so as to undermine the effectiveness of an exception in a manner that the Appellate Body has described, under similar circumstances, as “abhorrent to the principles of treaty interpretation.” *United States-- Import Prohibitions of Certain Shrimp and Shrimp Products*, WT/DS58/R, WT/DS58/AB/R, reports adopted 8 Nov. 1998, para 121. See also *United States – Gasoline*, p. 20 where the Appellate Body rebuked the Panel for giving the primary anti-discrimination provisions in the GATT “so broad a reach as effectively to emasculate [the relevant exception] and the policies and interests [the exception] embodies”.

WTO Members' right to protect public health and, in particular, to promote access to medicines for all."⁶⁶

59. The ordinary meaning of the TRIPS Agreement and, in particular, the relationship between its basic rights and obligations, and the exceptions to those rights and obligations, must also be informed by the relevant rules and practice under the Paris Convention. The Paris Convention expressly provides that each party "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*."⁶⁷ Article 8.2 of the TRIPS Agreement recognises that Members may need to take measures "to prevent the abuse of intellectual property rights by [patent] holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."
60. Nothing in the ordinary meaning of the TRIPS Agreement, when read in good faith and in light of these objects and purposes, expressly prohibits the use of compulsory licensing as a means of requiring local working of a patent for the purpose of ensuring access to affordable essential medicines. Neither Article 27 nor Article 28 applies to compulsory licensing provisions, such provisions being governed by TRIPS Article 31.
61. The TRIPS Agreement specifically provides in Article 6 that nothing in its provisions shall be used to address the issue of parallel imports and therefore a WTO Panel would have no jurisdiction to consider this issue. A good faith interpretation of the TRIPS Agreement would not prohibit the use of parallel imports as a means of requiring the local working of patents for the purpose of ensuring access to affordable essential medicines.
62. Evidence from the Uruguay Round negotiations reveals that several delegations active in the design of the TRIPS Agreement defended their rights to use compulsory licensing as means of enforcing "local working" requirements, and to thereby promote the transfer of technology. It would be an unreasonable result to infer from the reading of an ambiguous text that Brazil and other WTO Members intended to forfeit this right.
63. The patent laws of a substantial number of WTO Members provide for the use of compulsory licensing as a means of requiring the local working of patents and reflect their right as governments to allow parallel imports. A substantial number of WTO Members, particularly those from developing countries, have recently reiterated their view that nothing in the TRIPS Agreement prevents them from enforcing local working requirements as a means of ensuring the access of their populations to affordable essential medicines.⁶⁸
64. If, however, a WTO Panel were to find that the use of compulsory licensing to enforce local working requirements did constitute a *prima facie* violation of the TRIPS Agreement, the measure would have to be defended under Article 30 or Article 31. The application of Articles 30 and 31 is difficult to assess in the abstract, particularly given that the TRIPS Agreement has yet to be applied by a Panel to such a regulation. Governments designing and applying compulsory licensing regulation need to be careful

⁶⁶ Ministerial Declaration on TRIPS, para 4.

⁶⁷ Art 5(A)(2) of the Paris Convention, emphasis added.

⁶⁸ Ministerial Declaration on TRIPS.

to ensure that the rights of both the patent holder and the licensee are protected by due process.

Prepared for Oxfam by Jake Werksman and Alice Palmer of the Foundation for International Environmental Law and Development (FIELD), with research assistance from FIELD interns Alicen Chow, Miranda Jenkin, Jacopo Panizza and Duncan Stone, November 2001.

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Annex I: Relevant Provisions of the TRIPS Agreement

Article 2 Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).
2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 6 Exhaustion

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

Article 7 Objectives

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

Article 8 Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27 Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁵ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall 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.

⁵For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

Article 28 Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing⁶ for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

⁶This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 30 Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

⁷"Other use" refers to use other than that allowed under Article 30.

Annex II: The Brazilian Legislation

Brazil Law 9.279

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Article 68. The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

Paragraph 1. The following also occasion a compulsory license:

I – non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or

II – commercialization that does not satisfy the needs of the market.

Paragraph 2. A license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent, that shall be destined predominantly for the domestic market, in which case the exception contained in Item I of the previous Paragraph shall be extinguished.

Paragraph 3. In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the provisions of Article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent.

Paragraph 4. In the case of importation to exploit a patent and in the case of importation as provided for in the preceding Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.

Paragraph 5. The compulsory license that is the subject of Paragraph 1 shall only be required when 3 (three) years have elapsed since the patent was granted.

Article 69. A compulsory license shall not be granted if, on the date of the application, the titleholder:

I – justifies the non-use based on legitimate reasons;

II – proves that serious and effective preparations for exploitation have been made;

III – justifies the failure to manufacture or to market on grounds of an obstacle of legal nature;

Article 70. The compulsory license shall also be granted when all the following circumstances apply:

I – there is a situation of dependency of one patent with regard to another;

II – the object of the dependent patent constitutes a substantial technical progress with regard to the earlier patent; and

III – the titleholder fails to reach agreement with the patentholder of the dependent patent on the exploitation of the earlier patent.

Paragraph 1. For the purposes of this Article, a dependent patent is considered to be a patent whose exploitation necessarily depends on the use of the object of an earlier patent.

Paragraph 2. For purposes of this Article, a process patent may be considered dependent on the respective product patent, and likewise, a product patent may be dependent on a process patent.

Paragraph 3. The patentholder licensed pursuant to the provisions of this Article shall have the right to a crossed compulsory license on the dependent patent.

Article 71. In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patentholder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, *ex officio*, without prejudice to the rights of the respective titleholder.

Sole Paragraph. The act of granting the license shall establish its term and the possibility of extension.

Article 72. Compulsory licenses shall always be granted on a non-exclusive basis, and sublicensing shall not be permitted.

Article 73. The application for a compulsory license shall be formulated upon indication of the conditions offered to the patentholder.

Paragraph 1. After an application for a license has been submitted, the titleholder shall be notified to submit comments within a period of 60 (sixty) days, at the end of which, if the titleholder has not submitted comments, the proposal shall be deemed to have been accepted under the conditions offered.

Paragraph 2. An applicant for a license who alleges abuse of patent rights or abuse of economic power must attach documentation that proves it.

Paragraph 3. In the case that the compulsory license is applied for on grounds of failure to exploit, the patentholder shall prove the exploitation.

Paragraph 4. If the application is contested, the INPI may conduct the necessary inquiries, including the establishment of a committee, which may include specialists who are not on the staff of that autarky, to arbitrate the remuneration to be paid to the titleholder.

Paragraph 5. The agencies and entities of direct or indirect, federal, state, and municipal public administration shall furnish the INPI with information as requested for purposes of assisting in the arbitration of the remuneration.

Paragraph 6. In the arbitration of the remuneration, the circumstances of each case shall be considered, and it shall consider, necessarily, the economic value of the license granted.

Paragraph 7. After evidence has been gathered in the case, the INPI shall decide about the granting and the conditions of the compulsory license within a period of 60 (sixty) days.

Paragraph 8. The appeal of the decision that granted a compulsory license shall not have suspensive effect.

Article 74. Unless in case of legitimate reasons, the licensee must begin the exploitation of the object of the patent within a period of 1 (one) year from the granting of the license, and an interruption for a same period of time shall be allowed.

Paragraph 1. The titleholder may require the cancellation of the license when the provision of this Article is not observed.

Paragraph 2. The licensee shall be invested with full powers to take action to defend the patent.

Paragraph 3. After a compulsory license has been granted, the assignment of such license shall only be allowed together with the assignment, transfer or leasing of the part of the enterprise that exploits it.