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# ARTICLE

## CROSSING THE TRIPS NONDISCRIMINATION LINE: HOW CAFTA PHARMACEUTICAL PATENT PROVISIONS VIOLATE TRIPS ARTICLE 27.1

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### I. INTRODUCTION

An estimated 1.6 million Latin Americans live with HIV/AIDS, the second leading cause of death in the region. In 2007, there were approximately 100,000 new cases of HIV, and 58,000 Latin Americans died of the disease.<sup>1</sup> As more effective drugs are developed and marketed, there is reason to hope for an end to the devastating epidemic. Each country in Latin America is party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which affords member countries the flexibility to issue compulsory licenses for patented drugs in the event of national emergency, such as a health

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<sup>1</sup> UNAIDS, FACT SHEET, KEY FACTS BY REGION—2007 AIDS EPIDEMIC UPDATE 2 (Nov. 2007), available at [http://data.unaids.org/pub/EPISlides/2007/071118\\_epi\\_regional%20factsheet\\_en.pdf](http://data.unaids.org/pub/EPISlides/2007/071118_epi_regional%20factsheet_en.pdf) (last visited April 17, 2008).

crisis of epidemic proportions.<sup>2</sup> Yet there is reason to doubt affordable new drugs will play a role in fighting disease in this region. Six Latin American countries effectively negated their ability to issue compulsory licenses for pharmaceutical products when they agreed to very restrictive intellectual property provisions in the Central America-Dominican Republic-United States Free Trade Agreement (CAFTA) in order to gain advantageous trading rights with the United States.<sup>3</sup>

The restrictive nature of these provisions may be their undoing. This Article argues two CAFTA provisions are so favorable to pharmaceutical patent holders and so disadvantageous to patent holders of similarly situated regulated products—without a bona fide reason for the difference—that they violate a TRIPS provision requiring patent rights to be enjoyable without discrimination as to field of technology. Part II gives a brief overview of the TRIPS Agreement, followed by an explanation of the specific TRIPS nondiscrimination provision at issue, Article 27.1, in Part III. Part IV analyzes a WTO dispute settlement panel's interpretation of the term "discrimination" in TRIPS Article 27.1. To better understand how CAFTA places nonpharmaceutical patent holders at a disadvantage, Part V explains the basic framework of compulsory licensing authorized under TRIPS Article 31. Part VI argues that two CAFTA provisions, applicable to patented pharmaceutical products but not to other patented products that must undergo regulatory review before marketing, violate the nondiscrimination provision in TRIPS Article 27.1. Finally, recent amendments to the United States Free Trade Agreement template are briefly discussed in Part VII to understand if, and how, the noncompliant CAFTA provisions will be implemented in future bilateral trade agreements.

## II. THE TRIPS AGREEMENT

With 151 member countries, TRIPS is the first and most important multilateral trade agreement incorporating intellectual property provisions.<sup>4</sup> Negotiated as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994, TRIPS is an annex to the agreement creating the World Trade Organization (WTO).<sup>5</sup> TRIPS incorporates most of the

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<sup>2</sup> See *infra* Part V.

<sup>3</sup> Dominican Republic-Central America-United States Free Trade Agreement, Aug. 5, 2004, 119 Stat. 462, 43 I.L.M. 514 [hereinafter CAFTA], available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/CAFTA/CAFTA-DR\\_Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/Section_Index.html) (last visited Feb. 7, 2008). The six Latin American countries are Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua. *Id.*

<sup>4</sup> World Trade Organization, Members and Observers, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited Feb. 7, 2008).

<sup>5</sup> To join TRIPS, a country must be a member of the WTO. To join the WTO, a country must meet established criteria relating to many aspects of trade (not just the intellectual property provisions of TRIPS), and all member states must agree to the accession. This

substantive requirements of the Paris and Berne Conventions protecting patents and copyrights, but also contains provisions relating to trademarks, trade secrets, and semiconductor chips.<sup>6</sup> The agreement is exceptional in its harmonization of substantive minimum standards for the protection of intellectual property rights, the establishment of the first viable system to enforce those rights internationally, and the obligation to resolve disputes under WTO dispute settlement procedures.<sup>7</sup>

In the area of patent protection, TRIPS represents a compromise between developed countries seeking to increase obligations under the Paris Convention<sup>8</sup> and developing countries seeking to limit their obligations to protect intellectual property under their national laws.<sup>9</sup> The TRIPS agreement explicitly acknowledges its attempt to balance private and public interests.<sup>10</sup> Negotiated over the course of five years, the final TRIPS agreement was highly favorable to developed countries because it elevated and harmonized the minimum standards of patent protection internationally (particularly in the areas of patent eligibility and duration), reflected the practices of developed countries, and imposed new limitations on a country's ability to deny protections to foreign patentees.<sup>11</sup>

### III. THE NONDISCRIMINATION PROVISION IN TRIPS ARTICLE 27.1

TRIPS Article 27.1 requires that patents "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."<sup>12</sup> Before

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relationship has led to widespread membership in TRIPS; many countries are willing to accede to the substantive intellectual property protections mandated by TRIPS to gain the many trade benefits of WTO membership. GRAEME B. DINWOODIE ET AL., *INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY* 43 (LexisNexis Publishing 2001).

<sup>6</sup> *Id.* at 42.

<sup>7</sup> World Trade Organization, Overview: The TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited Feb. 7, 2008).

<sup>8</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 2, 828 U.N.T.S. 107, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1538, 828 U.N.T.S. 303.

<sup>9</sup> GRAEME B. DINWOODIE ET AL., *supra* note 5, at 425.

<sup>10</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Prologue, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] ("*Recognizing* that intellectual property rights are *private rights*; *Recognizing* the underlying *public policy objectives* of national systems for the protection of intellectual property, including developmental and technological objectives . . . ." (second and fourth emphasis added)).

<sup>11</sup> GRAEME B. DINWOODIE ET AL., *supra* note 5, at 42, 425.

<sup>12</sup> TRIPS, *supra* note 10, art. 27.1 (emphasis added). This nondiscrimination provision is expressly made subject to three paragraphs: Paragraph 4 of Article 65 provides that if a developing country member is required to extend product patent protection to a previously unprotected area of technology solely to comply with its TRIPS obligations, it can delay

exploring the implications of a WTO dispute settlement panel's interpretation of this provision,<sup>13</sup> it is valuable to understand what various commentators believe the provision requires of a member country in formulating its domestic laws.

The most restrictive interpretation of this provision is that "discrimination means any form of differential treatment." Under this view, a member must establish a "one-size-fits-all" patent system<sup>14</sup> that does not treat patents protecting food and medicines any differently than those protecting mechanical devices or software.<sup>15</sup> Some commentators and industry groups implicitly endorse this interpretation when they argue Article 27.1 prohibits members from treating patentees in one field of technology unfavorably relative to patentees in all other fields of technology.<sup>16</sup> For example, the International

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applying certain patent provisions to these areas of technology for up to five years. Paragraph 8 of Article 70 requires a member to give certain retroactive protections to patent applications for pharmaceutical and agricultural chemical products, if that member does not protect these products commensurate with its Article 27 obligations as of the date of entry into force of the WTO Agreement. Finally, Article 27's nondiscrimination provision is subject to the third paragraph of that article, which expressly authorizes members to deny patent protection to "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and "plants and animals other than micro-organisms." *Id.*

<sup>13</sup> Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada Pharmaceuticals*].

<sup>14</sup> Jonathan Michael Berger, *Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity*, 17 CONN. J. INT'L L. 157, 200 (2002).

<sup>15</sup> Robert C. Bird, *Defending Intellectual Property Rights in the BRIC Economies*, 43 AM. BUS. L.J. 317, 346 n.198 (2006).

<sup>16</sup> Berger, *supra* note 14, at 199 (noting that in response to the inquiry "whether it is permissible to design provisions such as a compulsory licensing scheme solely in relation to pharmaceutical products," the pharmaceutical industry argues that Article 27.1 "prohibits member states from adopting compulsory licensing regimes that specifically target the pharmaceutical industry without being applicable to other sectors"); Robert Chalmers, *Evergreen or Deciduous? Australian Trends in the "Evergreening" of Patents*, 30 MELB. U. L. REV. 29, 47 (2006) ("Arguably these [anti-evergreening] provisions [in Australia's Therapeutic Goods Act], in mounting additional hurdles for patentees seeking to enforce their rights over pharmaceutical inventions, do discriminate in relation to the enjoyment of patent rights."); Natalie M. Derzko, *A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization Appropriate?*, 44 IDEA 1, 48 (noting that 35 U.S.C. § 271(e)(1) is an experimental use exception for regulatory submissions in the United States and applies solely to the "development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*," and may therefore violate Article 27.1's mandate that patent rights be enjoyable without discrimination as to field of technology (emphasis added)); Bryan Mercurio, *The Impact of the Australia–United States Free Trade Agreement on the Provision of Health Services in Australia*, 26 WHITTIER L. REV. 1051, 1094 (2005) ("[T]he International Federation of Pharmaceutical Manufacturers (IFPMA) felt that [the Australian government's amendments to the United States Free Trade Agreement Implementation Bill restricting drug manufacturer infringement claims] violated the TRIPS Agreement by discriminating against

Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) establishes a multilateral, communal seed bank to facilitate the exchange of food and feed seeds for research, breeding, and crop development, benefiting farmers in developing countries.<sup>17</sup> “Benefit sharing,” a condition of access to the bank, requires a party that uses genetic material in the bank to develop a commercial product to pay “an equitable share of the benefits arising from the commercialization of that product” into a trust account.<sup>18</sup> This disparate obligation has been raised as potentially in conflict with TRIPS Article 27.1, because it impairs patent rights enjoyable by holders of biotechnology patents but not holders of other patents.<sup>19</sup>

While the vast majority of patent laws are indeed “technology-neutral”<sup>20</sup> on their face, most commentators agree Article 27.1 does not strictly require a “single level of IP protection for all technologies or industries.”<sup>21</sup> After the *Canada Pharmaceuticals* WTO panel rejected a strict interpretation of Article 27.1 prohibiting any differentiation between fields of technology,<sup>22</sup> the more

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pharmaceutical patent holders and dissuading holders from seeking to protect and enforce their rights.” (footnote omitted)); LiLan Ren, Comment, *A Comparison of 28 U.S.C. § 1498(a) and Foreign Statutes and an Analysis of § 1498(a)’s Compliance with TRIPS*, 41 HOUS. L. REV. 1659, 1696 (arguing House Bills 1708 and 3235 “as currently written could face opposition because they only regulate pharmaceutical and safety-related patents” and should be changed to cover all fields of technology to “avoid any issue of discrimination” under TRIPS Article 27.1).

<sup>17</sup> International Treaty on Plant Genetic Resources for Food and Agriculture, ITPGR Website, Frequently Asked Questions, [http://www.planttreaty.org/faq\\_en.htm](http://www.planttreaty.org/faq_en.htm) (last visited Feb. 7, 2008).

<sup>18</sup> Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 41 (2004).

<sup>19</sup> *Id.* (concluding that the benefit sharing provision probably does not conflict with TRIPS after a WTO panel rejected a claim that a facially neutral statute which in reality only applies to pharmaceutical patent holders violates Article 27.1, discussed *infra* Part IV).

<sup>20</sup> Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2857 (2006) (quoting Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL LEG. STUD. 11, 13-21 (1998)).

<sup>21</sup> Berger, *supra* note 14, at 200. See also Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism*, 8 J. INT’L ECON. L. 77, 85 [hereinafter Abbott, *New Era*] (“[Article 27.1] does not, however, mean that a patent with respect to an Internet search engine must be treated the same as a patent on a steam turbine. . . . Inventions are not neutral with respect to field of technology. The invention of a new variety of disease-resistant rice has fundamentally different implications than the development of a new microprocessor or machine tool.”); Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 7 [hereinafter Correa, *Public Health*] (“[D]ifferential treatment does not necessarily mean discriminatory treatment, because different technologies might require different treatment.”).

<sup>22</sup> See *infra* Part IV.

accepted view is that “the pejorative concept of ‘discrimination’ must be distinguished from differentiation for *legitimate reasons*.”<sup>23</sup> It is also widely accepted that Article 27.1 prohibits both de jure discrimination, where unjustified differentiation is evident from the very nature of the law, and de facto discrimination, where unjustified differentiation occurs in the manner of applying the law. Thus, “a facially neutral exception may discriminate in violation of Article 27.1 if in practice it is invoked repeatedly in respect of a single technology, such as pharmaceuticals.”<sup>24</sup>

One final aspect of Article 27.1 is important to note: a law that unjustifiably *favours* patentees in one field of technology over all other fields can be just as discriminatory as a law that unjustifiably *disadvantages* patentees in one field of technology relative to all other fields.<sup>25</sup> Canada alleged such a form of positive discrimination in 2001 when it requested a WTO dispute resolution panel against the European Union. Canada alleged the European Union’s patent term extension regulation was inconsistent with Article 27.1 because it

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<sup>23</sup> *Canada Pharmaceuticals*, *supra* note 13, ¶ 7.94 (interpreting “discrimination” in Article 27.1 to mean “the *unjustified* imposition of differentially disadvantageous treatment,” not mere differentiation (emphasis added)). *Accord* Abbott, *New Era*, *supra* note 21, at 85. *See also* Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT’L L. 331, 344 (2004) [hereinafter Correa, *Investment Protection*] (“It is to be noted that differentiation in legal treatment is not the same as discrimination, and that WTO members can adopt different rules for particular areas, provided that the differences are adopted for *bona fide purposes*.” (emphasis added)); Thomas Cottier, *From Progressive Liberalization to Progressive Regulation in WTO Law*, 9 J. INT’L ECON. L. 779, 796 n.43 (“[The] general principle of equal treatment . . . requires that comparable situations not be treated differently and different situations not be treated alike unless such treatment is *objectively justified*.” (emphasis added and internal citation omitted) (quoting Case C-292/97, *Kjell Karlsson & Others v. Jordruksverket*, 2000 E.C.R. I-2737)); Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445, 452 (2007) (“We suggest that those defending an exclusion as compliant with Article 27 should be permitted to rebut a showing of disparate treatment by demonstrating a *legitimate purpose*.” (emphasis added)).

<sup>24</sup> Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 233 (2004). *See also* Panel Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (Oct. 12, 1998) (stating “that it is not just the substance of a rule that is reviewable for discrimination” as “the manner in which that rule is applied . . . is also reviewable”).

<sup>25</sup> Correa, *Public Health*, *supra* note 21, at 7 (“[A]rticle 27.1 of TRIPs bans any discrimination, in either the recognition or exercise of patent rights, based on the field of technology. This means that both negative discrimination (e.g., reducing the rights available to pharmaceutical patent holders) and *positive discrimination* (*broadening such rights*) may be deemed inconsistent with TRIPs. In the latter case, broadening rights available to holders of pharmaceutical patents could be deemed inconsistent because it could discriminate against patent owners in other fields of technology.” (emphasis added)).

only applied to, and therefore solely benefited, pharmaceutical and agricultural chemical products.<sup>26</sup>

#### IV. THE CANADA PHARMACEUTICALS DECISION

The March 2000 WTO dispute settlement panel's decision in the *Canada Pharmaceuticals* case provides the most authoritative interpretation of "discrimination" under Article 27.1. Significantly, the decision does not foreclose the possibility that CAFTA provisions that solely benefit pharmaceutical patent holders could be unjustifiably discriminatory.

At issue in the dispute between Canada and the European Union were two provisions of Canada's Patent Act. First, the "Regulatory Review Exception" in Section 55.2(1) of the Act stated there is no liability for patent infringement in Canada for making, constructing, using, or selling a patented product if the use is reasonably related to the development and submission of information required by regulatory law. Second, Section 55.2(2), known as the "Stockpiling Exception," stated that it is not patent infringement in Canada to make, construct, use, or sell a patented invention under Subsection (1) during a period set by regulation for the manufacture and storage of products intended for sale after the patent expires. On their face, these two exceptions to patent rights applied to all patents. But the only regulations enacted pursuant to the Stockpiling Exception were the Manufacturing and Storage of Patented Medicines Regulations (MSPMR), which set the time period in Section 55.2(2) as the six month period before a patent expires and *only applied to the manufacturing and storage of patented medicines*. Thus, the combined effect of Sections 55.2(1)–(2) and the MSPMR was to permit Canadian generic drug manufacturers to make and use a patented drug during the last six months of the patent's term to (1) prepare and develop information for submission to a regulatory agency and (2) store stockpiles of the drug for immediate release on the market as soon as the patent expired and the regulatory agency granted marketing approval. Because of these exceptions to their patent rights during the last six months of their patent term, holders of expired drug patents no longer enjoyed years-long periods of exclusivity after their patents expired while generics awaited regulatory approval and manufactured sufficient drug quantities to satisfy a national market. Under Canadian law, these activities could *legally* take place while the patent was still in force, in direct

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<sup>26</sup> Request for Consultations by Canada, European Communities—Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS153/1 (Dec. 7, 1998). Canada's panel request, which appears to have been in response to the European Union's claim against Canada for its stockpiling and regulatory review exceptions to patent rights, *see infra* Part IV, was ultimately not pursued. *See also* Correa, *Public Health*, *supra* note 21, at 30 (noting that a 1995 amendment to U.S. patent law, lowering the nonobvious requirement for biotechnology process claims, might have been deemed to violate Article 27.1 for benefiting biotechnology process patents only, but for the fact that the law has been extended to other fields of technology by caselaw).

contravention of the exclusive right to make, use, and sell a patented invention during its term.

As complainant in the dispute, the European Union claimed Canada's domestic law, in the form of the Regulatory Review and Stockpiling Exceptions, violated the exclusive patent rights conferred by TRIPS Article 28.1, the mandatory term of protection conferred by TRIPS Article 33, and the nondiscrimination provision of Article 27.1.<sup>27</sup> In particular, the European Union claimed Patent Act Section 55.2 violated Article 27.1 because it treated drug patents less favorably than patents for inventions in other fields of technology.<sup>28</sup> Canada responded that its laws were "limited exceptions" to patent rights authorized by TRIPS Article 30,<sup>29</sup> and that Article 27.1 did not apply to such limited exceptions to patent rights under TRIPS Article 30. Alternatively, Canada argued that if Article 27.1 did apply to exceptions under Article 30, its laws did not violate Article 27.1 because "the limited exceptions of Section 55.2(1) and 55.2(2) are not expressly related to any particular field of technology."<sup>30</sup>

The Panel's findings were mixed for Canada and the European Union,<sup>31</sup> but

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<sup>27</sup> TRIPS, *supra* note 10, art. 28.1 ("A patent shall confer on its owner the following exclusive rights: . . . to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product . . ."); *id.* art. 33 ("The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.").

<sup>28</sup> Among the findings and recommendations requested by the European Union: "That Canada, by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less [favorably] than inventions in all other fields of technology, violated its obligations under Article 27.1 of the TRIPS Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology." *Canada Pharmaceuticals*, *supra* note 13, ¶ 3.1. The European Union also argued: "The Canadian authorities had confirmed . . . [Section 55.2(1)] was applied only to pharmaceuticals. This was particularly interesting in a situation where for many other categories of products 'the development and submission of information [is] required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of (such) products.' *The product categories meeting this condition included agricultural chemical products, certain foodstuffs, motor vehicles, aircraft, ships and many more.*" *Id.* ¶ 4.5 (emphasis added).

<sup>29</sup> To successfully argue its laws were permissible under TRIPS Article 30, Canada was required to show its exceptions to patent rights were "limited," did not "unreasonably conflict with the normal exploitation of the patent," and did not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." *See* TRIPS, *supra* note 10, art. 30.

<sup>30</sup> *Canada Pharmaceuticals*, *supra* note 13, ¶ 3.2.

<sup>31</sup> The panel found the Stockpiling Exception violated TRIPS Article 28.1 because it was not a "limited" exception under the first element of TRIPS Article 30. *Id.* ¶ 7.38. The panel also found the Regulatory Review Exception violated TRIPS Article 28.1, but that it satisfied all three elements of TRIPS Article 30 and was therefore a valid exception to TRIPS Article 28.1. *Id.* ¶ 7.84. In sum, the Stockpiling Exception violated TRIPS, while

provided the most persuasive interpretation of the Article 27.1 nondiscrimination clause to date. First, the Panel rejected Canada's claim that Article 27.1 did not apply to permissible exceptions under Article 30. Thus, any exceptions to basic patent rights made under Article 30 must also be nondiscriminatory. In support of its defense that Article 27.1 did not apply to Article 30, Canada argued that if a country is not able to discriminate based on field of technology in creating an allowable exception to patent rights under Article 30, it would be virtually impossible to make the exception "limited," as required by Article 30. Canada further argued other negative consequences would result if Article 27.1's nondiscrimination provision applied to Article 30: targeting particular social problems would be more difficult and "requiring that exceptions be applied to all products would cause needless deprivation of patent rights for those products as to which full enforcement of patent rights causes no problem."<sup>32</sup> Among other reasons for rejecting Canada's interpretation, the Panel offered this response to Canada's negative consequences argument:

[I]t is not true that Article 27 requires all Article 30 exceptions to be applied to all products. . . . Article 27 does not prohibit *bona fide exceptions* to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.<sup>33</sup>

Thus, the Panel recognized that a law that merely differentiates between fields of technology is not necessarily inconsistent with Article 27.1; an exception supported by a "bona fide" reason to differentiate is permitted. In dicta, the Panel offered one such "bona fide" reason to differentiate: "to deal with the problems that may exist only in certain product areas."<sup>34</sup>

Significantly, the Panel went on to acknowledge that TRIPS members do not have an unbounded ability to balance public and private interests merely because TRIPS Articles 7 and 8.1 support those goals. According to the Panel, Article 27.1 places a definitive and purposeful limit on a country's ability to pass domestic patent laws targeting particular products if there is no bona fide reason to differentiate. Finally, and most importantly, the Panel recognized the

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the Regulatory Review Exception did not.

<sup>32</sup> *Id.* ¶ 7.89.

<sup>33</sup> *Id.* ¶ 7.92 (emphasis added). See *infra* notes 46, 47, and accompanying text for the relevant text of TRIPS Articles 7 and 8.

<sup>34</sup> *Canada Pharmaceuticals*, *supra* note 13, ¶ 7.92.

TRIPS drafters may have had a particular reason to impose a nondiscrimination requirement on basic patent rights and exceptions to those rights: “to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.”<sup>35</sup> The Panel’s reasoning does not lose its force in the context of free trade agreement provisions favoring pharmaceutical patent holders: Article 27.1 may have been intended to ensure governments do not succumb to domestic pressures to grant *additional* patent rights in areas where right holders tend to be *domestic* producers.

Having decided that Canada’s Regulatory Review Exception was an allowable exception to patent rights under Article 30, the Panel then analyzed whether the Regulatory Review Exception discriminated as to field of technology.<sup>36</sup> It first provided the following interpretation of the term “discrimination” in Article 27.1:

The ordinary meaning of the word “discriminate” . . . certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the *unjustified* imposition of differentially disadvantageous treatment. Discrimination may arise from explicitly different treatment, sometimes called “*de jure* discrimination”, but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called “*de facto* discrimination.”<sup>37</sup>

Accepting Canada’s interpretation that the exception is available not just to pharmaceutical products but to “any product” that requires regulatory approval for marketing (including agricultural products, certain foods, cosmetics, automobiles, ships, and aircraft), the panel concluded the exception imposed no *de jure* discrimination.<sup>38</sup> The Panel explicitly noted, however, that its finding of legal conformity on this issue “would no longer be warranted if, and

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<sup>35</sup> Dinwoodie & Dreyfuss, *supra* note 23, at 448-49, 454 n.38 (equating “domestic pressures” with domestic political pressures, such as those imposed by commercial interests and lobbying groups).

<sup>36</sup> *Canada Pharmaceuticals*, *supra* note 13, ¶ 7.38 (stating that because the Stockpiling Exception was inconsistent with Article 28.1, the Panel did not need to address the European Union’s claim that the Stockpiling Exception violated the nondiscrimination provision of Article 27.1).

<sup>37</sup> *Id.* ¶ 7.94 (first emphasis added).

<sup>38</sup> *Id.* ¶ 7.99 (“With regard to the issue of *de jure* discrimination, the Panel concluded that the European Communities had not presented sufficient evidence to raise the issue in the face of Canada’s formal declaration that the exception of Section 55.2(1) was not limited to pharmaceutical products. *Absent other evidence, the words of the statute compelled the Panel to accept Canada’s assurance that the exception was legally available to every product that was subject to marketing approval requirements.* In reaching this conclusion, the Panel took note that its legal finding of conformity on this point was based on a finding as to the meaning of the Canadian law that was in turn based on Canada’s representations as to the meaning of that law . . . .” (emphasis added)).

to the extent that, Canada's representations as to the meaning of that law were to prove wrong."<sup>39</sup> Thus, if the Regulatory Review Exception did not apply to all products subject to regulatory approval, but only to pharmaceutical products, the Panel may have found *de jure* discrimination.

Turning to *de facto* discrimination, the Panel defined the term<sup>40</sup> and divided the inquiry into two parts: (1) Is there a *de facto* discriminatory effect, such that the actual effect of the law "is to impose differentially disadvantageous consequences on certain parties?"; and (2) Is there a discriminatory purpose, such that there are "objective characteristics of the measure from which one can infer the existence or non-existence of discriminatory objectives?"<sup>41</sup> The panel found no discriminatory effect, because the European Union provided no evidence showing the actual effect of the Regulatory Review Exception solely disadvantaged pharmaceutical patent holders. In support of discriminatory purpose, the European Union offered uncontroverted evidence that before Canada passed the Regulatory Review Exception, all public debates focused solely on its impact on pharmaceutical products. The Panel found this evidence unpersuasive, however, and found no objective indications of a purpose to disadvantage pharmaceutical patent holders in particular:

[P]reoccupation with the effects of a statute in one area does not necessarily mean that the provisions applicable to other areas are a sham, or of no actual or potential importance. Individual problems are frequently the driving force behind legislative actions of broader scope. The broader scope of the measure usually reflects an *important legal principle that rules being applied in the area of primary interest should also be applied to other areas where the same problem occurs*. Indeed, it is a common desideratum in many legal systems that legislation apply its underlying principles as broadly as possible. So long as the broader application is not a sham, the legislation cannot be considered discriminatory. In the absence of any proof that the broader scope was a sham, it must be found that the evident concentration of public attention upon the effects of Section 55.2(1) on the pharmaceutical industry is not, by itself, evidence of a discriminatory purpose.<sup>42</sup>

Although offered in support of the Panel's finding that there was no *de facto* discrimination, this passage offers insight into the Panel's thinking on what *would* constitute *de facto* discrimination. A measure of narrow scope, not reflecting the "common" and "important" legal principle that rules applied in

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<sup>39</sup> *Id.*

<sup>40</sup> *Id.* ¶ 7.101 ("[D]e facto discrimination is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose differentially disadvantageous consequences on certain parties, and because those differential effects are found to be wrong or unjustifiable.").

<sup>41</sup> *Id.* The Panel also noted that the purpose inquiry is objective, not an inquiry into the subjective purposes on the part of the drafters of the provision.

<sup>42</sup> *Id.* ¶ 7.104 (emphasis added).

an “area of primary interest should also be applied to other areas where the same problem occurs,” might constitute de facto discrimination if discriminatory effect and purpose is shown to exist relative to the excluded areas that are similarly afflicted with the same problem. In fact, a simpler case of de jure discrimination may be established on the face of the measure if no bona fide reason can be offered for excluding the similarly-afflicted areas from the very terms of the measure’s scope.

The preceding analysis is framed as a hypothetical because the Panel expressly declined to consider “whether measures that are limited to a particular area of technology—de jure or de facto—are necessarily ‘discriminatory’ by virtue of that fact alone, or whether under certain circumstances they may be justified as special measures needed to restore equality of treatment to the area of technology in question.”<sup>43</sup> Nonetheless, the Panel’s definitions of de jure and de facto discrimination, and its statements regarding domestic pressures and the application of rules to areas with the same problem, provide valuable insight into how a different panel might interpret the CAFTA provisions directed solely to holders of pharmaceutical patents.

#### V. COMPULSORY LICENSING UNDER TRIPS ARTICLE 31

The CAFTA provisions may very well come before a WTO panel because much is at stake in the fight to end the global HIV/AIDS epidemic. As originally drafted, TRIPS envisions that member countries will have the ability to issue compulsory licenses *in any and all fields of technology*, subject to some limitations and after meeting certain requirements.<sup>44</sup> Articles 27 through 34 set out substantive patent protections all members must grant. Article 30 then states that members should tolerate only limited exceptions to the exclusive patent rights conferred in Article 28.<sup>45</sup> TRIPS explicitly authorizes members to adopt limited exceptions to these exclusive rights, however, when necessary

to protect public health and nutrition . . . to promote the public interest in sectors of vital importance to their socio-economic and technological development . . . [and] 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.<sup>46</sup>

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<sup>43</sup> *Id.* ¶ 7.105 n.439.

<sup>44</sup> DINWOODIE ET AL., *supra* note 5, at 427-28.

<sup>45</sup> *See supra* note 29.

<sup>46</sup> TRIPS, *supra* note 10, art. 8.1, 8.2. Most commentators agree “abuse of intellectual property rights” includes refusal “to grant licenses on reasonable terms [thereby hampering] industrial development, or . . . not supply[ing] the national market with sufficient quantities of the patented product, or demand[ing] excessive prices for such products.” J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT. LAWYER 345, 355 (1995) (internal

Some have argued Article 7 may also be invoked to limit exclusive patent rights.<sup>47</sup>

Article 31 establishes the conditions a member must meet before resorting to the remedial action of compulsory licensing. Such conditions include negotiating with the patent holder prior to any use without the patent holder's consent; ensuring any such use is "predominantly for the supply of the domestic market of the Member authorizing such use"; and paying the patent holder adequate remuneration.<sup>48</sup> Notably, the domestic market limitation effectively prevents developed countries from manufacturing patented drugs under a compulsory license and exporting those drugs to developing countries with few or no manufacturing capabilities.

In response to uncertainty on the part of developing countries as to how to interpret the flexibilities embodied in Article 31, the 2001 Doha Declaration on the TRIPS Agreement and Public Health affirmed the fundamental understanding that members may invoke compulsory licensing to protect public health.<sup>49</sup> The Declaration asserts that the "TRIPS Agreement does not and should not prevent members from taking measures to protect public health" and recognizes that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."<sup>50</sup> The Declaration then instructed the TRIPS Council to report to the General Council with a solution to this problem before 2003. The General Council

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quotation marks omitted).

<sup>47</sup> Article 7 promotes "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." TRIPS, *supra* note 10, art. 7.

<sup>48</sup> *Id.* art. 31(b) ("[S]uch 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"); *id.* art. 31(f), (h).

<sup>49</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration], available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm). See also Christine A. Chung, Comment, *A Cry for Cheap Drugs: CAFTA's Inflexible Intellectual Property Protections Create an Ominous Impact on Life-Saving Medicines*, 13 Sw. J. L. & TRADE AM. 171, 175 (2006) ("[A]n intense campaign ensued among developing nations seeking legal clarifications and the need to address the seriousness of the public health problems afflicting them.").

<sup>50</sup> Doha Declaration, *supra* note 48, ¶¶ 4, 6. See also *id.* ¶ 4 ("[W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. . . . [W]e reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.").

issued a decision on the implementation of the Declaration in August 2003.<sup>51</sup> The most important aspect of the decision is the partial waiver of a member country's Article 31(f) obligation not to export a product manufactured under compulsory license. The waiver allows a member country to grant a compulsory license to produce a *pharmaceutical product* for export to an "eligible importing member."<sup>52</sup> As part of the Declaration, member countries agreed that the Article 31(f) waiver would remain in effect until Article 31 is amended.<sup>53</sup>

It is possible, however, that the text of TRIPS will not be formally amended.<sup>54</sup> In a Protocol to Amend the TRIPS Agreement, the TRIPS Council (consisting of all WTO member countries) approved changing the TRIPS agreement to make the August 2003 Declaration permanent. The text will only be amended formally, however, when two-thirds of the 151 WTO member countries accept the change.<sup>55</sup> If two-thirds of the member countries approve the change, it would be the first amendment to the core WTO agreement.<sup>56</sup> As of the December 1, 2007 deadline for formal acceptance of the change, only thirteen countries out of the required 102 countries had accepted. It is still possible the amendment will be approved formally, as the TRIPS Council agreed in late October 2007 to extend the deadline to December 31, 2009.<sup>57</sup>

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<sup>51</sup> Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/530 (Sept. 1, 2003) [hereinafter 2003 Waiver]. Two earlier 2002 General Council decisions, implementing paragraph 7 of the Declaration, extended the deadline for least-developed countries to protect pharmaceutical patents and test data and to grant exclusive marketing rights to patented pharmaceuticals until January 1, 2016.

<sup>52</sup> An "eligible importing Member" is defined as a least developed country Member or any other Member that notifies the TRIPS Council of its intention to use the system as an importer. Twenty-three developed countries announced they would not use the new system as an importing Member. Other member countries stated that if they did use the waiver, it would be solely in the event of a national emergency or other situation of "extreme urgency." 2003 Waiver, *supra* note 51, at n.3. The latter statements merely reaffirm these countries' obligations to comply with Article 31(b), which says the requirement to negotiate with the patent holder before granting a compulsory license "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." *See* TRIPS, *supra* note 10, art. 31(b).

<sup>53</sup> World Trade Organization, Members Accepting Amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last visited Feb. 7, 2008).

<sup>54</sup> *But see infra* note 57.

<sup>55</sup> 2003 Waiver, *supra* note 51, at n.3.

<sup>56</sup> World Trade Organization, Members OK Amendment to Make Health Flexibility Permanent, [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm) (last visited Feb. 7, 2008).

<sup>57</sup> The ultimate importance of this formal acceptance process, resulting in an actual change to the text of the TRIPS agreement, is unclear. If two-thirds of the member countries accept, the amendment will take effect in those countries and replace the 2003

Given that the General Council has adopted a specific waiver for the production and exportation of pharmaceutical products under compulsory licenses, one might conclude that a trade agreement provision applying solely to pharmaceutical patents could not possibly violate Article 27.1. If the General Council sanctions the differential treatment of pharmaceutical patents in this manner and has determined the waiver, applicable solely to pharmaceutical patents, is consistent with the rest of the TRIPS agreement, why could not a member country pass a domestic law with such a narrowly drawn scope? Such reasoning must fail, however, because it does not take into account the General Council's bona fide reason for limiting the scope of the waiver to pharmaceutical products.<sup>58</sup> The problem associated with Article 31(f), and its restriction on exporting drugs manufactured under compulsory license to developing countries in need of less-expensive drugs to fight devastating epidemics, is not shared by other technologies or industries (at least not at present).<sup>59</sup> Thus, under a theory of *de jure* or *de facto*

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waiver. For the remaining countries, the 2003 waiver will remain in effect until the member accepts the amendment. Thus, all member countries have the benefit of the 2003 waiver allowing them to export pharmaceutical products manufactured under a compulsory license to an eligible importing member, whether or not the text of the TRIPS agreement is formally amended.

<sup>58</sup> See *supra* notes 49-50 and accompanying text.

<sup>59</sup> Thus, for example, developing countries are not clambering to import "generic" agricultural chemicals, genetically-modified foodstuffs, cosmetics, automobiles, ships, and aircraft, or at least not nearly on the scale they seek generic drugs to fight the AIDS, malaria, and tuberculosis epidemics. Here is one account of one developing nation's need for affordable, generic AIDS drugs:

Generic drug availability has been helpful in driving down prices for antiretroviral drugs ("ARV") needed to treat poor patients in the Central American region. . . . These ARV drugs, which need to be taken for life, have been widely available in the United States, but have been, because of the cost, "out of reach for most of those living with HIV/AIDS around the world." "In 2000, the average worldwide price for patented ARVs was more than \$10,000 per patient per year." Today, the same medicine sold in generic form costs as little as \$168 per patient per year.

In Guatemala, more than 78,000 people are currently living with HIV/AIDS. Approximately 13,500 of them are in urgent need of antiretroviral treatment; only 3,600 were receiving it as of December 2004. Because the ARV medicines have not been patented in Guatemala yet, generic competition has decreased the prices of ARV medicines, enabling better access to essential medicines. [Doctors Without Borders] has been treating patients since 2001 and dispensing drugs that are 75-99% cheaper than the brand-name drugs bought by the Guatemalan government. The generic drugs cost \$216 per person per year, while the brand-name drugs cost \$4,818 per person per year.

Chung, *supra* note 49, at 172-73 (citations omitted). If a situation unfolded where the need to import off-patent genetically-modified food or seeds were to arise to the same degree as the need to import generic drugs, and if the 2003 Waiver were not amended to include such products, then it would be possible to argue that the 2003 Waiver treats pharmaceutical patent holders disadvantageously, because their products are subjected to a less restrictive compulsory license scheme while other products are subjected to the original, more

discrimination, there are objective indications the Council had a bona fide reason to limit the 2003 waiver to the only type of patent at the heart of the “access to cheaper drugs” crisis—pharmaceutical patents.

VI. CAFTA PROVISIONS FAVORING PHARMACEUTICAL PATENTS VIOLATE TRIPS ARTICLE 27.1

The same cannot be said for the drafters of CAFTA, who chose to include provisions favoring pharmaceutical patent holders, to the exclusion of patentees of products subject to the same stringent regulatory laws, without a bona fide reason to differentiate. As a result, these CAFTA provisions violate the nondiscrimination provision of TRIPS Article 27.1. Interestingly, the CAFTA drafters included a nondiscrimination provision of significantly less bite than that of TRIPS Article 27.1. This occurred despite the fact that, as members of the WTO, each of the signatories is bound to the full scope of the nondiscrimination provision in Article 27.1.<sup>60</sup> CAFTA’s nondiscrimination provision states:

Each Party shall make patents *available* for any invention, whether a product or a process, *in all fields of technology*, provided that the invention is new, involves an inventive step, and is capable of industrial application.<sup>61</sup>

Note that the provision is limited to nondiscrimination in the *availability* of patent rights, and is conspicuously missing any reference to nondiscrimination in the *enjoyment* of patent rights. In addition, the provision only refers to nondiscrimination as to field of technology, and fails to mention two of the three areas in which Article 27.1 prohibits discrimination: place of invention and whether products are imported or locally produced. This is in sharp contrast to the requirements of NAFTA Article 1709, which contains a nondiscrimination provision of the same scope as that of TRIPS Article 27.1:

Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.<sup>62</sup>

Why the CAFTA drafters did not model the CAFTA nondiscrimination provision on equivalent provisions in the NAFTA and TRIPS agreements

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demanding terms of Article 31.

<sup>60</sup> CAFTA, *supra* note 3, art. 15.1(7) (“Further to Article 1.3 (Relation to Other Agreements), the Parties affirm their existing rights and obligations under the TRIPS Agreement and intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO) and to which they are party.”).

<sup>61</sup> *Id.* art. 15.9(1) (emphasis added).

<sup>62</sup> North American Free Trade Agreement, U.S.-Can.-Mex., art. 1709(7), Dec. 17, 1992, 32 I.L.M. 605 (1993).

remains unclear, especially because all CAFTA member countries' domestic laws must comply with TRIPS Article 27.1. At least one commentator has speculated the omissions were purposeful:

Curiously, recent [Free Trade Agreements] subscribed to by the United States reproduce only part of Article 27.1 and omit the non-discrimination clause contained therein. A possible explanation for this is that such treaties incorporate conditions that benefit, in particular, pharmaceutical companies, such as restoration of the patent term with respect to any pharmaceutical product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. Similar rights are not available for patents covering agrochemical products or genetically modified organisms, though they also require approval for commercialization.<sup>63</sup>

Determining a reason for the drafting omission is not necessary to reach the conclusion that two CAFTA provisions unjustifiably discriminate in favor of pharmaceutical patent holders. The first provision mandates that a member country extend the patent term of a pharmaceutical product patent if the regulatory approval process imposes unreasonable delays. Subsection (b) of Article 15.9(6) provides:

With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party.

To understand how this provision unjustifiably favors pharmaceutical patent holders, one must understand what comparable rule applies to patents on nonpharmaceutical products that are also subject to marketing approval requirements. The less favorable subsection (a) of Article 15.9(6) applies to such nonpharmaceutical patents:

Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later . . . .

Thus, the term of a cosmetic product patent, for example, may be adjusted for an unreasonably delay, but solely for unreasonable delay in the *granting of the patent*.<sup>64</sup> If a CAFTA country molds its domestic laws to conform to the

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<sup>63</sup> Correa, *Investment Protection*, *supra* note 23, at 345 n.58 (noting that, as an example of other regulated products, the European Communities have applied a "de facto moratorium" on genetically-modified organisms in foods since 1998).

<sup>64</sup> Presumably by the governmental authority responsible for granting patents, such as the

letter of the CAFTA agreement,<sup>65</sup> the cosmetic product patent holder is prohibited by the very terms of Article 15.9(6)(b) from using that provision to seek restoration of his patent term for “unreasonable curtailment of the effective patent term *resulting from the marketing approval process related to the first commercial marketing of the product.*” A pharmaceutical patent holder, on the other hand, can seek adjustment of his patent term for unreasonable delays in the general patent granting process *and* seek restoration of the patent’s term if the marketing approval process unreasonably curtailed the term.

One can make a case of de jure discrimination if there is no bona fide reason to exclude from the text of Article 15.9(6)(b) other patented products that are subject to marketing approval processes. Given that authorities grant patents on agricultural chemicals, genetically-modified foodstuffs, cosmetics, and medical devices<sup>66</sup> and that these products are often, if not always, subject to marketing approval processes that require tremendous capital investments and shorten the effective term of a patent,<sup>67</sup> Article 15.9(6)(b) is a “rule . . . applied in [an] area of primary interest [but not] applied to other areas where the same problem occurs.”<sup>68</sup> Thus, according to the provisions, like products experiencing like problems are not being treated alike, such that patent holders of other regulated products subject to an extensive marketing approval process

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United States Patent and Trademark Office or its equivalent.

<sup>65</sup> That a CAFTA country would have to pass domestic laws that exactly follow the CAFTA provisions, in order to find a violation of TRIPS Article 27.1, is a basic assumption of the arguments in this Part. A country may pass laws that offer *more* protections and benefits than that provided in CAFTA, as long as they do not conflict with CAFTA. Thus, in this case, a country could include other regulated products in its version of CAFTA Article 15.9(6)(b), but the key here is that it is *not required* to include these products by CAFTA’s terms.

<sup>66</sup> Although not included on the European Union’s list of regulated products in *Canada Pharmaceuticals*, see *supra* note 13, ¶ 7.95, new medical devices are regulated products that require marketing approval before their first commercial use and are frequently protected by patents. Any attempt to fit medical devices into the category of a “pharmaceutical product” would run up against the plain meaning of the term “pharmaceutical”—“of, relating to, or engaged in pharmacy or the manufacture and sale of [a medicinal drug].” See Merriam-Webster Online Dictionary, <http://www.merriam-webster.com/dictionary/pharmaceutical> (last visited Feb. 7, 2008).

<sup>67</sup> For example, a short list of the products the United States Food and Drug Administration regulates includes food ingredients and packaging, nutritional supplements, pesticides, medical devices, cosmetics, and radiation-emitting products, in addition to drugs for humans and animals. While some of these products may obtain marketing approval from the FDA in less time and with less expense than that of most pharmaceutical drugs, the clinical performance data that is required to obtain regulatory approval for a medical device intended for use in the human or animal body is comparable to that required by pharmaceuticals. Food and Drug Administration Homepage, <http://www.fda.gov> (last visited Feb. 7, 2008).

<sup>68</sup> *Canada Pharmaceuticals*, *supra* note 13, ¶ 7.104.

cannot enjoy the same patent rights as pharmaceutical product patent holders.

De facto discrimination is harder to establish because the complaining party must demonstrate discriminatory purpose and effect.<sup>69</sup> This proof, however, is unnecessary because the narrow drafting of Article 15.9(6)(b), which offers extra protections to a single class of regulated products without an objective reason, demonstrates de jure discrimination. Interestingly, had the CAFTA drafters merely included all regulated products in the scope of Article 15.9(6)(b) for reasons that are not “sham[s],” a panel following the reasoning of the *Canada Pharmaceutical* panel would likely refuse to find de facto discrimination.

The second CAFTA provision that discriminatorily favors pharmaceutical patent holders is Article 15.10(2). The first subsection of that provision provides:

Where a Party permits, as a condition of approving the marketing of a *pharmaceutical product*, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, *unless by consent or acquiescence of the patent owner . . .*<sup>70</sup>

This provision effectively negates a CAFTA country’s ability to issue a compulsory license on a pharmaceutical product. Ordinarily, if a government issues a compulsory license on a drug or other regulated product, the licensee must still register for marketing approval before selling the product.<sup>71</sup> Under TRIPS Article 31(b), the government may issue the license after making “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and [if] such efforts have not been successful within a reasonable period of time.”<sup>72</sup> In stark contrast, CAFTA Article 15.10(2)(a) requires a CAFTA country to implement procedures that prevent a third party, such as a licensee of a compulsory license, from marketing a patented drug, including a drug under a compulsory license, during the patent term, *unless the patent owner consents or acquiesces*. Thus, the licensee of a government-issued compulsory license who seeks marketing approval for a pharmaceutical product manufactured under the compulsory license cannot market the drug

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<sup>69</sup> See *supra* notes 40-41 and accompanying text.

<sup>70</sup> CAFTA, *supra* note 3, art. 15.10(2)(a) (emphasis added).

<sup>71</sup> Chung, *supra* note 49, at 183-84 (“Generic companies usually obtain regulatory approval by relying on the brand-name companies and by showing that their product is chemically equivalent and bioequivalent (that the generic drug will work the same in the human body as the brand-name drug).”).

<sup>72</sup> TRIPS, *supra* note 10, art. 31(b).

without the patent owner's consent. This renders the government's compulsory license worthless without the patent owner's consent to market the drug during his patent term, even though the government satisfied TRIPS Article 31(b)'s requirement to try to negotiate reasonable commercial terms with the patent owner. CAFTA Article 15.10(2)(a) is the quintessential "TRIPS-Plus" provision, providing parties, in this case pharmaceutical products patentees, with powerful protections beyond those the original TRIPS document requires.<sup>73</sup>

Article 15.10(2)(b) grants pharmaceutical patent holders another unjustified benefit by mandating that CAFTA countries' agencies inform the pharmaceutical patent owner "of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use." This provision requires regulatory agencies to notify *only* patentees of pharmaceutical products that a third party has requested marketing approval on a product that is claimed by their patent. Thus, these agencies have an affirmative obligation to notify pharmaceutical patent holders of possibly infringing activity.<sup>74</sup> Academics criticize this provision for requiring regulatory agencies, which have no experience determining the scope or validity of patents, to make precisely those judgments.<sup>75</sup> The key term is

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<sup>73</sup> Chung, *supra* note 49, at 183-84 ("How can a compulsory license ever become effective if the marketing approval requires the patent owner's consent or acquiescence? Most likely, the profit-minded patent holder will reject the authorization to market the drug. Clearly, this provision undermines the whole notion of a compulsory license and subverts the Doha Declaration's purpose of flexibility in dealing with public health and intellectual property protections." (quoting Frederick M. Abbott, *Intellectual Property Rights in Global Trade Framework: IP Trends in Developing Countries*, 98 AM. SOC'Y INT'L L. PROC. 95, 98 (2004)) (footnotes omitted)).

<sup>74</sup> The request to market a patented drug during the patent term is not infringing activity by itself, but if the third party has made, used, sold, or imported the patented drug in preparing its marketing approval request without the patent owner's consent, infringement is likely. This provision gives the patent owner a "heads up" about potentially infringing activity.

<sup>75</sup> Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 89 (2004) [hereinafter Correa, *Bilateralism*] ("The patent-registration linkage ignores that patents are private rights, as stated in the Preamble of the TRIPS Agreement, and that, whether a given product infringes or not, a patent is a legal matter entirely separate from the technical issues concerning safety and efficacy of drugs. Health authorities have no knowledge or experience whatsoever to assess the claims of a patent."). One commentator explains another problem with linking:

[D]rug regulatory authorities, generally speaking, do not have the capacity to evaluate the validity of patents. This is what the U.S. Food and Drug Administration (FDA) says. The FDA allows companies to list any patent they want in its Orange Book, and those listed patents form the basis for blocking marketing of generics. It is, as our own Federal Trade Commission recently reported, a system rife with abuse by patent holders; it effectively requires generic applicants to engage in multiyear litigation with

“claiming,” because a regulatory agency seeking to satisfy its affirmative obligation under CAFTA Article 15.10(2)(b) must understand and apply nuanced patent law to determine whether the claims of a valid patent cover an allegedly infringing product.<sup>76</sup>

The disadvantageous and disparate treatment of patentees of other regulated products by this provision and CAFTA Article 15.10(2)(a) poses a much larger problem, however, than the requirement to apply nuanced patent law. What owner of a patented, regulated product would not want notification that a third party has, without his consent, asked for marketing approval of his claimed invention during the term of the patent? Even if the patent’s claims fail to cover the third party’s product, a notified patent owner could immediately begin to investigate and save time and resources discovering the possibly infringing activity. It is difficult to imagine a bona fide reason why owners of patented pharmaceutical products receive this advantageous notification while other patent owners, using the same regulatory approval process, investing resources to prevent and stop infringement on a similar scale, and seeking to enjoy the same twenty-year period of exclusivity, do not.

The extremely advantageous ability of a pharmaceutical patent owner to block any compulsory license of his product during the patent term, the only time during which a compulsory license would be needed, may also support a claim of de jure discrimination. By requiring the consent or acquiescence of a patent owner to market a patented pharmaceutical product, even one manufactured under a government-issued compulsory license after reasonable efforts to negotiate with and compensate the patent owner, CAFTA Article 15.10(2)(a) vitiates the defining characteristic of a compulsory license: “authorization given by the government for the use by a third party, *without the consent of the right-owner*, of a patent . . . .”<sup>77</sup> Every patent owner values the exclusive rights a patent grants and would value the statutory right to preclude any compulsory license, in time of national emergency or otherwise. Patent owners who are closely or identically situated relative to pharmaceutical patent owners—that is, those who must undergo the same delay and extreme expense of regulatory approval to market their patented product—present the strongest case of differentially disadvantageous treatment. In sum, the omission of “enjoyment of patent rights” from the CAFTA nondiscrimination provision,

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patent holders before they may market their medicines. If we cannot make that system work well here in the United States, it is fair to assume it will not work terribly well in Honduras.

Abbott, *supra* note 73, at 98.

<sup>76</sup> Most commentators claim this provision requires a regulatory agency to actually *certify* that a generic drug does not infringe a patent before granting marketing approval. Sarah Lueck, *In Trade Deal, a Shift on Generics; Agreement Opens the Door to Cheaper Drugs Abroad, Easing Some Patent Rules*, WALL ST. J., May 17, 2007, at A4 (stating that linkage “requires local drug regulators to make sure a generic product doesn’t violate any patents before allowing it on the market”).

<sup>77</sup> Correa, *Investment Protection*, *supra* note 23, at 346 (emphasis added).

the lack of an objective and bona fide reason for narrowing CAFTA's scope to one type of regulated product, and the very powerful ability to preclude compulsory licensing despite the Doha Declaration's reaffirmation that WTO members can issue compulsory licenses, would support a claim of de jure discrimination in violation of TRIPS Article 27.1.<sup>78</sup>

#### VII. RECENT REVISIONS TO THE UNITED STATES FREE TRADE AGREEMENT TEMPLATE

A May 2007 bilateral trade deal between President Bush and the democratically-controlled Congress produced significant changes to provisions in the United States Free Trade Agreement (FTA) template—the standard text with which the U.S. enters all FTA negotiations.<sup>79</sup> These changes will affect future U.S. free trade agreements, but lack retroactive effect on a ratified agreement such as CAFTA. Changes to the provisions favoring pharmaceutical patent holders notably eliminate or ameliorate some of the Article 27.1 problems, but potentially create new problems.

The changes modify the CAFTA provision requiring regulatory agencies to ascertain whether a marketing request covers a patented pharmaceutical and to notify the patent owner of the request. Now the template requires “a transparent system [for providing] notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use.”<sup>80</sup> While replacing “claiming” with “covering” might relieve the regulatory agency of the obligation to answer difficult infringement questions outside its area of expertise, the new provision still requires the regulatory agency to notify a pharmaceutical patent holder—and only a pharmaceutical patent holder—of a request to market its patented drug, similar to CAFTA Article 15.10(2)(b). Conspicuously missing from the revised template, however, is CAFTA Article 15.10(2)(a), requiring the consent or acquiescence of a pharmaceutical patent owner before a third party can market the patented drug. Instead, the template reaffirms a party's ability to “take measures to protect public health” in

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<sup>78</sup> The “Data Exclusivity” provision in CAFTA Article 15.9(5) also provokes much controversy. This Article, however, does not discuss this provision for two reasons: (1) the provision is not expressly limited to pharmaceutical product patents and a patentee of any regulated product may use the provision to protect data submitted to a regulatory agency, and (2) TRIPS Article 27.1's requirement that *patent* rights be enjoyable without discrimination is not implicated. The provision relates solely to the protection of data submitted to a regulatory agency without reference to the grant or enjoyment of patents. See Abbott, *supra* note 73, at 97-98, and Chung, *supra* note 49, at 184-86, for more details on the controversy surrounding data exclusivity.

<sup>79</sup> See Lueck, *supra* note 76.

<sup>80</sup> United States – Panama Trade Promotion Agreement, U.S.-Pan., art. 15.10(3)(b), [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Panama\\_FTA/Final\\_Text/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Panama_FTA/Final_Text/Section_Index.html) (last visited Feb. 7, 2008).

accordance with the Doha Declaration, the 2003 waiver, and any eventual amendment to TRIPS to implement the Declaration.<sup>81</sup> The template also imposes a new requirement that parties implement procedures to resolve patent disputes more quickly and efficiently.<sup>82</sup>

The amended template sets up an interesting dichotomy between pharmaceutical and nonpharmaceutical patents in the area of patent term extensions. The template now provides that while a party must adjust the term of a nonpharmaceutical patent to compensate for unreasonable delays that occur in granting the patent, a party has discretion to adjust the term of a pharmaceutical product patent to compensate for unreasonable delays in granting the patent. Whether this revision now discriminates against holders of pharmaceutical patents in allowing a country to choose *not* to grant automatic patent term extensions for unreasonable delays is an interesting question outside the scope of this Article.<sup>83</sup>

#### VIII. CONCLUSION

The European Union's discrimination claim in *Canada Pharmaceuticals* and the WTO dispute settlement panel's lengthy consideration of the meaning of the term "discrimination" suggests the prohibition on discrimination along field of technology lines is not an outlying, obscure provision in the TRIPS framework. Indeed, while the WTO panel can be said to have set a low bar to defend a claim of de facto discrimination,<sup>84</sup> the very narrowly targeted provisions in CAFTA, exclusively benefiting pharmaceutical patents, are a ripe target for a claim of de jure discrimination. Unlike domestic legal systems where private parties may have standing to assert legal claims, the "parties" in the TRIPS dispute settlement system are entire nations,<sup>85</sup> seeking to hold other

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<sup>81</sup> *Id.* art. 15.10(2)(e).

<sup>82</sup> *Id.* art. 15.10(3)(a) ("Each Party shall provide: procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use.").

<sup>83</sup> But one can still speculate briefly on the outcome of such a challenge: As long as the pharmaceutical patent holder enjoys the minimum patent term of twenty years from the date of filing an application, mandated by TRIPS Article 33, any argument that this provision violates TRIPS would focus on Article 27.1. It is possible a developing country could offer a bona fide reason to differentiate between pharmaceutical and nonpharmaceutical patents if it could provide evidence of national health emergencies being prolonged as a result of patent term extensions for pharmaceutical patents, but not for nonpharmaceutical patents.

<sup>84</sup> *Canada Pharmaceuticals*, *supra* note 13, ¶ 7.104 ("So long as the broader application is not a sham, the legislation cannot be considered discriminatory.").

<sup>85</sup> Hypothetically, if private parties could allege TRIPS violations, the parties most likely to have standing to claim a violation of Article 27.1 would be patent holders of nonpharmaceutical regulated products, who are injured by being deprived, without a bona fide reason, of the exclusive benefits afforded to similarly-situated pharmaceutical patent

nations to the binding international commitments they made when they joined the WTO. *Canada Pharmaceuticals* demonstrates the TRIPS dispute settlement system is an effective enforcement tool that has been and can be used to raise TRIPS Article 27.1 claims.

CAFTA Articles 15.9(6)(b) and 15.10(2), giving pharmaceutical patent holders the unique ability to extend the term of their patents for delays in the regulatory approval process and to halt any attempt to manufacture their patented product under compulsory license, do not just dance around the line set by TRIPS on impermissible discrimination. CAFTA boldly goes where no United States free trade agreement has gone before it,<sup>86</sup> and where no United States free trade agreement will (likely) go after it.<sup>87</sup> Because these provisions touch on the ability to fight devastating health epidemics on a global scale, the TRIPS dispute settlement system is an apt forum to challenge them, and Article 27.1 offers the strongest argument to invalidate them.

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holders. Any class of patent holders, however, is unlikely to argue in favor of weakening intellectual property rights in U.S. free trade agreements. Humanitarian aid groups and the governments of developing countries, on the other hand, have a very strong incentive to challenge the CAFTA provisions at issue, as they foot the bill for the drugs needed to fight global health epidemics. Costa Rica, a member of CAFTA with a state-paid universal healthcare system, is a prime candidate to challenge the provisions at issue.

<sup>86</sup> See *supra* note 62 and accompanying text.

<sup>87</sup> See *supra* Part VII.