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EXCLUDING PATENTABILITY OF THERAPEUTIC METHODS, INCLUDING METHODS USING PHARMACEUTICALS, FOR THE TREATMENT OF HUMANS UNDER TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS ARTICLE 27(3)(A)

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I. INTRODUCTION

The Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”),¹ the General Agreement on Tariffs and Trade (“GATT”),² and the World Trade Organization (“WTO”)³ debacle has

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1. TRIPS was one result of the Uruguay Round of Trade Negotiations, under which the rules of so-called intellectual property, previously limited to national legal regimes, were effectively internationalized and made compulsory upon all World Trade Organization (“WTO”) members on pain of various sanctions. *See* DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 11-28 (3d ed. 2008) [hereinafter GERVAIS, *TRIPS AGREEMENT*]. *See generally* INT’L CHAMBER COMMERCE, *INTELLECTUAL PROPERTY & INTERNATIONAL TRADE: A GUIDE TO THE URUGUAY ROUND TRIPS AGREEMENT* (1996) [hereinafter *INTELLECTUAL PROPERTY*].

2. GATT was a postwar forum or organization that administered international trading practices under its General Agreement. The updated GATT is now the updated agreement under which the WTO administers international trade. Though paradoxical, anti-intuitive, and a little bit perverse, GATT actually spawned its own parent, the WTO. *See* GERVAIS, *TRIPS AGREEMENT*, *supra* note 1, at 3-10, 11-28; *INTELLECTUAL PROPERTY*, *supra* note 1, at 123-24.

3. The WTO’s agreements are often called the Final Act of the 1986-1994 Uruguay Round of Trade Negotiations. The WTO is formally an organization that was founded as a result of the Uruguay Round of Negotiations that started in 1986 under the GATT accords—negotiations that culminated in a 1994 agreement that, as of January 1, 1995, WTO would be the umbrella organization under which GATT and TRIPS would be administered. GERVAIS, *TRIPS AGREEMENT*, *supra* note 1, at 3, 27-28. Thus, although WTO is structurally the parent organization of GATT, in fact, it is GATT which fathered WTO. *See supra* note 2.

radically altered the traditional ability of nations to adopt whatever patent regime seems appropriate to them.⁴ Instead, TRIPS requires all member nations, even those which never thought it appropriate to grant such state monopolies, to afford patent protection to areas which had never been granted before—most dramatically in the area of health-related innovations and, most expensively, pharmaceuticals.⁵ Until TRIPS, most—or at least a number approaching half—countries simply did not grant patents to pharmaceuticals based on the notion that nobody could claim the right to substances and methods essential for human life.⁶ TRIPS appears to require most nations in most circumstances to

4. The principle of national treatment, at least until TRIPS (and even after, but obviously thereafter only in a nominal and essentially meaningless way), is the very basis for all international intellectual property conventions. Under this principle, each country is free to tailor the patent regime it chooses, and its sole obligation is, therefore, to treat foreigners on par with nationals (hence the principle of national treatment). It is recognized that “[b]ecause of the accepted territorial nature of intellectual property rights, both [the Berne and Paris] Conventions relied largely upon a ‘national treatment’ standard to assure uniform protection.” INTERNATIONAL INTELLECTUAL PROPERTY ANTHOLOGY 199, 205 (Anthony D’Amato & Doris Estelle Long eds., 1996) (“[T]he Paris Convention grants each signatory country the right to determine what is patentable. This means that each country creates its own specific intellectual property regime.”).

5. Prior to TRIPS, many, and perhaps even most, countries simply did not recognize the patentability of pharmaceuticals. *See infra* notes 6-7 and accompanying text. Under TRIPS, patents may not be excluded based on the field of technology, and most commentators assume—though with no real factual or textual basis—that this means that pharmaceutical patenting is compulsory. *See infra* Part III.

6. In a 1987 article, Professor A. Samuel Oddi listed forty-three countries, both developed (seven countries) and undeveloped (thirty-six countries), that did “not protect pharmaceuticals.” A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 5 DUKE L.J. 831, 845 nn.68-69 (1987) (citing 2 J. BAXTER, *WORLD PATENT LAW & PRACTICE*, app. 2 (1987); U.N. DEP’T OF ECON. & SOCIAL AFFAIRS, UNCTAD SECRETARIAT AND INT’L BUREAU OF THE WIPO, *THE ROLE OF THE PATENT SYSTEM IN THE TRANSFER OF TECHNOLOGY TO DEVELOPING COUNTRIES* 116 tbl. 14, U.N. Doc. TD/B/AC.11/19 (1974)). His list, however, did not include China, which had no pharmaceutical protection. Patent Law of the People’s Republic of China (promulgated by the Fourth Session of the Standing Committee of the Sixth National People’s Congress, Mar. 12, 1984), *reprinted in* 2C JOHN P. SINNOTT, *WORLD PATENT LAW AND PRACTICE* 12-13 (1991). Professor Oddi also did not include Indonesia, which another article included in a list of “problem countries,” a list that included others countries on Oddi’s list. J. Davidson Frame, *National Commitment to Intellectual Property Protection: An Empirical Investigation*, 2 J.L. & TECH. 209, 212 (1987). It is necessary to note that Davidson Frame’s article was commissioned by the Pharmaceutical Manufacturer’s Association at a time when that group was apparently conducting a public relations campaign to publicize the fact that many countries were not coming on board with the growing tide of pharmaceutical patent countries. *Id.* at 209; *see* Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J.L. & TECH. 307, 311 (1987) (noting that “[l]ess developed countries often prohibit [product patents] on pharmaceuticals”). Indeed, a recent WTO Secretariat Background Note listed five more countries (Angola, Cuba, Madagascar, Qatar, and United Arab Emirates) not included in the Oddi list which—as late as 1995—still excluded pharmaceuticals. JAYASHREE WATAL, *WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS* 8 & n.4 (2001), *available at* http://www.wto.org/english/tratop_e/trips_e/wto_background_e.pdf. It is difficult to explain these discrepancies, but one factor might have been the ambivalence that the

mimic the patent regimes of the most advanced countries that alone—because they have the infrastructure to develop and sell drugs to the entire world—find it profitable to grant monopolies over pharmaceutical products and methods (and to charge other nations—notably undeveloped ones—tribute for access to this aspect of health care).⁷

The crisis in health care, starting with HIV/AIDS, but not limited only to that epidemic, has caused many less-developed countries to seek an escape route from the oppressive demands of TRIPS.⁸ There are two such paths. One is to grant compulsory licenses⁹ to domestic manufacturers in order to achieve more affordable prices, pursuant to

major lobbyists—the pharmaceutical industry, for the most part—must have felt just prior to the passage of TRIPS. On the one hand, identifying countries defying pharmaceutical patent protection may have bolstered their claim that intellectual property was being “pirated.” On the other hand, the greater that number was, the less it could be said that they were defying an international norm. Thus, it might have been to the advantage of the industry to list only those countries from which the industry could gain a profit in the foreseeable future. Either way, of course, it is deceptive.

7. Many commentators have ascribed the historical and traditional reluctance to patent pharmaceuticals only to undeveloped nations. As one commentator observed, “prohibitions on patents for food, pharmaceuticals, and chemicals are not uncommon in the patent laws of developing countries.” David Ben Kay, *The Patent Law of the People's Republic of China in Perspective*, 33 UCLA L. REV. 331, 359 & n.141 (1985) (citing Gelatt, *China's New Patent Law Needs Clarification*, ASIAN WALL ST. J., Apr. 2, 1984, at 6). But, the Oddi list (and the New Zealand and Israeli litigation as only additional evidence, discussed *infra* Part IV) shows that this has not been historically limited to one economic sector. See *supra* note 6.

8. See Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 963-66 (2000); Warren Kaplan & Richard Laing, *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues and Opportunities for Future Research*, 1-2 (Health Nutrition & Population, Discussion Paper, Paper No. 32036), available at http://www-wds.worldbank.org/external/default/WDSPContentServer/WDSP/IB/2005/04/14/000090341_20050414083224/Rendered/PDF/320360KaplanLocalProductionFinal.pdf. Recent events reveal that several countries—especially India, Brazil, and Cuba—are attempting to manufacture drugs despite patents held by multinational corporations, and South Africa is attempting to compel licenses on a number of expensive drugs patented by the multinationals. Kaplan & Laing, *supra*, at 13-16, 26-28; see also Ford, *supra*, at 952-53.

9. For more on TRIPS and compulsory licenses on pharmaceuticals, see Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* 8-9, 19-20 (South Centre Trade-Related Agenda Development and Equity Working Papers, Paper No. 5, 1999), available at http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf. More information is available on compulsory licenses in individual countries. For India, see Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 390 (2011). For Canada, see generally Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS, and an Overview of the Practice in Canada and the USA* (UNCTAD-ICTSD Project on IPRs & Sustainable Dev., Issue Paper No. 5, 2003), available at <http://ictsd.org/i/publications/11764/?view=details>. For South Africa, see Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 212-15 (2002).

TRIPS Articles (“Article(s)”) 30¹⁰ and 31,¹¹ involving (at least if it is to

10. Article 30 states that “[m]embers 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.” Agreement on Trade-Related Aspects of Intellectual Property Rights art. 30, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

11. Article 31 states that:

[w]here the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, 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 [sic] 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.

be accomplished efficiently in a reasonable amount of time) the declaration of a national emergency pursuant to Article 31(b).¹² Vague in its initial form, the WTO provided guidance to the interpretation and application of Article 31 when it adopted the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”).¹³ It acknowledged the need to recognize a sovereign nation’s right to protect public health, even at the expense of intellectual property rights.¹⁴ The Doha Declaration affirmed a sovereign nation’s authority to grant compulsory licenses during national emergencies, and to define what constitutes a national emergency.¹⁵ A country that was suffering a major epidemic could compel licensure for domestic production of patented medication that they could not otherwise afford.

Many countries, including South Africa, chose this route, seeking compulsory licenses on various pharmaceuticals (even though, in the end, compulsory licenses involve payments to the patent holder, with TRIPS not providing a specific method of calculation).¹⁶ In a baffling development, however, then-President Thabo Mbeyelwa Mbeki of South Africa refused to declare the national emergency that may in fact be a prerequisite to the granting of such compulsory licenses without intolerable delays.¹⁷ Mbeki stated that “[t]he incidence is persuasive in itself . . . [a]ccordingly, we do not need to declare a national emergency to underscore the point.”¹⁸ Why the South Africans chose a route that requires a declaration of emergency for compulsory licenses to be

Id. art. 31 (footnote omitted).

12. For the text of Article 31(b), see *supra* note 11.

13. World Trade Organization, Ministerial Declaration of 20 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

14. *Id.*

15. *Id.*

16. James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INT’L, Mar. 2007, at 1, 9-18, available at http://www.keionline.org/misc-docs/recent_cls.pdf; Ford, *supra* note 8, at 952-53; see also *supra* notes 8-9 and accompanying text. As the WTO cautioned at the “WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs” conference in Norway:

[T]he grounds on which this can be done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner. There is not space to discuss all of these here, but two of the main such conditions are that, as a general rule, an effort must first have been made to obtain a voluntary licence [sic] on reasonable commercial terms and conditions and that the remuneration paid to the right holder shall be adequate in the circumstances of each case, taking into account the economic value of the licence [sic]

WATAL, *supra* note 6, at annex 26.

17. Rachel L. Swarns, *No National Emergency, South African Leader Says*, N.Y. TIMES, Mar. 15, 2001, at A14.

18. *Id.* (internal quotation marks omitted).

implemented in a reasonable time, but were unwilling to make that declaration, is inexplicable, especially because another route was and is available. That route does not require a declaration of national emergency and, furthermore, does not require the payment of any royalties. That route is described in Article 27(3)(a).¹⁹

Before addressing the blanket advantage offered by Article 27(3)(a), note that also, as part of the Doha Declaration, for WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector facing difficulties in making effective use of compulsory licensing, WTO members decided, in 2003, on a “waiver” that removed limitations on exports under compulsory licenses to least-developed country Members and other Members that have insufficient or no manufacturing capacities in the pharmaceutical sector for the patented product in question.²⁰ Subsequently, India protested against the seizure of generic drugs exported by Indian pharmaceutical companies to destinations abroad via European ports.²¹ India argued before the TRIPS Council that the widespread and repeated seizures, under the European Council Regulation 1383, had an adverse systemic impact on the principle of universal access to medicines, national public health budgets, legitimate trade of generic medicines, and also seriously impaired the efforts of civil society organizations engaged in providing medicines and improving public health in the least-developed parts of the world.²² Under the later Hong Kong Declaration and related WTO decisions, including the decision to make permanent some provisions of the Doha Declaration which favored poor countries with waivers, the WTO seems to constantly wave candy before the least-developed and developing world, and then take the candy away.²³ Most recently, the

19. Article 27(3)(a) reads: “Members may also exclude from patentability . . . diagnostic, therapeutic and surgical methods for the treatment of humans or animals” TRIPS Agreement, *supra* note 10, art. 27(3)(a).

20. See Justin Erickson, Note, *Call for Reform: Analyzing TRIPS Through European Seizure of Generic Medication*, 21 MINN. J. INT’L L. 382, 395 (2012).

21. See *id.* at 388-91.

22. *Id.* at 390-91.

23. See *id.* at 386-87. For more on the Hong Kong Declaration, see, for example, Daniel Benoliel & Bruno Salama, *Towards an Intellectual Property Bargaining Theory: The Post-WTO Era*, 32 U. PA. J. INT’L L. 265, 338-64 (2010). For one of the most recent discussions of the waivers (which were due to expire in 2013) offered to poor countries, see, for example, Jennifer M. Champagne, *Access to Essential Medicines in Developing Countries: The Role of International Intellectual Property Law & Policy in the Access Crisis*, 22 ALB. L.J. SCI. & TECH. 75, 92 (2012). Champagne states:

In 2005, the WTO approved the changes to the TRIPS Agreement proposed by the Paragraph 6 Waiver The deadline for these changes to be formally accepted by two-thirds of the WTO and built into the TRIPS Agreement was extended from December 2011 to December 2013. However, since the acceptance of the Paragraph 6 Waiver, the

waivers that were set to expire for the least-developed nations were extended once more, this time until 2021.²⁴ A large part of these waivers would be unnecessary and cost-free, if those countries were to exercise their rights to exclude pharmaceutical processes under Article 27(3)(a).

Additionally, many countries, including India, Thailand, and others, have recently been the focus of heated discussions in this area.²⁵ Using the “to promote access to medicine for all” aspect of the Doha Declaration as a basis for the decision, India issued a compulsory license for the cancer drug, sorafenib tosylate (sold under the brand name “Nexavar”) in March 2012, on the grounds that the drug “was not available to the public at a reasonably affordable price.”²⁶ Bayer

implementation of compulsory licensing by developing countries has been almost non-existent. Furthermore, post-TRIPS and the Paragraph 6 Waiver, cost and access to affordable essential medicines remains a crucial problem in developing countries, as indicated by the continued inability of developing countries to provide proper access to antiretroviral therapy for HIV/AIDS patients.

Id. For the text of the 2005 extension, see Council for the Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, IP/C/40 (Nov. 30, 2005).

24. Council for the Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, IP/C/64 (June 12, 2013). For a discussion of the decision, see, for example, *Poorest WTO Countries Granted New TRIPS Extension*, INT’L CTR. TRADE & SUSTAINABLE DEV. (June 13, 2013), <http://ictsd.org/i/news/bridges-africa/167516>.

25. See, e.g., *Hearing on U.S.-India Trade Relations: Opportunities and Challenges: Hearing Before the H. Subcomm. on Trade of the Comm. on Ways and Means*, 113th Cong. 13-14 (2013) (statement of Roy Waldron, Senior Vice President and Chief Intellectual Property Counsel, Pfizer) [hereinafter *Hearing on U.S.-India Trade Relations*]; Thomas C. Berg, *Intellectual Property and the Preferential Option for the Poor*, 5 J. CATH. SOC. THOUGHT 193, 195-96 (2008). Thomas Berg states:

A 2003 decision of the TRIPS General Council permitted exports of generic drugs to the poorest nations under compulsory licenses in order to address the grave public-health problems. But to many critics, that step was insufficient because the process it implements is too cumbersome and excludes some highly effective drugs. More recently, the application of TRIPS’s full IP-protection obligations to India, whose generic industry was the largest, has raised questions of whether sufficient supplies of low-cost drugs will continue to be produced. Finally, the TRIPS mechanisms for authorizing generic drugs have been sidestepped through bilateral agreements under which nations like the U.S. require their poorer trading partners to give stronger, ‘TRIPS-plus,’ protection to intellectual property.

Berg, *supra*, at 195-96 (footnotes omitted). Whether TRIPS-plus is itself a TRIPS violation is unresolved, but it is surely dishonest.

26. See *In re Natco Pharma Ltd. & Bayer Corp.*, C.L.A. No. 1 of 2011, at 1, 20-24, 35-36 (2012), available at http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf. It is important to note that although this case does not explicitly reference the Doha Declaration, it indirectly relied upon the “to promote access to medicine for all” aspect of the Doha Declaration when utilizing section 83(7)(a)(ii) of the Patent Act of 1970—which states that a compulsory license may be issued if the “reasonable requirements of the public” have not been met—to reach its decision.

Corporation, which holds the patent for the drug, challenged the validity of the issuance.²⁷ Its appeal to the Intellectual Property Appellate Board to issue a stay on the license was dismissed in September 2012.²⁸ In the meantime, the government of India has indicated its desire to increase its use of compulsory licenses in the long term.²⁹ India has issued licenses, or is in the process of doing so, with respect to at least four cancer drugs, including Nexavar.³⁰

Furthermore, although the drug companies have mounted what appears to be fierce resistance³¹ (although even this is uncertain in view of their recent concessions) to the developing countries' attempts to compel Article 31 compulsory licenses, they may be shedding what amounts to only crocodile tears. The fact is that Article 31 compulsory licenses still require the payment of "adequate remuneration."³² Thus, the pharmaceutical companies will still be able to demand and receive what is found to be their moneys' worth. If, however, developing countries were to simply declare that therapeutic method patents are simply not recognized, the pharmaceutical companies could demand nothing, and these countries would be free to practice these inventions without any intellectual property consequences (because no patents would be granted for these innovations, no royalties could be claimed).

Taking this step undoubtedly may lead the developing countries to create some conflict in the international political arena. However, the commotion created is no greater than issuance of compulsory licenses under the reasonable affordability banner. The fear of many such developing and less-developed countries that such takings show a lack of respect for intellectual property rights, and consequently, decay trade relations, seem unwarranted.³³

27. Divya Rajagopal, *Bayer Petition Against Natco Over Manufacture of Nexavar Dismissed*, ECON. TIMES (Sept. 16, 2012, 10:27 PM), http://articles.economictimes.indiatimes.com/2012-09-16/news/33880177_1_nexavar-cancer-drug-compulsory-license.

28. *Id.*

29. See Naval Satarawala Chopra & Dinoo Muthappa, *The Curious Case of Compulsory Licensing in India*, COMPETITION L. INT'L, Aug. 2012, at 34, 35-39 (discussing the impact of *Natco Pharma Ltd. v. Bayer Corp.*, Application No. 1/2011, on the enforcement of India's competition legislation).

30. *Hearing on U.S.-India Trade Relations*, *supra* note 25, at 13-14.

31. See, e.g., Uché Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203, 240-77 (2005).

32. TRIPS Agreement, *supra* note 10, art. 31(h) ("[T]he right holder shall be paid adequate remuneration in the circumstances of each case.").

33. For an additional analysis of the interplay between regimes of national and international property law protection, see, for example, Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 856-72 (2007).

II. SOME NECESSARY PATENT BASICS ON THE DISTINCTION BETWEEN METHOD AND PRODUCT PATENTS

Article 27(3)(a) cannot be understood unless some very basic patent law, regarding the distinction between method and product patents, is mastered. Patent law, at all times and in all places, has always covered only two kinds of possible inventions: (1) those involving new things or products; and (2) those involving new ways of doing things or methods.³⁴ There are, thus, product patents and method patents. Method patents are also called “process patents” or “use patents,” but these terms simply are interchangeable with method patents, and help describe one of the only two kinds of inventions eligible for patent protection: (1) things (products); and (2) ways of doing things (methods, processes, or uses).³⁵

The distinction between product and method patents raises more than issues of simple terminology because the possibility of gaining a process patent, instead of a product patent, has extraordinary consequences. The most important of these is that, while a product patent can only be acquired by one who invents something that never existed before, a method patent can be acquired by one who involves old and well-known things.³⁶ This is because the things or products are not what is invented. Instead, the way of using the invention is the arguably patentable innovation.

For instance, one can obtain a patent on a chemical only if that chemical was never known before. But, especially in the pharmaceutical area, it remains possible even with very old and well-known chemicals to gain a patent (a twenty-year or more monopoly) on a new way of using an old substance. One of the most notorious examples of this is, in fact, an AIDS-related discovery: that of azidothymidine (“AZT”). AZT was invented in the 1960s and, by the time its use for AIDS was discovered, it had long passed the point of having any patentable life as a product.³⁷ But, the discovery of AZT’s effectiveness against HIV allowed the Burroughs-Wellcome Company to file dozens of new patent applications covering all sorts of uses and dosages of AZT for the AIDS epidemic.³⁸ Not being patents on the product, they were the stereotypical method patents—therapeutic methods.

34. See, e.g., 35 U.S.C. § 101 (2012); TRIPS Agreement, *supra* note 10, art. 27(1).

35. See, e.g., 35 U.S.C. §§ 100(b), 101 (2012).

36. See, e.g., § 100(b) (defining “process” as a “process, art or method . . . includ[ing] a new use of a known process, machine, manufacture, composition of matter, or material”).

37. For more on the patent history of AZT, see, for example, Evan Ackiron, Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 156-59, 166-69 (1991).

38. *Id.* at 167.

A pharmaceutical manufacturer would always prefer a product patent because that prevents anybody else from using that product, without permission, in any way for any purpose for twenty years. But, a twenty-year patent on the particular use of a chemical—especially one that has no other use (like AZT)—is frequently as effective as a patent on the product itself. And often, it is even more effective, in an important sense, because of the process of “evergreening,” by which unscrupulous pharmaceutical manufacturers file additional uses for drugs whose patents are imminently expiring—thus triggering an additional twenty-year period for each use, extending the effective patent term of the underlying drug.³⁹

An understanding of “Swiss claims” concepts and similarly evasive claim drafting techniques is also essential. A pure Swiss claim over, say, product X, takes the form of “use of X for the manufacture of a medicine to treat Y.”⁴⁰ In Europe, the first use (usually medical) of a known product (protected by a product patent) is patentable by the use of a purpose-limited-product claim.⁴¹ Though not a pure Swiss claim, it achieves the same purpose: avoiding any bar against the patent of a therapeutic use or process. Other uses of the same substance can be patented provided the claims are directed to the use of the substance.⁴² A Swiss claim would assert a patent not over the drug or over the therapeutic use, but instead over the manufacturing process, even though there is neither novelty nor non-obviousness involved in the manufacturing.⁴³ Thus, the novelty for such items lies in the new use, without taking into consideration whether the pharmaceutical was previously known. Therefore, Swiss claims are equivalent to method patents, and that method is a therapeutic use. Moreover, “[p]atent applications over the therapeutic use of a known product essentially are instructions to the physician about how to employ a certain substance to treat a particular disease. Such a new use, hence, is equivalent to a *method of therapeutic treatment . . .*”⁴⁴

39. See MICHIE I. HUNT, PRESCRIPTION DRUG COSTS: FEDERAL REGULATION OF THE INDUSTRY 46 (BLUE CROSS/BLUE SHIELD ASS'N 2000).

40. Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 15 n.58 (2001).

41. SRIVIDHYA RAGAVAN, PATENT AND TRADE DISPARITIES IN DEVELOPING COUNTRIES 156 (2012).

42. *Id.*

43. UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 357 (2005).

44. *Id.*

III. THE CONFUSION OVER TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS ARTICLE 27(3)(A)

As it turns out, TRIPS allows member countries to exclude entirely from their patent systems therapeutic methods for the treatment of humans.⁴⁵ A patent over the therapeutic use of a chemical—the very definition of a pharmaceutical—need not, under Article 27(3)(a), be granted by any TRIPS member.

Why, then, do TRIPS members persist in recognizing these patents, and why have so many developing and least-developed nations, like South Africa and India, foregone this route and attempted—rather half-heartedly, as it turns out—to impose compulsory licenses, with their requirement of adequate remuneration, instead? The answer seems to be that most experts have not fully understood the import of Article 27(3)(a), because they do not understand the difference between method and product patents.

The history of Article 27(3)(a), while not as well documented (an unfortunate characteristic of WTO, GATT, and TRIPS provisions generally)⁴⁶ as most domestic U.S. legislation, is not very complicated, and it is clear that those who drafted it did not want the exclusion of method patents to embrace product patents as well. In fact, early drafts retained a qualification, apparently borrowed from the European Patent Convention, excepting from the therapeutic method exclusion the

45. See TRIPS Agreement, *supra* note 10, art. 27(3)(a).

46. LARS ANELL, *Foreword* to GERVAIS, *supra* note 1, at viii (1998) [hereinafter ANELL, *Foreword*] (“[T]he essential part of the deliberations were informal. There is no record of the oral arguments made. The history of the negotiations is only reflected in the numerous versions of the Chairman’s draft.”). Daniel Gervais has written that:

[T]here is no record of the most important part of the deliberations, the informal sessions during which progress was made on successive versions of the Chairman’s text. . . . The only traceable evidence of the emergence of TRIPS, apart from the brief notes on the monthly formal meetings where the exact wording was seldom discussed, are the Chairman’s texts, *some of which* have been de-restricted.

GERVAIS, TRIPS AGREEMENT, *supra* note 1, at ix (emphasis added). This is unfortunate, however, only in the sense that U.S. law values legislative history. With respect to international agreements, however, resort to legislative history or “*travaux préparatoires*” is not encouraged. See Maria Frankowska, *The Vienna Convention on the Law of Treaties Before United States Courts*, 28 VA. J. INT’L L. 281, 332-38 (1988). This probably means, however, that traditional legislative history in the form of comments and testimony is excluded whereas the actual development of textual material, in the form of early drafts, is generally considered. See *infra* note 47 and accompanying text. That much of the legislative history does not even exist, however, it is certainly not encouraging from the American perspective, and becomes unsettling in view of the fact that the restriction of what remains receives, at best, sanguine acceptance. It cannot be ignored that Anell was the Chairman, and that only some of the texts which he oversaw, according to Gervais, have been made available.

products used in those methods.⁴⁷ This seems to be due to a sentiment that discoverers of wholly new chemicals might merit a patent, whereby those who simply found new uses for existing chemicals might be less deserving. For instance, the European Patent Convention language is similar to Article 27(3)(a), but expressly qualifies it by saying, “[t]his provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”⁴⁸ Note that this clearly does not include the method. Even some commentators who are not favorably inclined towards pharmaceutical patents generally agree that Article 27(3)(a) does not mean to exempt products used in these methods and processes: under Article 27(3)(a), “[t]he exclusion . . . correctly interpreted, would not apply either to any apparatus used for diagnostics or treatment or to products . . .”⁴⁹ But, it bears noting that this is true, of course, only if those products are separately patentable as inventive products. Under no circumstances would it be argued that the exclusion from patentability coupled with the exception reserving the possibility of product patentability somehow renders patentable those products which are not, in and of themselves, inventive.

Indeed, the WTO itself continues to demand that while therapeutic methods may be excluded from patentability, this exclusion does not, or should not, cover the products used in these methods.⁵⁰ Thus, in response to questions by a WTO panel, a French legislative group explained that its Article 27(3)(a) exclusion was limited, saying, “[t]his exclusion does not apply to products (notably substances or compositions) which are necessary in order to implement one of these methods[.]” (again reserving for exclusion of the methods themselves).⁵¹

But, this insistence that Article 27(3)(a)’s exclusion does not cover the products used in the excluded processes has been hopelessly

47. See GERVAIS, TRIPS AGREEMENT, *supra* note 1, at 334-36, 350-53. As noted above, legislative history is not normally considered when interpreting WTO documents such as TRIPS. See *supra* note 46 and accompanying text. Legislative history in that sense, however, does not seem to include the various earlier drafts of the particular text—drafts which are apparently routinely consulted in doubtful areas. GERVAIS, TRIPS AGREEMENT, *supra* note 1, at ix (“It has been a constant practice in ‘GATT law’ to consider the evolution of a text as one of the elements to understand its meaning, where this is not entirely clear.”).

48. Convention on the Grant of European Patents art. 52(4), Oct. 5, 1973, 1065 U.N.T.S. 255.

49. INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 231 (Carlos M. Correa & Abdulqawi A. Yusef eds., 2d ed. 2008).

50. CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 67 (2000).

51. Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-Competitive Practices in Contractual Licenses*, § III.2, IP/Q3/FRA/1 (Feb. 4, 1998).

confused and misunderstood by most, if not all, commentators. It is one thing to say that a patentable product should be eligible for potential patent protection even if the methods utilizing it may not. It is quite another to misunderstand this exclusion so entirely as to conclude that any product used in an excluded method can somehow be protected by patent law, irrespective of its own patentability. In fact, it is the failure to understand that method and product patents are different, which explains why some commentators have failed to understand that Article 27(3)(a) is a viable means by which a country can exclude therapeutic method patents from coverage, even if patentable products nevertheless remain, as the WTO seems to insist, fully protected. Or, more importantly, an otherwise patentable process may be excluded and, even though Article 27(3)(a) does not exclude any associated products, if the products are not patentable on their own (that is, if they do not satisfy the traditional patent requirements of novelty, non-obviousness, and utility), nothing patentable remains.

Consider, for instance, one recent commentary piece that discusses the Article 27(3)(a) exclusion. The author states:

This is intended to facilitate the dissemination of innovations in medical treatment methods; it does not condone a refusal to patent pharmaceuticals. This is certain because Article 70(8) requires member countries to set up a means of collecting applications for pharmaceutical patents, and if pharmaceuticals were excluded under this exception that requirement would be nonsensical.⁵²

But, this author is clearly wrong if he means that pharmaceutical method patents as well as product patents are not excluded when they are the very focus of the exclusion. This passage appears not to understand the distinction between method and product patents.⁵³ Of course, the argument does not even address the method/product distinction. It is entirely possible for Article 70(8) to be fully respected, and for pharmaceutical product patent applications to be collected, filed, and granted, while at the same time therapeutic method patents are excluded from a patent regime. All that are excluded are the method patents (even though they may be pharmaceutical in character), not the

52. George K. Foster, Comment, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 290 (1998).

53. The comment received an award for being the best comment of the year, showing that this ignorance of fine distinctions in patent law is not only widespread, but also not a bar to excellence. *Id.* at 283. It is, however, fatal to understanding how poor nations can escape the oppressive hold of the worst aspects of the TRIPS accord.

product patents. That assumes, of course, that the product is independently patentable.

One objection to treating Article 27(3)(a) as a blanket provision allowing for the exclusion of all pharmaceutical method patents seems to be that, in some metaphysical, or even psychoanalytical sense, the drafters never really intended this to apply to therapies involving products, as well. But, this is contradicted by the history of this language (in which it is accompanied by qualifications excepting the products used in these methods from the exclusion)⁵⁴ expressly recognizing, for example, that the excluded methods do, or at least might, involve use of pharmaceuticals, including patentable ones. Legal language is generally interpreted not by the secret intentions of its drafters, but by the plain meaning of its words.⁵⁵ And the fact that this language is traditionally accompanied by provisions clearly excepting from its exclusion the products used in connection with these methods makes it clear that, in fact, this provision does contemplate methods which are used in conjunction with products—in other words, pharmaceutical method patents.

Alternative interpretations of the therapeutic method exclusion are difficult to sustain. One might imagine that the drafters really intended to exclude only those manipulative methods associated with unpatentability and other activities to which there was traditionally free access, such as chiropractic procedures or acupuncture, or methods of examination or even surgery (an area that was traditionally excluded from patent law but that has recently been the object of patent protection).⁵⁶ But, Article

54. See GERVAIS, TRIPS AGREEMENT, *supra* note 1, at 334-36. For a history of TRIPS, see generally GERVAIS, TRIPS AGREEMENT, *supra* note 1 and INTELLECTUAL PROPERTY, *supra* note 1.

55. See *United States v. Albertini*, 472 U.S. 675, 680 (1985); *Park 'N Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 194 (1985); *Watt v. Alaska*, 451 U.S. 259, 265-67 (1981); John Paul Stevens, Essay, *The Shakespeare Canon of Statutory Construction*, 140 U. PA. L. REV. 1373, 1374 (1992). TRIPS is apparently subject to Article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401. Article 3.2 specifies that the purpose of a dispute settlement is to clarify the provisions of the WTO Agreements "in accordance with customary rules of interpretation of public international law," which in turn imposes traditional rules of international law with regard to textual construction. *Id.* art. 3.2. The Vienna Convention, therefore, seems to govern. See Vienna Convention on the Law of Treaties, art. 1, May 23, 1969, 1155 U.N.T.S. 331. Its rules of construction for international accords, at least with respect to the interpretation of the phrases with which we are concerned here, are basically the same as the rules traditionally applied to domestic U.S. legislation. Article 31.1 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." *Id.* art. 31.1. Article 31.4 provides that "[a] special meaning shall be given to a term if it is established that the parties so intended." *Id.* art. 31.4.

56. For a discussion of what could be excluded, see Correa, *supra* note 40, at 16-17.

27(3)(a) specifically mentions diagnostic and surgical methods in addition to therapeutic methods, so that, under traditional rules of legal textual construction, therapeutic methods must be separate and apart from those two areas.⁵⁷ In addition, if tradition is the measure, then it must be noted that pharmaceutical method patents have been excluded traditionally from the patent regimes of many states.⁵⁸ If anything is addressed by the therapeutic methods excluded by Article 27(3)(a), it would seem drug therapies are the prime candidate (especially because of the qualification that products used in conjunction with these therapeutic methods may not be excluded).

But, there seems to be an undeniable tendency to view treatment methods in physical—rather than pharmaceutical—terms. It is quite probable that many believe, however wrongly, that “therapeutic methods” are somehow limited to such manipulative, tangible, procedures akin to surgery and diagnosis, even though TRIPS addresses those separately. One note vigorously opposed the granting of “medical process” patents, objecting as it did to recent patents over embryo transfers.⁵⁹ In its concentration upon—and almost visceral objection to—patents over such physical methods, it ignored, somewhat characteristically it seems, the intimate overlap of such patents with pharmaceuticals. The note, for instance, never once employed the word “pharmaceutical.” Paradoxically, although it did not recognize that pharmaceutical method patents are themselves medical process patents, it did discuss *Wellcome Foundation, Ltd. v. Commissioner of Patents*,⁶⁰ which it characterized as “a long and well-researched opinion.”⁶¹ That 1983 New Zealand Court of Appeals opinion addressed a patent office decision that the new use of an old chemical, though indeed a medical process (processes which theretofore had been considered unpatentable), was nevertheless patentable.⁶² The New Zealand Court of Appeals reversed that patent office determination, leaving the premise that it was indeed a medical process untouched, instead basing its decision on its

57. TRIPS Agreement, *supra* note 10, art. 27(3)(a). The universal rule of statutory construction is that words are to be interpreted so as to avoid rendering any of them surplusage. *See, e.g.,* Pa. Dep’t of Pub. Welfare v. Davenport, 495 U.S. 552, 562 (1990); Mackey v. Lanier Collection Agency & Serv., Inc., 486 U.S. 825, 837 (1988); United Sav. Ass’n of Tex. v. Timbers of Inwood Forest Assocs. Ltd., 484 U.S. 365, 372-75 (1988). To the extent this represents customary international practice as well, TRIPS should be interpreted in the same manner. *See supra* notes 46-47, 54 and accompanying text.

58. *See supra* note 6 and accompanying text.

59. Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1152-61 (1987).

60. [1983] NZLR 385 (CA).

61. Burch, *supra* note 59, at 1164.

62. *Wellcome Found. Ltd.*, [1983] NZLR, at 385-86.

view that such patents were unethical.⁶³ The principle that the use of a drug is in fact a medical process was, therefore, recognized explicitly and implicitly in both proceedings.

And, indeed, the language used by pharmaceutical manufacturers in their own patent applications compels the conclusion that “therapeutic methods” means pharmaceutical methods. Because pharmaceutical companies routinely describe their drug method patents—in the very patent documents they file—as “therapeutic methods.”⁶⁴ It would be difficult to deny, therefore, that therapeutic methods mean exactly what the drug companies say they are: pharmaceutical processes involving drugs which may or may not be separately patentable aside from the processes themselves.

To illustrate, we originally looked at the top five pharmaceutical companies worldwide and their method patent activity over the last thirty years. Looking at Pfizer, which is listed as the assignee in approximately 2791 U.S. patents that claim, as inventive, a method for achieving a particular result, 1271 (45.46%) of those patents specifically describe the method using the words “therapeutic” or “therapy.”⁶⁵ Similarly, Roche is

63. *Id.* at 391-92.

64. *See, e.g.*, U.S. Patent No. 5,859,021 (filed Feb. 22, 1996); U.S. Patent No. 5,733,915 (filed Mar. 30, 1995).

65. These results were generated with a Lexis search of all utility patents since 1983 through 1991 for: (1) “Assignee(company) and method for” designed to discover virtually all method patents; and (2) “Assignee(company) and method for and therap! w/25 (method or procedure or process)” to discover those method patents which described the invention in terms of a derivative of the root “therap.” Clearly there is some error here, as not all method patents use the term “method for” in their claims, and the words “therapy” or “therapeutic” along with the words “method,” “procedure,” or “process,” may be found in a part of the patent document other than that describing the invention at issue. But, the risks of overinclusion, as well as underinclusion, may well balance out, and it seems to be a highly realistic way of discovering the relevant information. The search was conducted again on March 4, 2013, with similar results, yielding an average of 39.35% holding method patents described as therapeutic or a variation thereof, using Johnson & Johnson, Pfizer, GlaxoSmithKline, Roche, and Sanofi-Aventis. We also took a similar look at a few predominantly high-tech companies, many involving genetic engineering. The results were, again, similar. These companies (Novo Nordisk, Amgen, Gilead Sciences, Biogen Idec, and Teva) held method patents that used the word therapeutic, or a variation, within 25 words of method, use, or process, on average, in 59% of their method patents. The range was from 25% (Novo Nordisk) to 79% (Amgen). Pfizer Utility Patents From 1983 to 2013 Search Results, LEXISNEXIS, <http://www.lexis.com> (follow “Legal” hyperlink; then follow “Area of Law - By Topic” hyperlink; then follow “Patent Law” hyperlink; then follow “Find Patents” hyperlink; then follow “Utility Patents” hyperlink; then enter “Assignee(pfizer) and method for”; then select “From 01/01/1983 To 03/04/2013”; then follow “Search” hyperlink); Pfizer Utility Patents Using a Derivative of the Word “Therap” from 1983 to 2013 Search Results, LEXISNEXIS, <http://www.lexis.com> (follow “Legal” hyperlink; then follow “Area of Law - By Topic” hyperlink; then follow “Patent Law” hyperlink; then follow “Find Patents” hyperlink; then select “Utility Patents”; then enter “Assignee(Pfizer) and method for and therap! w/25 (method or procedure or process); then select “From 01/01/1983 To 3/4/2013”; then follow “Search” hyperlink).

identified as the assignee of approximately 4128 method patents, of which 1704 (41.28%) describe the invention in those terms.⁶⁶ In other words, on average, a majority of the pharmaceutical companies themselves significantly describe these patents in terms that characterize them as therapeutic methods. These traditional companies, of course, routinely patent pharmaceutical products as well as pharmaceutical methods, so that one might expect a large proportion of their patents to address only products, and thus, use these terms less often. Biotechnological companies, on the other hand, dealing with biologics which are more often unpatentable natural substances, involve a higher proportion of purely method applications of genetically engineered materials, and unsurprisingly describe their inventions even more frequently as therapeutic methods. Amgen, for instance, received approximately 1188 method patents in which 938 (78.96%) used terms similar or identical to the words “therapeutic methods;”⁶⁷ in fact, Pfizer expressly describes 104 pharmaceutical patents as “therapeutic methods.”⁶⁸ For the biotechs, Amgen expressly describes 122 as therapeutic methods.⁶⁹ Thus, the argument that a therapeutic method, in the sense Article 27(3)(a) uses it, does not encompass the use of pharmaceuticals in health care, simply does not wash. The pharmaceutical companies themselves routinely admit this in their own patents.

Indeed, it is not only in their pharmaceutical patents that the drug manufacturers admit that therapeutic methods include pharmaceuticals, but also in their public relations. Gerald Mossinghoff, president of the Pharmaceutical Manufacturer’s Association admitted, perhaps inadvertently, exactly the same thing in a 1987 article apparently designed to support international pressure to expand pharmaceutical

66. See *supra* note 65 and accompanying text.

67. See *supra* note 65 and accompanying text.

68. Pfizer Utility Patents Using the Term “Therapeutic Method” From 1983 to 2013 Search Results, LEXISNEXIS <http://www.lexis.com> (follow “Legal” hyperlink; then follow “Area of Law - By Topic” hyperlink; then follow “Patent Law” hyperlink; then follow “Find Patents” hyperlink; then select “Utility Patents” hyperlink; then enter “assignee(Pfizer) and ‘therapeutic method’”; then select “From 01/01/1983 To 03/04/2013”; then follow “Search” hyperlink); see, e.g., U.S. Patent No. 5,859,021 col. 4 l. 9-16 (filed Feb. 22, 1996); U.S. Patent No. 5,733,915, col. 2 l. 27-35 (filed Mar. 30, 1995); U.S. Patent No. 5,627,186 col. 4 l. 4-11 (filed Mar. 28, 1994).

69. Amgen Utility Patents Using the Term “Therapeutic Method” From 1983 to 2013 Search Results, LEXISNEXIS <http://www.lexis.com> (follow “Legal” hyperlink; then follow “Area of Law - By Topic” hyperlink; then follow “Patent Law” hyperlink; then follow “Find Patents” hyperlink; then select “Utility Patents” hyperlink; then enter “assignee(Amgen) and ‘therapeutic method’”; then select “From 01/01/1983 To 03/04/2013”; then follow “Search” hyperlink). There is of course an error rate similar to that described above. See *supra* note 65.

patents through the adoption of TRIPS.⁷⁰ Additionally, “[i]n a limited number of foreign nations, a method of use patent is available when a new use is discovered for an old compound,” Mossinghoff lamented, but then observed, “[a] method of use claim is often available in nations in which a method for the treatment of the human body is patentable.”⁷¹ In other words, despite the general bar in many countries against pharmaceutical patents, a method patent might nevertheless succeed, but only if human body treatments were allowed, making it clear that pharmaceutical method patents are in fact therapeutic treatment methods. The industry was clearly willing to characterize pharmaceutical method patents as treatment methods when it would help them evade a bar against pharmaceutical patents generally. One cannot help wondering whether it will nevertheless answer the argument that Article 27(3)(a) covers pharmaceutical methods by denying that they are methods of treatment.

Others, besides the drug industry itself, have also recognized that pharmaceutical method patents are included within therapeutic methods or “methods for the treatment of diseases.” Another 1987 article, in lamenting that Chinese patent law “contains certain deficiencies in the pharmaceutical and agrichemical areas,” identified the pharmaceutical “deficiencies” as the exclusion from the Chinese Patent Act of “methods for the treatment of diseases,” thus adopting the argument that treatment methods inherently include pharmaceutical methods.⁷²

IV. JUDICIAL DECISIONS EQUATING THERAPEUTIC METHODS WITH PHARMACEUTICAL METHOD PATENTS

As mentioned earlier, the New Zealand courts have characterized pharmaceutical method patents as “therapeutic.”⁷³ In *Wellcome Foundation Ltd.*, the Court of Appeals considered “a method of treating or preventing meningeal leukemia or neoplasms in the brain of man or other mammal by the use of known compounds (such as methiodichlorophen and ethiodichlorophen, known respectively as metoprime and etoprime),” a classically pharmaceutical patent not unlike that over the use of AZT or stavudine (“D4T”) for HIV infection.⁷⁴ At various places throughout the opinion, the judges referred to the

70. See generally Mossinghoff, *supra* note 6.

71. *Id.* at 311.

72. Harvey J. Winter, *The Role of the United States Government in Improving International Intellectual Property Protection*, 2 J.L. & TECH. 325, 330 & n.35 (1987).

73. See *supra* notes 60-63 and accompanying text.

74. *Comm'r of Patents v. Wellcome Found. Ltd.* [1983] NZLR 385 (CA).

invention as one that involves a “therapeutic use,” a “therapeutic drug,” and a “therapeutic treatment.”⁷⁵

In *Wellcome Foundation Ltd. v. Plantex Ltd.*,⁷⁶ the Israeli High Court referred to a pharmaceutical method patent as a “therapeutic treatment.”⁷⁷ As this 1974 case and the 1983 New Zealand case were apparently well-known cases, and both predate the adoption of TRIPS, it would be difficult to sustain any argument that the words “therapeutic method” did not clearly include pharmaceutical method patents at the time TRIPS was adopted.

V. THE PROBLEM OF SWISS AND SWISS-TYPE EVASIVE CLAIMS

Despite the fact that, as has been discussed here, it is fairly clear—in fact, extremely clear—that developing countries (and others as well, of course) can avoid the patenting of therapeutic pharmaceutical patents and still be TRIPS-compliant; this will surely not be accepted by the international pharmaceutical industry sector.⁷⁸ One way they have already managed to avoid bars against the patentability of pharmaceuticals in countries that have traditionally opposed such patents is by Swiss claims or variations thereof.⁷⁹ But, any country that is committed enough to adopt the position advocated in this Article should easily pierce the ethereally gossamer veil behind which those claims evade the therapeutic exclusion. It is, in a sense, all done with mirrors.

The true Swiss claim effectively (that is, in countries that legitimize it, notably Switzerland) covers therapeutic pharmaceutical uses by claiming the manufacturing process (and, thus, not the therapeutic process) that produces the therapeutic drug.⁸⁰ The Swiss formula and its variants either attempt to patent a use of a product by nominally claiming the product, even though it is usually unpatentable as such (because, if it were, they would certainly seek the far more powerful product patent), or they shift the focus of the use on the manufacture, while in reality covering the therapeutic use.⁸¹

75. See generally *id.*

76. CA [1973] RPC 514.

77. *Id.* at 539.

78. See *supra* Part III.

79. See *supra* notes 40–44 and accompanying text.

80. UNCTAD-ICTSD, *supra* note 43, at 357.

81. *Id.*

The 'Swiss formula' . . . concerns the patenting of the use of the product, thus a method, and not a product.

—United Nations Conference on Trade and Development⁸²

The variants of a pure Swiss claim fall into the category of “second indication” patents, which allow a patent over later-discovered therapies.⁸³ These types of claims are allowed, even where therapeutic processes are prohibited, by interpreting them to be product claims.⁸⁴ Such an interpretation is surely “nonsensical.”⁸⁵

VI. CONCLUSION: THE IMPORTANCE OF THE EXCLUSION OF THERAPEUTIC METHODS FROM PATENTABILITY

If a country that excludes therapeutic methods from patentability must still respect pharmaceutical product patents, has it gained any effective advantage? The answer to that is a resounding and profound yes. This is so for the simple reason that although some therapeutic method patents involve independently-patentable pharmaceutical products, many therapeutic method patents involve well-known and old chemicals that are not, in and of themselves, eligible for patent protection.⁸⁶ It turns out, in fact, that many, and perhaps a majority of, the most important pharmaceutical patents useful in treating the most expensive and threatening diseases, such as malaria, tuberculosis, and AIDS, are only method patents, not product patents. AZT and D4T, for instance, are purely method patents.⁸⁷ They are exactly what Article 27(3)(a) contemplates: therapeutic methods for the treatment of humans that just happen to involve unpatentable products. Any country can exclude these therapeutic methods from patentability and, unlike an Article 31 compulsory license, need not pay one cent for the practice of these therapies.⁸⁸ And, since the products themselves—AZT and D4T—are not, and cannot be, patented in any country, they can be freely manufactured by the least expensive generic drug manufacturer available.

82. *Id.* (partial emphasis added).

83. *Id.* at 356-57.

84. *Id.* at 387.

85. See *supra* note 52 and accompanying text. George Foster used the word “nonsensical” to describe the fairly obvious conclusion that Article 27(3)(a) allows the exclusion of pharmaceuticals as therapeutic methods.

86. See *supra* notes 37-38 and accompanying text.

87. See *supra* notes 37-40 and accompanying text.

88. See *supra* notes 31-33 and accompanying text.

And, of course, it is not just AZT and D4T, but a host of other pharmaceutical therapies that are at stake here. Most pharmaceuticals under patent are not patented as products, but as new methods of using old and well-known drugs. All of those patents, constituting perhaps the bulk of useful new therapies,⁸⁹ can be excluded from the patent regime of any country wishing to conserve its limited health care resources.

The failure to understand that Article 27(3)(a) truly includes therapeutic methods involving pharmaceuticals stems from the failure to understand that such method patents can be excluded and that, nevertheless, the TRIPS requirement to respect pharmaceutical product patents can still be honored. This failure is due, in turn, to a failure to understand patent law itself, and the crucial distinction between product and method patents. This is an ignorance that carries a high price. And in health care, price has become everything.

89. It proves almost impossible to calculate exactly how many useful drugs are covered only by method patents, and how many are covered by product patents. This is, at least partly, because if one simply counts up issued patents, one has no way of knowing how many of those patents really cover useful drugs. Only indirect measures are available, but they seem to yield consistent results. For instance, the FDA lists twenty-four single drugs currently approved for use in HIV infection treatment. See *HIV Treatment: FDA-Approved HIV Medicines*, NAT'L INST. HEALTH, <http://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines> (last updated Sept. 30, 2013). Of those, eleven are covered only by method patents (DLV, EFV, ETR, ABC, FTC, 3TC, D4T, AZT, DRV, IDV, and TP), yielding a figure of forty-six percent. A brief review of those patents shows that five have expired, making later patents depending upon them almost certainly pure method patents. Others are close to expiration (some, of course, are just at the beginning of their twenty-year term). Using the search "ABST(THERAPEUTIC OR PHARMACEUTIC!)" in the Lexis Patent Utility File, shows that of the first fifty patents, thirty-six were product patents and fourteen were method patents, yielding a figure—twenty-eight percent—somewhat lower than the specific FDA-approved drugs. It seems probable, therefore, that perhaps as many as one-third to one-half of patented drug therapies are method patents which might be excluded from the patent regimes of developing countries pursuant to Article 27(3)(a). If you include future attempts at evergreening, every last one would be excluded. And this, of course, cannot be limited to HIV drugs. The newest malaria drugs are largely based on known chemicals, mostly artesunate ("ARS"), which makes their patents essentially therapeutic uses, ready to be excluded from patentability under Article 27(3)(a) by any nation with the determination and competent legal advice to do so. See, e.g., *Artesunate Is Available to Treat Severe Malaria in the United States*, CTR. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/malaria/diagnosis_treatment/artesunate.html (last updated Feb. 8, 2010) (describing the availability of ARS for use as malaria treatment).
