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Suppression of Parallel Trade in Pharmaceuticals

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**EMBRACING PRICE DISCRIMINATION: TRIPS AND THE  
SUPPRESSION OF PARALLEL TRADE IN  
PHARMACEUTICALS**

JEFFERY ATIK\* & HANS HENRIK LIDGARD\*\*

ABSTRACT

In December 2005, the World Trade Organization (“WTO”) responded to the HIV/AIDS pharmaceutical crisis in the least-developed world by voting to make the first permanent amendment to the WTO Agreements since their original negotiation during the Uruguay Round. New Article 31*bis* will amend the TRIPS Agreement to permit compulsory manufacturing licenses in order to facilitate supply of needed pharmaceuticals to those countries lacking the technological capacity to produce these drugs themselves. The amendment reflects a substantial shift in the essential TRIPS bargain, constituting a significant “give-back” to those developing countries that specialize in the generic production of pharmaceuticals. To date, however, there has been no significant utilization of this facility (which was provisionally established in August 2003). Rather, patent holders have determined – perhaps under the *threat* of these newly authorized compulsory licenses – to supply these markets directly with HIV/AIDS drugs at prices much lower than those prevailing in developed country markets. As a condition of doing so, both the pharmaceutical industry and those WTO members that champion their interests have sought and obtained limitations on the parallel trade of drugs subject to differential pricing. This shift away from TRIPS’ prior neutrality on parallel trade may well spill over into additional areas beyond the particular context in which the amendment developed.

We make the following observations:

TRIPS was previously neutral on the permissibility of parallel

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trade. Until now, WTO members were free to either permit or prohibit the import and sale of intellectual property ("IP")-covered goods that had been placed into commerce in foreign markets. That is, IP-right holders may or may not be provided with an ancillary right to block the importation and sale of "grey-market" goods.

Parallel trade has not been a solution to assuring the supply of needed drugs to AIDS-stricken regions of the least-developed world. Quite simply, there has not been an adequate source-of-supply at prices that the afflicted least-developed countries ("LDCs") are capable of paying.

Compulsory licensing now has a clear legal basis as a result of the TRIPS amendment (and the provisional rule in place since August 2003), yet virtually no countries have resorted to compulsory licensing.

HIV/AIDS drug prices in LDC markets have fallen significantly, which suggests that pharmaceutical manufacturers have determined to supply LDC markets directly, instead of permitting LDC demand to be met by generic producers utilizing the amended TRIPS rules on compulsory licensing. Their determination to do so may have been motivated, at least in part, by the threat of compulsory licenses.

Both the WTO community and the pharmaceutical industry have embraced a policy of differential prices: high prices in developed markets and dramatically lower prices in LDC markets. There has also been significant differentiation in products supplied.

Effective controls on parallel trade are necessary to attain effective differential pricing. Without limits, low-priced drugs supplied to LDC markets would flow back, by operation of arbitrageurs, into high priced markets. This would undercut the economic returns in the high priced markets and starve LDCs of their supply. Thus, at least within the drug sector, TRIPS formal neutrality as applied to parallel trade cannot stand.

The European Union ("EU") and the United States have non-IP restrictions that sharply reduce the likelihood of parallel trade in pharmaceuticals.

The observed positional shift in TRIPS from "neutrality" on parallel trade to opposition may well spill over from the HIV/AIDS pharmaceuticals context into a larger rethinking of the appropriateness of IP-holders engaging in price discrimination.

## 1. INTRODUCTION

The December 2005 amendment<sup>1</sup> of the TRIPS Agreement<sup>2</sup> and the debate among the WTO members that led to the amendment, at the very least, constitute a significant shift in TRIPS' declared "neutrality" as to the exhaustion of intellectual property rights with respect to pharmaceuticals. TRIPS now rejects exhaustion in this context. The political accord struck on the provision of patented pharmaceuticals to WTO members suffering public health emergencies will necessarily require price discrimination in order to be effective. While the amendment facilitates the issuance of compulsory licenses, the emerging reality is that the threat of compulsory licenses has helped persuade IP holders to provide needed pharmaceuticals at low prices. The solution is one of differential prices—that is, price discrimination. Low prices should be set in the LDCs facing the AIDS crisis while high prices should be maintained in developed markets in order to underwrite the cost of developing these drugs.<sup>3</sup> The segmentation of these national markets should be implemented through a variety of techniques that implicate various areas of WTO law, including IP-based import exclusions and other exclusions.

The WTO regime has demonstrated a strange ambivalence towards market segmentation and the use of price discrimination. On the one hand, a world of free trade, established through the

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<sup>1</sup> See WTO General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 6, 2005) (amending TRIPS by inserting a new Article 31*bis* after Article 31 of TRIPS, and inserting the Annex after Article 73 of TRIPS). New Article 31*bis* will make permanent the waiver that had been established with respect to article 31(f) of TRIPS. This new rule will permit compulsory manufacturing licenses in third countries in order to service the afflicted markets that lack the capacity to locally manufacture pharmaceuticals.

<sup>2</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS].

<sup>3</sup> One can imagine other solutions. The pharmaceutical industry at one time advanced the solution of global high prices, subsidized through financial assistance offered by wealthy states to those nations challenged by the AIDS pandemic. Workshop on Differential Pricing and Financing of Essential Drugs Convened by the World Health Organization and World Trade Organization Secretariats, Apr. 8–11, 2001, *Report*, available at <http://whqlibdoc.who.int/hq/2001/a73725.pdf>. Such a solution would have certainly resulted in more revenue, and hence higher return on investment, for the pharmaceutical companies. It would also have constituted a wealth transfer from prosperous states to profitable business enterprises with the added "feel-good" benefit of facilitating the provision of needed drugs.

eradication of trade barriers, anticipates the establishment of single global prices for most goods. The WTO's permissive stance towards anti-dumping laws may be read to evidence a policy preference against price discrimination between national markets. Note that antidumping law rejects price discrimination asymmetrically; only price discrimination involving lower prices in the export market is disciplined. Presumably, lower prices in the home market may be addressed by internal competition law (antitrust law) provisions on price discrimination, such as the U.S. Robinson-Patman Act.<sup>4</sup> Yet the WTO agreements, and particularly the TRIPS Agreement, countenance the maintenance of trade restrictions using intellectual property rights.

Holders of intellectual property rights can often effectively isolate national markets and foster price discrimination. By exercising the exclusive right to sell, an IP-holder can effectively eliminate intra-brand competition sourced in foreign markets where lower prices prevail, thus maintaining price discrimination. Price discrimination maximizes return to the IP-holder, as it permits more effective capture of consumer surplus in the national markets where demand is strong. The resulting market segmentation has economic, political, and social consequences. This phenomenon was addressed in European Union jurisprudence involving the EU's internal markets. In a series of cases, the European Court of Justice struck down the exercise of national IP rights that had the effect of isolating national territories and so permitting price discrimination within the EU's single market.<sup>5</sup>

TRIPS has, until recently, displayed a "neutral" position with respect to price discrimination effected by the use of intellectual property rights. Article 6 famously provides that "nothing in . . . [the TRIPS] Agreement shall be used to address the issue of the exhaustion of intellectual property rights."<sup>6</sup> This has been understood as a permissive policy with respect to import exclusion of IP-protected goods: each WTO member may decide for itself (as a matter of its internal IP law) whether a holder of an IP right may block the sale or importation of an IP-protected good that was produced by or under the authority of that IP right holder. Where no such right to block imports is recognized, the WTO member is said to practice "exhaustion." The IP rights established under national

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<sup>4</sup> Robinson-Patman Act of 1936, 15 U.S.C. § 13 (2000).

<sup>5</sup> See discussion *infra* Section 2.2.

<sup>6</sup> TRIPS art. 6.

law are “exhausted” by the IP holder’s placing of the goods onto their market of origin. Where an IP-holder is permitted to block the importation of such goods, the IP right is said to not be “exhausted” by its prior commercialization in another territory. Of course, all states practice “exhaustion” with respect to original sales made within their respective territories; absent an express contractual undertaking, IP-holders cannot restrict the right of a vendee to sell a good to another.

TRIPS does grant an IP-holder a general right to prevent importation of goods embodying that IP right. For example, TRIPS Article 28(1)(a) makes explicit that a patent shall confer on its owner the exclusive right to prevent third parties lacking the owner’s consent from importing that product for the purpose of “making, using, offering for sale, [or] selling” it. A footnote to Article 28 reminds the reader that the import exclusion right “is subject to the provisions of Article 6.” This in turn clarifies that an explicit import exclusion right need not apply to goods originally placed in commerce in other states. That is, despite recurring arguments to the contrary<sup>7</sup>, Article 28 did not settle, as a matter of WTO law, the parallel trade debate by excluding the possibility of national adoption of international exhaustion.<sup>8</sup>

The HIV/AIDS pharmaceutical controversy has altered the balance struck in TRIPS. The debate has centered around the legitimacy under TRIPS of compulsory manufacturing licenses in states with vibrant generic drugs sectors (such as Brazil and India) that would be used to service those WTO members lacking the technological and structural capacities to produce the needed drugs themselves. The effective resolution of that dispute presumes the maintenance of effective price discrimination.

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<sup>7</sup> The United States has at times asserted that the import exclusion right mandated by TRIPS article 28(1)(a) means that patent holders must have the right to block parallel trade. TRIPS art. 28. The U.S. Patent Act, 35 U.S.C. § 271(a) (2000), grants U.S. patent holders a right to block infringing imports: “[W]hoever *without authority* makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” *Id.* (emphasis added). *Jazz Photo* holds that the right to block imports extends to parallel trade. See discussion *infra* Section 2.3.

<sup>8</sup> See Case C-355/96, *Silhouette Int’l GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, 1998 E.C.R. I-4799 (depicting the European Court of Justice’s examination of EU trademark law and their conclusion that international exhaustion was a mandatory exclusion).

Compulsory licenses for HIV/AIDS drugs, including those for export, are now clearly permitted by TRIPS. Yet there has been no significant movement towards the use of compulsory licenses since the provisional adoption of this new rule just prior to the Cancún ministerial in August 2003. During this same period, the cost of anti-AIDS treatment in many LDCs has fallen precipitously. While the existence of a link is not clear from doubt, it may be fair to surmise that the potential compulsory licenses have posed a sufficiently credible threat that has induced pharmaceutical patentees to provide drugs at much lower prices than they had earlier been disposed to offer—and at lower prices than these same drugs command in other markets.<sup>9</sup>

The willingness of the pharmaceutical industry to distribute drugs at low cost, however, depends on its confidence that these drugs will not filter back into high priced markets. This article will discuss the embrace of differential pricing—or price discrimination—by TRIPS in the pharmaceutical sector and its possible extension to other goods embodying IP rights. A world of price discrimination featuring segmented national markets is hardly the original vision of the founders of the GATT or the WTO.

### 1.1. *The HIV/AIDS Crisis and the December 2005 TRIPS Amendment*

The AIDS pandemic was already in full crisis by the time of the conclusion of the Uruguay Round. Notwithstanding this, advanced countries (led by the United States) obtained the commitment of the eventual WTO membership to mandate universal patent protection “without regard to [the] field of technology.”<sup>10</sup> This last provision was included to make clear that WTO members could not categorically exclude pharmaceuticals from patent protection (as many countries had in fact done prior to the establishment of the WTO). The universal extension of IP protection and its application to pharmaceuticals represented a negotiating victory for the North. In turn, the developing world presumably won compensating access to Northern textile and agriculture markets as

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<sup>9</sup> There may be other factors in play which account for or contribute to the observed fall in prices. Patented anti-AIDS drugs compete with patent-free generic alternatives. JULIAN MORRIS ET AL., *IDEAL MATTER: GLOBALISATION AND THE INTELLECTUAL PROPERTY DEBATE* 7 (2002).

<sup>10</sup> See, e.g., TRIPS art. 27; Anthony Prenol, *WTO Panel Rules on Regulatory Review and Stockpiling Exceptions in Patent Act*, *BLAKES INTELL. PROP. BULL.*, July/Aug. 2000, [http://www.blakes.com/english/publications/brip/article.asp?A\\_ID=120&DB=blakesProperty](http://www.blakes.com/english/publications/brip/article.asp?A_ID=120&DB=blakesProperty).



part of the Uruguay Round's "grand bargain." Moreover, the TRIPS mandate to concede patent rights was subject to phase-ins for countries classified as developing and least-developed.

TRIPS requires that all WTO members provide patent protection for a minimum of twenty-years, subject to the phase-ins for developing and least-developed countries. Compulsory licensing is permitted by TRIPS, but is subject to significant limitations. A WTO member may authorize a compulsory license (a license to a third-party to produce or market a patented product such as a pharmaceutical without the consent of the patent holder) according to the terms of TRIPS Article 31. Under ordinary conditions, the WTO member is required to first negotiate with the patent holder for the provision of the patented product on commercial terms.<sup>11</sup> A compulsory license may issue only upon the failure of such negotiations unless there is a state of emergency – in which case the requirement of prior negotiation is suspended. The patent holder is entitled to compensation in the event of a compulsory license. The scope and the duration of the license shall be limited to the purpose for which it was authorized.

The scheme provided in TRIPS Article 31 is also flawed with regard to a number of unclear notions, which have created tensions regarding when and how compulsory licensing may be applied. For example, it is unclear:

- (1) when a situation of national emergency may be invoked;
- (2) how much effort must be exerted to reach a voluntary agreement with the patent holder before a failure has been established;
- (3) what royalty compensation must be awarded to the rights-holder; and
- (4) whether LDCs with no production capacity may rely on importation to supply their markets.

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<sup>11</sup> TRIPS starts with the assumption that the importing country shall first approach the rights-holder. Only if an agreement cannot be reached on commercially reasonable terms may the importer approach others. See, e.g., Stephanie A. Barbosa, Note, *Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals*, 36 RUTGERS L.J. 205, 258 (2005) (suggesting that there are reasons to allow the rights-holder a second bite at the apple; specifically, once the importer has made a tentative agreement with a third party, the rights-holder could be offered a right to supply on the same terms and conditions offered by the third party). It would not only be fair to the rights-holder, but it may also be in the interest of the buyer to have access to an approved product, which is produced according to established high safety standards, rather than a product that is merely less expensive.

Under TRIPS, the resolution of many of these uncertainties is in the hands of the importing country. As long as it follows the TRIPS procedure, the importing country can make the final determination itself.<sup>12</sup>

There can be little doubt that least-developed and developing countries most affected by epidemic diseases are in an emergency situation under TRIPS Article 31 and that they are fully entitled to use the system of compulsory licensing.<sup>13</sup> That, however, has not been sufficient to permit a supply of needed pharmaceuticals. A real problem is that most such countries lack the know-how, education and technology to produce the essential medicines required.<sup>14</sup> In addition, national infrastructures are oftentimes insuf-

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<sup>12</sup> *But see* Press Release, World Trade Org. News, The General Council Chairperson's statement (Aug. 30, 2003) ("Any Member may bring any matter related to the interpretation or implementation of the Decision . . . to the TRIPS Council for expeditious review, with a view to take appropriate action.") available at [http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm) [hereinafter General Council Chairperson's Statement]; Barbosa, *supra* note 11, at 249 (arguing that a special WTO committee should be set up to oversee the proposed action in order to establish that the proposed activity is optimal and that no equally good generic alternatives exist). The Chairperson's statement may reduce the control of the importing state.

<sup>13</sup> The European Communities ("EC") and their Member States circulated a position paper to WTO members on this subject. Section 12 states:

The view of the EC and their member States is that the absence of any explicit reference to public health in Article 31 does not prevent WTO Members from invoking public health concerns. Article 7 ('Objectives') refers to 'social and economic welfare' as an objective of the Agreement while Article 8 ('Principles') allows Members to take measures necessary to protect public health, provided such measures are consistent with the provisions of the Agreement. Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by Members to meet health objectives.

Communication from the European Communities and Their Member States to the Council for Trade-Related Aspects of Intellectual Property Rights (June 12, 2001), available at [http://www.wto.org/English/tratop\\_e/trips\\_e/paper\\_eu\\_w280\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/paper_eu_w280_e.htm) [hereinafter TRIPS Communication].

<sup>14</sup> A different stance is presented in a position paper submitted to the TRIPS Council by the Developing Country Group ("DCG"). Developing Country Group, *TRIPS and Public Health* (June 19, 2001) [hereinafter DCG position paper], available at [http://www.wto.org/English/tratop\\_e/trips\\_e/paper\\_develop\\_w296\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/paper_develop_w296_e.htm). The DCG, consisting of the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, places the protection and enforcement of IP rights in the context of the interests of society. *Id.* The group claims that "[l]ocal manufacturing of pharmaceutical products also encourages sustainable access to medications by insulating the price of patented

ficient to distribute medicines to larger groups of the population, even when they have access to the essential drugs. Transfer of know-how and technology from the industrialized world is required, but such development is long-term and the needs are immediate. The shortcomings of TRIPS were obvious. In 2001, WTO members recognized the gravity of the health problems affecting many developing and least-developed countries at the Ministerial Conference meeting in Doha. The Doha Declaration affirmed that the TRIPS Agreement "can and should be interpreted in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."<sup>15</sup> Thus, WTO members could both freely grant compulsory licenses and decide on the grounds for their issue. In order to provide relief for countries with no production capacity in the pharmaceutical sector, Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution before the end of 2002.<sup>16</sup>

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medicines against currency devaluations, as well as supporting the development of local expertise, which is vital in addressing local needs." *Id.* In other words, the DCG takes the stance that the mere recognition of IP rights encourages transfer of technology and know-how by encouraging domestic production of pharmaceutical products. Accordingly, the group supports compulsory licensing as a means of ensuring transfer and dissemination of technology in the case of market failure. *Id.*

The DCG also reads Article 8.2 of TRIPS, which prevents the abuse of IP rights and practices that unreasonably restrict or negatively impact trade and technology transfer, as permitting developing countries to take action where patent rights are exercised in ways that conflict with public health policies. Such instances include patent holders pricing drugs excessively beyond reasonable profit margins, and therefore effectively stymieing access to medication, or patent holders refusing to provide products in sufficient amounts. *Id.*

<sup>15</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

<sup>16</sup> See *id.* ("We recognize 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."). A subsequent WHO/WTO report concluded that this "landmark" declaration "demonstrates that a rules-based trading system is compatible with public health interests. The careful and systematic attention which WTO Members afforded to fine-tuning the balance that needs to be found in the intellectual property system is indicative of the prominence accorded to public health on the international trade agenda." World Health Organization & the World Trade Organization, *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat* 111 (2002), available at [http://www.who.int/media/homepage/en/who\\_wto\\_e.pdf](http://www.who.int/media/homepage/en/who_wto_e.pdf) [hereinafter WTO Study].

In spite of the clear language of the Doha Declaration,<sup>17</sup> finding a solution to secure access to medicines turned out to be a difficult task.<sup>18</sup> Countries were acting in their own self-interest either because they felt essential values were at stake (as with the United States)<sup>19</sup> or because they saw opportunities for domestic industry to expand into new fields (India and Brazil).<sup>20</sup> The U.S. position was to limit the types of products that would be available for compulsory licensing to medicines that combat epidemic diseases and to reduce the number of countries that would be eligible as both importers and exporters of these products.<sup>21</sup> The European Union advanced a compromise solution.<sup>22</sup> The December 2002 deadline passed without any agreement being reached.<sup>23</sup> It was not until

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<sup>17</sup> The Doha Declaration is an interpretative statement by the organization. It does not amend or change the TRIPS Agreement, but still serves as a persuasive authority.

<sup>18</sup> See Hans Henrik Lidgard, *Internationell handel med patentskyddade läkemedel*, NORDISK IMMATERIELLT RÄTTSSKYDD [N.I.R.] 2004:1 (Nor.).

<sup>19</sup> See EUROPEAN COMMISSION, DEVELOPING COUNTRIES AND ACCESS TO MEDICINES: HOW DID WE GET HERE?, [http://www.ec.europa.eu/trade/issues/global/medecine/argu\\_en.htm](http://www.ec.europa.eu/trade/issues/global/medecine/argu_en.htm) (last visited Dec. 7, 2006) (accusing the United States, Australia, Canada, Japan, and Switzerland on the grounds that "their unambitious draft underscores their reluctance to do anything substantial and serious at [this] stage").

<sup>20</sup> See generally Daniel Pruzin, *Brazil Offers Compromise to Break TRIPs/Medicines Deadlock in WTO*, 20 INT'L TRADE REP. (BNA) 339 (2003) (proposing to set new disciplines on domestic manufacturing capacity, and to defer to the WHO's decision-making authority on the issue of whether a country qualifies for the use of new compulsory licensing rules).

<sup>21</sup> See Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the Trade Agreement and Public Health*, IP/C/W/358 (July 9, 2002), ("[I]t currently would be inconsistent with Article 31(f) [regarding patented pharmaceutical products] for that WTO Member to grant a compulsory licence to its manufacturer to produce the drug solely for export to the country that has insufficient or no manufacturing capacities in the pharmaceutical sector.").

<sup>22</sup> See TRIPS Communication, *supra* note 13 (indicating that another possible interpretation of the Agreement is to allow a Member to issue a compulsory licence to a manufacturer in another country (provided the government of that other country recognized the licence) and the goods manufactured were exported to the country granting the licence). The EU made the observation "that it is far from certain whether such a 'permissive' reading of the Agreement would stand scrutiny by a panel or the Appellate Body." *Id.* ¶ 13.

<sup>23</sup> See, e.g., Pascal Lamy, E.C. Trade Comm'r, Address to the Association of Pharmaceutical Industry Managers: International Trade in Drugs—It's Role in Equitable Development (Mar. 21, 2003), available at [http://ec.europa.eu/archives/commission\\_1999\\_2004/lamy/speeches\\_articles/spla162\\_en.htm](http://ec.europa.eu/archives/commission_1999_2004/lamy/speeches_articles/spla162_en.htm) (last visited Dec. 7, 2006) [hereinafter Pharmaceutical Address] (singling out the United States as the sole country refusing to join the consensus on the grounds that it wanted to restrict the mechanism to HIV/AIDS, malaria, and tuberculosis).

August 30, 2003, that the TRIPS Council was finally able to reach a decision<sup>24</sup> (the “August 30 Agreement”) shortly before the Cancún Ministerial Conference.<sup>25</sup> The August 30 Agreement is somewhat of a compromise. The Agreement itself only refers to pharmaceutical products needed to address a public health problem with a reference to the Doha Declaration.<sup>26</sup> The statement of the chairperson,<sup>27</sup> which is attached to the decision, adds that the decision should be used in good faith to protect public health and should not be an instrument to pursue industrial or commercial policy objectives. It applies not only to formulated pharmaceuticals produced and supplied under the system, but also to active ingredients and to finished products produced using such active ingredients. The right to use compulsory licensing is not limited to least-developed countries, but can be invoked by others as well. The difference is that an emergency situation is presumed in the least-developed countries, whereas others have to show that such problems exist.

The chairperson’s statement further clarifies that a number of WTO Members will not avail themselves of the opportunity to import products under compulsory licensing or will only do it in emergency situations. As the statement is appended to the decision, it carries at best interpretive weight—the question remains as to how much.<sup>28</sup>

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<sup>24</sup> See generally Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003), [http://docsonline.wto.org/GEN\\_searchResult.asp](http://docsonline.wto.org/GEN_searchResult.asp) [hereinafter August 30<sup>th</sup> Agreement] (detailing the obligations and process for compulsory licensing of pharmaceutical products by export countries).

<sup>25</sup> See World Trade Organization, Ministerial Statement of 14 September 2003, WT/MIN(03)/20 (2003) (memorializing the progress made toward compliance with the mandates of the Doha Declaration).

<sup>26</sup> See August 30<sup>th</sup> Agreement, *supra* note 24, ¶ 1 (“[P]harmaceutical product’ means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration.”).

<sup>27</sup> See Pharmaceutical Address, *supra* note 23 (“[O]ur goal is to provide cut-price drugs to the developing countries, not to undermine prices on the European markets.”).

<sup>28</sup> See Markus Nollf, *Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the Decision of the WTO Regarding Its Implementation: An “Expedient Solution”?*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 291, 300 n.22 (2004) (indicating that the chairman’s statement does not clarify whether any agreement made among the parties to the Vienna Convention would affect “the context for the purpose of the interpretation of a treaty”).

Under the August 30 Agreement, the requirement of domestic production in TRIPS Article 31(f) is waived on the following conditions:

The importing country must make an application to the WTO;

The compulsory license granted in the exporting country shall also be reported to the WTO and be limited to the amount necessary to meet the needs of the importing country;

Products shall furthermore be distinguishable through specific labelling and marking and information must be published on the internet.<sup>29</sup>

Accordingly, a combined reading of TRIPS Article 31 and the August 30 Agreement sets out a number of steps that must be carried out before a compulsory license may be granted. First, negotiations for a voluntary license on commercially reasonable terms must have failed. Only then can an application for a compulsory license be introduced to the WTO. In its application, the importing country must demonstrate an emergency situation and its own inability to produce the product locally. Also, the potential exporter must also seek a voluntary license and must obtain an approval from its national government. Royalties must be established and a distinguishable product produced and approved. These procedures must be repeated for each export transaction. Each step does not in itself present an insurmountable hurdle – but cumulatively they constitute a significant burden.<sup>30</sup>

The interests of the rights-holder shall be secured in the process. In line with the general requirements for compulsory licensing provided in TRIPS Article 30, the rights-holder shall receive ade-

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<sup>29</sup> See August 30<sup>th</sup> Agreement, *supra* note 24, ¶ 2. In an attachment to the statement made by the chair a “best practices guideline” for distinguishing products is initiated. The suggestive list also refers to the practice of prohibiting reexportation. See the General Council Chairperson’s Statement, *supra* note 12. The statement is regarded as an integral part of the Agreement and it specifies that the Agreement must not be an instrument to pursue industrial or commercial policy objectives and that several developed countries have opted out of benefiting from the Agreement as importers.

<sup>30</sup> See Anthony P. Valach, Jr., *TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries*, 4 CHI.-KENT J. INTELL. PROP. 156, 168 (2005).

quate compensation, but only from the country of exportation. In addition, it is expected that the importing country shall take reasonable measures to prevent trade diversion of the products and that other WTO Members shall take measures to prevent importation of such products.

In the August 30 Agreement it was stipulated that the agreement was provisional and should be replaced by an amendment of TRIPS. This revision was supposed to be undertaken within a six month period. Unfortunately, the matter was not addressed during the unsuccessful Cancún discussions that followed,<sup>31</sup> which was probably just as well.

The TRIPS Council held regular meetings on the issue. On June 16, 2004 the Chair reported that positions had not evolved and that work continued with the aim of having a proposal for the meeting in March 2005.<sup>32</sup> A special problem, which may have contributed to the delay, is how developing countries can secure access to technology and confidential data supplied by the rights-holder to national authorities. If TRIPS only grants protection to *new chemical entities*, there should be no need to protect a new dosage form or new use of a known product. Article 39.3 of TRIPS permits a national competent authority to rely on data in its possession to assess further applications relating to the same drug, since this would not imply any “unfair commercial use.” This right could, in principle, be extended to support developing countries.

In December 2005, the WTO membership determined to make the August 30 Agreement permanent by amending TRIPS. The mere fact of amendment is a seismic event fraught with risk<sup>33</sup>—as other political bargains could unravel as well. Moreover, definitive adoption of new TRIPS Article 31*bis* requires ratification in national legislatures throughout the WTO membership that may well provide opportunity for domestic interests with these and other WTO-related agendas to intervene.<sup>34</sup> All that said, ratification and

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<sup>31</sup> See *Cancún's Charming Outcome*, THE ECONOMIST, Sept. 20, 2003, at 13.

<sup>32</sup> TRIPS Council, Regular Meeting of 16 June 2004.

<sup>33</sup> See Marrakesh Agreement Establishing the World Trade Organization, art. X, Apr. 15, 1994, 33 I.L.M. 1144, 1149-51 (1994) (establishing the WTO amendment process).

<sup>34</sup> Article 31*bis* has been submitted to the WTO membership for acceptance. Adoption requires acceptance by two-thirds majority of the WTO membership. The provisional deadline for acceptance is December 1, 2007.

eventual incorporation of the new Article 31*bis* into TRIPS is expected.

## 2. PATENT-BASED LIMITS ON PARALLEL TRADE

### 2.1. Exhaustion

The high cost of medicines is more a consequence of high research and development costs than actual production and distribution costs. A new chemical entity appears on average to require an investment far exceeding \$100 million<sup>35</sup> and requires more than ten years of systematic development and testing before the final product can be commercialized.

Patent protection, which assures a period of exclusivity, is one essential incentive to the research-based pharmaceutical sector,<sup>36</sup> as

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The procedure for amending TRIPS is set forth in Article X of the Marrakesh Agreement Establishing the World Trade Organization. The Agreement authorizes a member or Council to submit a proposed amendment to the Ministerial Conference. The Ministerial Conference then decides by consensus whether to submit the proposed amendment to the WTO membership for acceptance, and whether the proposed amendment would "alter the rights and obligations of the Members" (unless the provisions of paragraphs 2, 5, or 6 apply). Unless it specifies a longer time period, the Ministerial Conference has 90 days to render its decision. If it reaches a consensus, it submits the proposed amendment to the WTO membership. If it fails to reach a consensus during that time, it then decides by a two-thirds majority whether to submit the proposed amendment to the members for acceptance. The proposed amendment is presumed to alter the rights and obligations of the members, unless the Ministerial Conference decides otherwise by a three-fourths majority.

The Ministerial Conference decided Article 31*bis* would alter the rights and obligations of the members. Therefore, paragraph 3 governs the procedure for acceptance. Accordingly, Article 31*bis* will take effect for the members that accept it upon acceptance by two-thirds of the WTO membership. Thereafter, it takes effect for each other member when that member accepts it. Finally, the Ministerial Conference may decide by a three-fourths majority that an amendment effective under paragraph 3 is "of such a nature that any Member which has not accepted it within a period specified . . . shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference."

<sup>35</sup> See Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107, 132 (1991) ("The average cost of [new chemical entity] development was estimated to be \$231 million in 1987 dollars . . ."). See also Press Release, Tufts Center for the Study of Drug Development, Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million (Nov. 30, 2001), <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=6>.

<sup>36</sup> See WTO Study, *supra* note 16, at 42-44 (discussing the effect of the patent system in promoting the invention, development and marketing of new drugs



the cost of imitation is low and it is relatively easy for free-riders to use the knowledge and data created by the original inventor.

In response to the massive investments made by the pharmaceutical industry, patent protection has gradually been strengthened. Protection is granted for the chemical composition, production methods, and the ensuing product, as well as different modes of application. The protection provided by an issued patent has also been prolonged, first by generally increasing patent protection to 20 years after filing and, subsequently, by granting extended protection for new chemical entities for supplementary periods.<sup>37</sup>

An important reason for introducing TRIPS was the pressure from the developed world to secure IP protection in developing countries. The intention was not primarily to satisfy the pharmaceutical industry, but increased protection would, of course, serve this end as well. The consequences of patent protection on the pricing of pharmaceuticals in developing countries have been the subject of economic debate. Scherer has concluded that countries with stringent patent protection have higher prices.<sup>38</sup> In general, there will be effects if developing countries introduce product patent protection for pharmaceuticals,<sup>39</sup> but these should not be exaggerated.<sup>40</sup>

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with further references confirming the importance of the patent system for the pharmaceutical research).

<sup>37</sup> See, e.g., Council Regulation 1768/92, 1992 O.J. (L 182) 1 (EC) (concerning the creation of a supplementary protection certificate for medicinal products). The United States and Japan have also introduced similar legislation.

<sup>38</sup> F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 112-14 (1993) (arguing that robust patent protection promotes greater profits since it reduces competition between drug producers).

<sup>39</sup> See CARSTEN FINK, HOW STRONGER PATENT PROTECTION IN INDIA MIGHT AFFECT THE BEHAVIOR OF TRANSNATIONAL PHARMACEUTICAL INDUSTRIES 1 (2000) ("The availability of close therapeutic substitute drugs that are not covered by patent rights can restrain prices and limit consumer welfare losses."); Pablo Challu, *The Consequences of Pharmaceutical Product Patenting*, 15 WORLD COMPETITION: L. & ECON. REV. 65 (1991) (estimating the total public cost that would be imposed on Argentina by the adoption of a patent system at over \$2 billion); and Jayashree Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement*, 23 WORLD ECON. 733, 747 (2000) ("[P]rices are likely to increase and welfare is likely to decrease, in moving from current market structure to patent monopoly.").

<sup>40</sup> See, e.g., HEINZ REDWOOD, NEW HORIZONS IN INDIA: THE CONSEQUENCES OF PHARMACEUTICAL PATENT PROTECTION (1994). According to this study, with or without patent protection a combination of price control, low purchasing power, reserve powers under pricing freedom, and therapeutic competition will allow a confident prediction that there will be no general price explosion in India. *Id* at 2-3.

The original manufacturers concentrate sales efforts on high priced countries where IP protection is available in order to capitalize on investments. Supply to low-priced countries could still be attractive at the margin, but the risk of product reexportation back to the high-priced market has been an industry deterrent.

The key question, then, is how the supply of essential medicines to developing countries can be increased. In principle, three legal alternatives are available:

(1) Most essential pharmaceutical products are not under patent protection and may already be produced without infringing any rights;

(2) Parallel trade in pharmaceuticals can be regulated in such a way to either allow or prevent international trade in IP-protected products. The issue is whether the international exhaustion principle or a more restrictive national or regional solution would better serve the interests of the developing world; and

(3) Rules on compulsory licensing can be designed in such a way as to allow production of IP protected products under specific conditions.

The patent protection for a pharmaceutical product lasts for a period of 20 years from the first filing. Of the 300 most essential medicines listed by the WHO, the absolute majority are outside patent protection and can be freely produced in developing countries or in the developed world and sold at competitive prices. The TRIPS agreement offers no protection for such products, nor does any national law. In fact, the expired patent will serve as an important recipe for the generic producer, who can thereby avoid major R&D costs. Still, generic production requires substantial know-how and sufficient investment to secure safe and reliable products.

The "off patent" situation may not apply to HIV/AIDS-medicines, which are a fairly recent development. They remain protected to a large extent and production and sale of such medicines will infringe IP rights for some years to come. It is, however, prudent to investigate countries in which patent protection has been awarded. Normally patents will only be sought in commercially desirable countries. It is probably not too bold an assumption that the rights-holder normally does not seek protection in the least-developed countries. Products could accordingly be free for production and sale in these countries if the technology and the infrastructure were available.

An important question has been the extent to which the patent protection covers non-commercial activities with pharmaceutical

products. In the United States, the Bolar exemption has applied, which allows companies to initiate trials with the product during the time of protection in order to release generic copies promptly upon expiry of patents.<sup>41</sup> The European position has been more ambivalent. Whereas Germany has allowed such experimentation<sup>42</sup>, other countries have been reluctant.<sup>43</sup>

In 1997, the EU pressured Canada under the WTO dispute settlement system to establish that exemptions for clinical trials and the stock-piling of commercial quantities of pharmaceutical products before patent expiration were in conflict with TRIPS.<sup>44</sup> Canada referred to TRIPS Article 30, which allows limited exceptions to patent protection in national law. In March 2000, the WTO dispute panel agreed that the Canadian law, which allowed clinical trials in anticipation of future marketing approvals, did not conflict with the TRIPS Agreement. However, the practice of producing and stockpiling the product before patent expiration was an unacceptable practice.

The combined effects of the above is that under most circumstances IP rights will not in themselves create an obstacle to securing competing products at low prices to either the developed or developing world. Other factors such as lack of education, basic technology, and general incentives will hinder capacity building efforts in the developing world.

One solution to the problem with protected pharmaceuticals could be to allow parallel trade in IP-protected products, which have been put on the market either by the rights-holder himself or with his consent. The converse solution would be to prohibit such

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<sup>41</sup> See *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (interpreting the experimental use exemption narrowly to "avoid a violation of the patent laws in the guise of a 'scientific inquiry'"). Shortly after this decision the Congress passed legislation, which exempts activities that are "reasonably related" to seeking FDA approval for a generic drug and thereby widened the scope of the exemptions. Pub. L. No. 98-147, § 202, 98 Stat. 1603 (1984), (codified as amended at 35 U.S.C. § 271(e)(1) (2000)).

<sup>42</sup> See, *Klinische Versuche (Clinical Trials) I*, Bundesgerichtshof [BGH] [Federal Court of Justice] 1997, 15 R.P.C. 623 (F.R.G.). (holding that experimentation with patented drugs is permitted before they are available generically).

<sup>43</sup> Compare, e.g., *Smith Kline & French Labs. Ltd. v. Evans Med. Ltd.*, 1 F.S.R. 513, 523-24 (Patents Ct. 1989) (U.K.) (holding that such experimentation of patented pharmaceutical products is not permissible).

<sup>44</sup> Request for Consultations by the European Communities, *Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/1 (Jan. 12, 1998) (arguing that Canada's patent protection laws violate their commitment to TRIPS).

trade and thereby allow original manufacturers to price discriminate and secure supply to the developing world at lower costs.<sup>45</sup>

A general international exhaustion principle would mean that exhaustion occurs when the rights-holder puts his product on the market anywhere in the world. Yet such a system would hardly increase availability of essential products in developing countries. The problem is not that there are cheap products in the world at large and expensive products in developing countries. Rather, it is that developing countries simply cannot afford the normal price the product commands.<sup>46</sup> If low-priced products were available in developing countries, it appears likely that they would be exported to developed countries where a premium price could be obtained. The principle would preempt developing countries of their needs.<sup>47</sup>

In order to perfect the conditions for differential pricing, developed markets must be isolated from developing markets. Intellectual property rights are only one legal premise for interdicting the importation (or reimportation) of low-price pharmaceuticals destined to AIDS-ravaged Third World markets. Yet these alternative premises, like exhaustion, are discretionary: countries may or may not make import-exclusion available to pharmaceutical producers. The signal advantage of using an import-exclusion right linked to intellectual property is that TRIPS can make the recognition of such a right mandatory with respect to the broad WTO membership. The outcome of the recent AIDS pharmaceutical debate is that international exhaustion may no longer be discretionary, but rather mandatory. That is, pharmaceutical producers should be given the legal right, through IP law or otherwise, to protect high-price markets from the threat of low-price pharmaceuticals intended for consumption in the developing world.

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<sup>45</sup> See Press Release, WTO, Experts: Affordable Medicines for Poor Countries are Feasible (Apr. 11, 2001), available at [http://www.wto.org/english/news\\_e/pres01\\_e/pr220\\_e.htm](http://www.wto.org/english/news_e/pres01_e/pr220_e.htm) (stating that price differentiation was the practical solution arrived at by a 2001 WTO expert meeting in Norway).

<sup>46</sup> But see Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the Permanent Mission of Brazil, TRIPS and Public Health*, IP/C/W/296 (June 29, 2001), (taking a different position and regarding parallel trade as "extremely relevant" for developing countries).

<sup>47</sup> See A. Bryan Baer, Note, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 128 (2001) ("Absent price controls, higher prices for pharmaceuticals in developing nations would be the necessary result of a new law allowing the parallel importation of pharmaceuticals.").

## 2.2. *The European Case*

The position of the European Union on parallel trade has developed in case law over three decades.<sup>48</sup> The Treaty of Rome did not cover IP other than to establish that the rules could be used to prevent the free movement of goods within the union under Article 30 of the European Community Treaty. In line with the exceptions in this stipulation, European case law has gradually established that national IP rights cannot be used to discriminate or create disguised restrictions to trade in the single market. Once a product has been lawfully put on the market anywhere in the Community, it is subject to free circulation, and any attached national IP right is extinguished. This judge-made rule<sup>49</sup> has subsequently been confirmed by legislative enactments both at the EU and national levels.<sup>50</sup>

Recently, the European focus has been on whether or not the exhaustion principle could be extended to the international field. Again, the European Court of Justice ("ECJ") has, in a range of

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<sup>48</sup> See THOMAS HAYS, *PARALLEL IMPORTATION UNDER EUROPEAN UNION LAW* (2004) (analyzing parallel importation in Europe by discussing the relevant common law); HANS HENRIK LIDGARD, *PARALLELLHANDEL - KONSUMTION AV IMMATERIALRÄTT I EUROPA OCH USA*, (2002); PETER OLIVER, *FREE MOVEMENT OF GOODS IN THE EUROPEAN COMMUNITY* (4th ed. 2003) (examining legislative and judicial developments concerning the provisions in the Treaty of Rome that prohibit quantitative restrictions on imports and exports among Member States).

<sup>49</sup> Compare, e.g., Case 434/85, *Allen & Hanburys Ltd. v. Generics (UK) Ltd.*, 1988 E.C.R. I-1245 (holding that a court of a Member State cannot issue an injunction prohibiting the importation of a product from another state even when such product is not covered by a parallel patent), Case 187/80, *Merck & Co. Inc., v. Stephar BV and Petrus Stephanus Exler*, 1981 E.C.R. I-2063 (extending the holding in *Centrafarm v. Sterling Drug Inc.* to situations where the patent holder's product has been marketed in another Member State where no patent protection exists), and Case 15/74, *Centrafarm v. Sterling Drug Inc.*, 1974 E.C.R. I-1147 (holding that the exercise of a national IPR is incompatible with the provisions in the European Economic Community Treaty regarding the free movement of goods within the Common Market once the patent holder's product has been marketed in another Member State by the patent holder, or with his consent), with *Joined Cases C-267 & C-268/95, Merck & Co. v. Primecrown Ltd., Beecham Group plc v. Europharm of Worthing Ltd.*, 1996 E.C.R. I-6285, 1997 C.M.L.R. 83 (1996) (finding an exception to the holding in *Merck v. Stephar BV* in cases where patent holder was obliged to market his product or where the product was subject to price control legislation).

<sup>50</sup> See, e.g., Council Directive 98/71, art. 15, 1998 O.J. (L 289) 33 (EU) (promulgating a regional exhaustion principle with regards to the legal protection of designs); Council Directive 89/104, art. 7, 1989 O.J. (L 40) 1 (EC), available at [www.wipo.org/clea/docs\\_new/pdf/en/eu/eu014en.pdf](http://www.wipo.org/clea/docs_new/pdf/en/eu/eu014en.pdf) (promulgating a regional exhaustion principle with regards to the legal protection of trademarks).

cases, taken a consistent view and confined the principle to internal application only.<sup>51</sup> Only when the physical product<sup>52</sup> has been put on the European market by the rights-holder or with his express consent, will exhaustion occur.<sup>53</sup> When there is doubt as to whether or not either of these circumstances exists, it is for the rights-holder to show that the relevant product is imported from a third country, and for the importer to prove that he has obtained the rights-holder's consent to the importation.<sup>54</sup>

Nothing prevents an original manufacturer from charging a high price in the European Union and a low price in a developing country. He would actually have an incentive to do so, as long as the price obtained in the latter would cover his marginal cost plus a slight contribution. The condition is that the producer must be confident that there will be no reimportation into the high-priced market. These rules on regional exhaustion have been firmly established despite opposition from a number of Member States.<sup>55</sup> However controversial this legal development may have been on

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<sup>51</sup> See Case C-355/96, *Silhouette Int'l Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, 1998 E.C.R. I-4799, I-4818 (holding that Member States are precluded from adopting the principle of international exhaustion).

<sup>52</sup> See Case C-173/98, *Sebago Inc. v. G-B Unic SA*, 1999 E.C.R. I-4103, I-4122 (holding that "the principal of exhaustion concerns only specific goods which have first been put on the market with the consent of the trade-mark proprietor.").

<sup>53</sup> See *Joined Cases C-414, C-415 & C-416/99, Zino Davidoff SA v. A & G Imports Ltd., Levi Strauss & Co. v. Tesco Stores Ltd, Levis Strauss & Co. v. Costco Wholesale UK Ltd.*, 2001 E.C.R. I-8691, I-8754 (holding that implied consent can be inferred, but only if it is expressed positively, and factors taken into consideration must demonstrate the proprietor's renunciation of intent to enforce his exclusive rights).

<sup>54</sup> See Case C-244/00, *Van Doren v. Lifestyle Sports*, 2003 E.C.R. I-3051, I-3093-94 (holding that where a third party establishes the existence of a real risk of "partitioning national markets" if he bears the burden of proof necessary to establish the existence of conditions for exhaustion, "it is for the proprietor of the [trademark] to establish that the products were initially placed [outside the European market] . . . and for the third party to prove the consent of the [trademark] proprietor . . ."); Council Directive 89/104, *supra* note 50, art. 7(1), ("[Trademark] shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market . . . under that [trademark] . . . with his consent.").

<sup>55</sup> See Press Release, Frederick Bolkestein, EU Comm'r, Communiqué from Commissioner Bolkestein on the Issue of Exhaustion of Trade Mark Rights, (June 7, 2000) [http://europa.eu.int/comm/internal\\_market/indprop/docs/tm/comexhaust\\_en.pdf](http://europa.eu.int/comm/internal_market/indprop/docs/tm/comexhaust_en.pdf) (recommending against a proposal to change to the Community-wide exhaustion regime).

the regional level, it actually forms a valuable base for the problems caused by infectious diseases in developing countries.<sup>56</sup>

That the EU has opted for regional exhaustion allows a rights-holder in the EU to prevent importation of products that have first been put on the market in a developing country. This allows pharmaceutical companies to price differentiate and charge lower prices in developing countries. Discriminatory as it may sound, this position has been reinforced by recent Community legislation. In Europe, the Commission shall, under Article 11 of Regulation 953, continuously monitor the volumes of exports from Europe of tiered priced products.<sup>57</sup> The monitoring is based on information provided by pharmaceutical manufacturers and exporters for each tiered priced product, which is to be submitted annually on a confidential basis. The Commission in turn shall periodically report to the Council. Although Regulation 953 has been in force for only a short time, considering the intense international debate on price differentiation, it might be expected that a report would have been made by now. However, this does not appear to be the case. In addition, the Commission has an obligation to revise the product annex of the Regulation every two months and appoint a special committee to support the Commission in the work under the Regulation. So far, however, only GlaxoSmithKline has been granted status for certain HIV medicines,<sup>58</sup> and there is no indication that the special committee has been appointed.

It is debatable to what extent a regulation was required to secure protection for rights-holders exporting products to developing countries. Currently, products destined for export to developing countries cannot be re-imported to the European Union by a third party without the consent of the right-holder. Likewise, customs legislation already provides relief for a rights-holder who is harmed by illegal importation of its products. Products should be stopped at the border in order to allow the rights-holder to take le-

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<sup>56</sup> Cf. Baer, *supra* note 48, at 134 ("While a law allowing for the parallel importation of drugs may bring benefits to U.S. consumers in the short term, in the long run, it could have severely negative consequences for consumers in poorer nations . . .").

<sup>57</sup> Council Regulation 953/2003, art. 11, To Avoid Trade Diversion into the European Union of Certain Key Medicines, 2003 O.J. (L 135) 5 (EC) [hereinafter Regulation 953].

<sup>58</sup> See List of Medicines for Which Protection Against Trade Diversion is Granted Under Regulation 953/2003, available at <http://trade-info.cec.eu.int/cgi-bin/antitradediversion/viewMedicines.pl?action=select> (last visited Dec. 7, 2006).

gal action. Accordingly, buying low priced pharmaceuticals in developing countries and bringing them back to the community is already prohibited. Sale of these drugs in Europe would often involve trademark infringement<sup>59</sup> and probably would also be in conflict with established rules for the distribution of pharmaceuticals.

Still, the Regulation makes perfect sense. It highlights a problem and reinforces a prohibition. There can be no doubt about the state of the law after the Regulation. The general public is made aware of the problem and enforcing authorities must be prepared to take action. Customs authorities can be expected to take proactive measures to prevent this importation and they will obtain precise and better information about potential infringements.

Regulation 953 is expressly intended to be in line with the WTO/TRIPS undertakings, even if it addresses a different aspect of the problem than what is achieved with compulsory licensing. The Regulation will allow the established industry to sell its products at low prices without fearing their reimportation to the developed world. As a result, the need for compulsory licenses under the August 30 Agreement should diminish.

### 2.3. *The Case of the United States*

U.S. rules on the international exhaustion of patents are not quite as clear as the rules in Europe. U.S. patent law unambiguously gives a patent holder the ability to block the patented product from entering the country.<sup>60</sup> This provision establishes a legal remedy to prohibit the importation of counterfeit or pirated or otherwise unauthorized goods, including generic pharmaceuticals produced in countries where no patent protection is in force or where they are produced pursuant to a compulsory license. As is noted above, many important medicines may be in the public domain, due either to expiry of patents or because they were never covered by patents in the relevant market of production. Any fears that a U.S. pharmaceutical patent holder may have with respect to the existence of generics are price effects in export markets; the patent law provides ample protections to prevent generics from reaching the U.S. market and destroying the patent monopoly.

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<sup>59</sup> See discussion of *Silhouette*, *supra* note 52.

<sup>60</sup> 35 U.S.C. § 271(a) (2000).



U.S. law is more ambiguous with respect to products produced by the patent holder or one of its affiliates. There are two fact patterns of concern here. In the first, patented products are manufactured in the United States and then exported. If there are price differentials between the U.S. and export markets, there may be incentives for parallel traders to reimport the patented product into the United States. This is the so-called "round trip" scenario.

The second scenario involves the production outside the United States of the patented product, either by an affiliate of the U.S. patent holder or by a manufacturing licensee. Note that the U.S. patent holder may well be a non-U.S. entity; major European and Japanese pharmaceutical firms own valuable U.S. patents and enjoy profitable returns from their access to the U.S. market. In this scenario there is often significant U.S. production intended to service the U.S. market. The presence of an identical imported product creates a quintessential "gray market" where U.S. prices are higher (as they typically are in pharmaceuticals) than are prices where the foreign product is sold.

There is no clear case law covering these two scenarios. The U.S. Supreme Court has issued several important decisions on the use of copyrights and trademarks to combat parallel trade, but because each form of intellectual property right in the United States depends on distinct statutory foundations, it is unclear how predictive the holdings in these cases can be with respect to the potential exhaustion of patents.

The 1998 copyright case, *Quality King Distributors, Inc. v. L'anza Research International*,<sup>61</sup> found that a U.S. copyright holder may not block reimportation, in a round-trip scenario, of copyrighted expression that was "lawfully made under [the Copyright Act],"<sup>62</sup> that is, copyrighted product created in the United States. However, the court suggests that in the more typical "gray market" scenario, where copies are produced outside the United States, a right

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<sup>61</sup> *Quality King Distribs., Inc. v. L'Anza Research Int'l, Inc.*, 523 U.S. 135 (1998). For further discussion of *Quality King*, see Janice Mueller & Jeffery Atik, *New International Dimensions in the Gray Market Goods Debate*, 1 JMLS CENTER FOR INTELL. PROP. L. NEWS SOURCE 6 (1999).

<sup>62</sup> See also 17 U.S.C. § 109(a) (1999) ("Notwithstanding the provisions of section 106(3), the owner of a particular copy or phonorecord lawfully made under this title, or any person authorized by such owner, is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord . . .").

to block imports might be obtained.<sup>63</sup> *Quality King* is based on a close reading of the Copyright Act, which specifically incorporates the “first sale doctrine” – the U.S. correspondent to the exhaustion principle. The Patent Act, however, has a markedly different statutory structure than the Copyright Act. Indeed, there is no expressed “first sale doctrine” in the text of the Patent Act (the “first sale doctrine” is rather a creature of judicial decision in U.S. patent law). As such, one cannot predict that the courts would follow the reasoning of *Quality King* in examining similar questions under U.S. patent law.

In contrast with copyright law, where there is likely no exhaustion occasioned by a first sale outside the United States of copies made outside the United States, U.S. trademark law appears to embrace international exhaustion, at least when the foreign manufactured goods are produced by an affiliate of the trademark owner. In its 1988 trademark decision, *K Mart Corp. v. Cartier, Inc.*,<sup>64</sup> the U.S. Supreme Court upheld a long-standing Customs regulation that exempted from import prohibition goods bearing a U.S. trademark that were produced by a firm under “common control” with the U.S. trademark owner. Thus, where a U.S. firm produces a trademarked product outside the United States, it may not use its trademark to block importation. Nor may a foreign firm incorporate a U.S. distribution subsidiary, transfer the U.S. trademark to the subsidiary, and then use the U.S. trademark to block parallel importation of its products. However, off-shore sales of foreign manufactured trademarked goods produced by a third-party licensee do not exhaust the U.S. trademark and may be blocked. And, in an important qualification to the *K Mart* holding, where the foreign-produced trademarked good is different in a technical way from the competing U.S. good, the foreign good may be prohibited under a traditional consumer disappointment theory.<sup>65</sup>

Round-trip importation of trademarked goods is unproblematic under U.S. trademark law. The portion of U.S. trademark law

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<sup>63</sup> See *Quality King*, 523 U.S. at 155 (Ginsburg, J., concurring) (observing that the Court’s decision did not address cases in which the products in question were foreign-produced).

<sup>64</sup> *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988).

<sup>65</sup> See *Lever Brothers Co. v. United States*, 981 F.2d 1330 (D.C. Cir. 1993) (holding Section 42 of the Lanham Act, 15 U.S.C. § 1124, bars foreign goods bearing a trademark identical to a valid U.S. trademark but physically different without regard to affiliation between the producing firms).

establishing a right of trademark owners to control importation (the Genuine Goods Exclusion Act<sup>66</sup>) only covers “merchandise of foreign manufacture.” In the case of round-trip trade, the goods are *ipso facto* of American manufacture and as such are not subject to the statute’s reach.

Thus, in the “round trip” scenario, neither copyright nor trademark law can be used to block importation. With respect to parallel trade of goods produced outside the United States, copyright seems to permit exclusion, while trademark would allow importation in the common instance where the trademark owner is under “common control” with the manufacturer of the trademarked good. In this “gray market” scenario one might observe that U.S. copyright law provides for national exhaustion (via the first sale doctrine), but not international exhaustion; whereas U.S. trademark principles seem to admit international exhaustion as well as national exhaustion in the common-control situation.

As discussed above, the treatment of patent law on this subject is less clear given the absence of an authoritative clarification by the Supreme Court. There is clearly national exhaustion of patents: an owner of a patented good purchased in the United States is free to re-sell the good, free of any claim by the patent holder. However, the “first-sale doctrine” in U.S. patent law is a court-created gloss;<sup>67</sup> there is no statutory exception to a U.S. patent holder’s basic right “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . .”<sup>68</sup> Because the “first-sale doctrine” is without statutory grounding, it is difficult to resolve whether the doctrine operates merely as an exception to the exclusive right to sell, or whether it also embraces the exclusive right to

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<sup>66</sup> See 19 U.S.C. § 1526(a) (2000). The law prohibits the importation into the United States any merchandise of foreign manufacture if such merchandise . . . bears a trademark owned by a citizen of, or by a corporation or association created or organized within, the United States, and registered in the Patent and Trademark Office by a person domiciled in the United States . . . , unless written consent of the owner of such trademark is produced at the time of making entry.

*Id.*

<sup>67</sup> *Adams v. Burke*, 84 U.S. 453, 457 (17 Wall. 1873); *United States v. Unis Lens Co.*, 316 U.S. 241 (1942) (explaining that when a patentee sells chattel article passes without the limit[s] of the monopoly). See PRINCIPLES OF PATENT LAW - CASES AND MATERIALS 1118-41 (Chisum et al. eds., 2d ed. 2001); see also JANICE MUELLER, AN INTRODUCTION TO PATENT LAW 362-63 (2003).

<sup>68</sup> 35 U.S.C. § 154 (2000).

import. Whether exists international exhaustion of the U.S. patent depends on whether the import exclusion right is subject to a "first-sale." There would then be subsequent inquiries into whether relevant that the first sale occurred in the United States or abroad; and further, whether it is relevant that the patent holder, its affiliate, or a third-party licensee manufactures the patented product. On all these points, there is considerable uncertainty.

It had long been thought that international exhaustion applied with respect to U.S. patents. In *Curtiss Aeroplane & Motor Corp. v. United Aircraft Engineering Corp.*, the Second Circuit held that a U.S. patent holder could not impede the importation of airplanes produced in Canada by the assignee of Canadian patent rights.<sup>69</sup> In so holding, the Second Circuit relied on the old case, *Adams v. Burke*,<sup>70</sup> which held that a purchaser of a patented item takes possession of the item clear of any territorial limits of the patent monopoly.

The Federal Circuit recently cast doubt on the *Curtiss* view that U.S. patents are subject to international exhaustion. In *Jazz Photo Corp. v. International Trade Commission*,<sup>71</sup> the Federal Circuit made clear that exhaustion applies only to goods first sold in the United States; goods first sold outside the United States are still subject to the patent holder's right to exclude. The language in *Jazz Photo* is fairly emphatic: "United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent."<sup>72</sup>

*Jazz Photo* addresses the repair/reconstruction distinction with respect to patented single-use cameras. The Federal Circuit held that the patentee could not block the importation of single-use cameras that had been first sold within the United States and then "repaired" (and thus restored to usefulness) outside the United States—i.e., cameras making a round-trip. The portion of the decision discussed above addressed the case of any "repaired" camera

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<sup>69</sup> *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*, 266 F. 71, 78 (2d Cir. 1920) ("The purchaser of a patented article from a territorial licensee . . . may, unless there is a specific agreement to the contrary, use the article so purchased outside of the territory without interference from the patentee.").

<sup>70</sup> *Adams v. Burke*, 84 U.S. 453, 457 (17 Wall. 1873) ("[W]e hold that in the class of machines or implements we have described, when they are once lawfully made and sold, there is no restriction on their *use* to be implied for the benefit of the patentee . . .").

<sup>71</sup> *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001).

<sup>72</sup> *Id.* at 1105.

shells that had never been sold in the United States. Because the vacated underlying ITC order seemed to not make any distinction between where the cameras were first sold, the views expressed above do not seem to form part of the core holding. Moreover, there is virtually no discussion (notwithstanding the self-assured tone of the court's statement that foreign sales do not exhaust U.S. patents) other than a citation to *Boesch v. Graff*, an opaque case involving goods produced and sold abroad, not by a patentee, but rather by a rival German manufacturer utilizing a prior use right. Additional opinions in the dispute, however, clarified that exhaustion only applied to those originating in the United States—as to foreign-sourced camera shells, the patent holder could block importation.<sup>73</sup>

### 3. NON-PATENT RESTRAINTS ON PARALLEL TRADE IN PHARMACEUTICALS

#### 3.1. European Restraints

In early 2001, the EC Commission issued a communication suggesting action in the form of a global tiered pricing system for essential pharmaceuticals. Products included in the communication were for the prevention, diagnosis, and treatment of HIV/AIDS, tuberculosis and malaria. The objective of this plan was to provide the least-developed countries with access to these medicines, yet avoid trade diversion of products back to the European market.

The Commission received prompt, full support for the proposed action, both from the Council and Parliament. Despite the urgency, however, it took two more years to enact binding regulation. The ongoing parallel discussion in WTO perhaps partly explains the delay, but equally plausible is the general lag in enacting final legislation in the Community.

On May 26, 2003 the Council issued Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines.<sup>74</sup> Regulation 953 became effective shortly thereafter, on June 4, 2003.

According to Regulation 953, a producer who is prepared to sell pharmaceuticals at a low price must differentiate the appear-

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<sup>73</sup> *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1376 (Fed. Cir. 2005).

<sup>74</sup> Regulation 953, *supra* note 57.

ance of these products from ordinary sales in order to make them identifiable for the customs authorities;<sup>75</sup> an application shall be made to the Commission to have the product included in a list of protected products; and the application shall indicate the name of the product, active ingredient and indications as to use, the price of the product, country of destination, customs nomenclature and distinguishing features.<sup>76</sup>

The Commission will promptly verify that the application is in conformity with the Regulation; a low price is of prime importance.<sup>77</sup> Article 3 of Regulation 953 provides two options for setting the price. It can either amount to 25% of the weighted average multiplied by the factory price charged in the Organisation for Economic Co-operation and Development markets, or the manufacturer's direct production costs plus 15%.<sup>78</sup> These percentages are established in separate annexes, suggesting that they may be subject to future review. If the manufacturer so prefers, he can provide a certificate issued by an approved auditor, establishing that the price corresponds to the Regulation.<sup>79</sup>

Regulation 953 is only valid for products related to the prevention, diagnosis, and treatment of HIV/AIDS, TB, and malaria. Annex IV adds "related opportunistic diseases," which presumably is not intended to extend the reach of the Regulation to other syndromes and especially not to prevailing life-style diseases presently attracting much attention in the Western world.<sup>80</sup> In line with the general practice of customs authorities, the Regulation does not apply to non-commercial goods contained in travellers' personal luggage for use within the limits laid down in respect of relief from customs duty. The limit is in the range of 150 euro.<sup>81</sup> Nothing in the Regulation indicates that protection should only be available

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<sup>75</sup> *Id.* at 5.

<sup>76</sup> *Id.* art. 4.

<sup>77</sup> *Id.* art. 4.

<sup>78</sup> *Id.* art. 3.

<sup>79</sup> *Id.* art. 4.

<sup>80</sup> *Id.* Annex IV.

<sup>81</sup> See Council Regulation 3295/94, Laying Down Measures to Prohibit the Release for Free Circulation, Export, Re-export, or Entry for a Suspensive Procedure of Counterfeit and Pirated Goods, 1994 O.J. (L 341) 8 (EC), amended by Council Regulation 241/1999, 1999 O.J. (L 27) 1 (EC) (setting out customs regulation whereby goods that infringe a patent or a supplementary protection certificate are included in the categories of goods subject to prohibition and action by customs authorities).

for products with an EU origin. It should, in a non-discriminatory fashion, also be available to third-country products, provided they are reported under the Regulation.

The country of destination must be one included in the list in Annex II of the Regulation. The list covers seventy-six poorer African, Latin American, and Asian countries. It includes, of course, not only the least-developed countries of the world, but also developing countries like India, China, and certain Russian republics.<sup>82</sup> Destination countries have the lowest per-capita income and are all countries where HIV/AIDS is particularly prevalent. The Commission has indicated that the number of countries may be extended at a later date.<sup>83</sup>

The product should be distinguished from ordinary high-priced products supplied in the developed world. Normally this will mean that the packaging must have a different appearance, but it also logically follows from the Regulation that the medicine have a different form or color in order to be easily distinguished from the ordinary product. In addition, the manufacturer shall mark the product with a logo, which has been designed specifically for purposes of the Regulation.<sup>84</sup> A photo of the product must be submitted together with the application.

The fundamental purpose of Regulation 953 is to secure that products, which have been sold at a significantly reduced price in developing countries, should not return to the European Union. Therefore, Article 2 provides that "(i)t shall be prohibited to import into the Community tiered priced products for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse."<sup>85</sup> The Regulation does not state the consequences of infringing the prohibition. The matter seems to be left to national law, unless future implementing provisions are enacted by the EC Commission.<sup>86</sup>

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<sup>82</sup> Regulation 953, *supra* note 57, Annex II.

<sup>83</sup> See Council Regulation 953/2003 Frequently Asked Questions, <http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl?action=faq> (last visited Dec. 7, 2006).

<sup>84</sup> Regulation 953, *supra* note 57, art. 7.

<sup>85</sup> *Id.*

<sup>86</sup> Implementing measures should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999, which lays down procedures for the exercise of implementing powers conferred on the Commission. 1987 O.J. (L 256) 1, amended by Commission Regulation 2176/2002/EC, 2002 O.J. (L 331) 3.

The Regulation appears as a *lex specialis*, but clearly indicates that it is not intended to interfere with intellectual property rights or the rights of intellectual property owners; nor shall it in any way prejudice the application of community legislation on proprietary medicines.<sup>87</sup>

Rather than contributing to potential infringements of intellectual property rights, the new legislation reinforces the rights of the proprietor in line with general EU developments on exhaustion of IPR, and yet has the intention to secure easier access to medicines for developing countries.

The question remains whether the legislation supports a solution to the HIV/AIDS crisis in developing countries or only supports IP right holders in the Community. Furthermore, it begs the question of whether these measures are in line with the subsequent WTO efforts to find a global solution to the supply of essential medicines in poor countries and whether the regulation is compatible with prevailing IP principles.

Under the regional principle, as discussed earlier, it could be argued that no further legislative measures were required. In situations where the rights-holder produces the product in the EU and thereafter exports and sells it to developing countries, the exhaustion principle would not be applicable and reimportation into the Community would be an infringement of existing IP rights. The rights-holder can require support from national customs authorities to prevent such products from being introduced into European commerce.

However, the Regulation explains that even if regulatory instruments are in place, "these instruments risk becoming insufficient where substantial volumes of heavily discounted pharmaceuticals are sold to the poorest developing country markets and the economic interest in trade diversion into high priced markets

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<sup>87</sup> According to Article 12 of the Regulation:

The application of this Regulation shall in no circumstances interfere with procedures laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001 O.J. (L 311) 67, amended by Directive 2002/98, 2003 O.J. (L 33) 30 (EC)] and Council Regulation 2309/93/EEC of 22 July 1993 laying down Community procedures for the authori[z]ation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993 O.J. (L 214) 1, amended by Commission Regulation 649/98, 1998 O.J. (L 88) 7 (EC)].

Regulation 953, *supra* note 57, art. 12.



therefore may increase significantly.”<sup>88</sup> Special measures were required to counteract the substantial economic interest that could otherwise be enticed.

Producers should always be encouraged to make products easily available at low prices and therefore Community law must ensure that exported products remain in the country of destination. Likewise, donated products and products sold under competitive tenders also qualify under the Regulation.<sup>89</sup>

The question remains – to what type of infringement would an importation of a protected product amount? Is it a regular crime, a breach of general customs legislation, or should it be regarded as an unlawful infringement of IP rights? Time will tell. If it is regarded as an infringement of IP rights, most national legislation includes imprisonment as a penalty for grave contraventions. Although rarely used, this remedy seems appropriate in this instance.

Exempted from the reimportation prohibition are: (a) re-export to countries of destination; and (b) placing the protected product “under a transit or customs warehouse procedure or in a free zone or free warehouse, for the purpose of re-export to a country of destination.”<sup>90</sup> These exemptions appear odd. It is unlikely that the original exporter sold the product to a developed country, and then someone else returned it to Europe with the intent to sell it to the original country of destination. Nor does it seem likely that the exemption is intended to protect products from third countries passing through the European Union. No explanatory memorandum sheds further light on this stipulation.

As with products infringing on IP rights, the primary control of tiered priced products will be carried out by the national customs authorities. The customs authorities shall suspend the release of, or detain, a potentially infringing product if there is sufficient information to consider the product in question a tiered priced product.<sup>91</sup>

Customs shall inform both the “competent authority” in the Member State and the manufacturer of the suspension or the detention of the product. This notion, too, is left to the Member States to substantiate. The Regulation only clarifies that the authority shall determine whether the relevant goods are tiered

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<sup>88</sup> *Id.* p.mbl., ¶ 6.

<sup>89</sup> *Id.* p.mbl.

<sup>90</sup> *Id.* art. 2(2).

<sup>91</sup> *Id.* art. 8.

priced products and gives instructions based on the outcome of the review.<sup>92</sup>

The absence of a specific definition could allow for the assumption that “competent authority” includes a court competent in customs matters; this again would make the procedure parallel with that of IP rights. On the other hand, the period of suspension or detention is very brief—normally it shall not exceed ten working days. This does not allow for any detailed legal scrutiny. The hastiness of the procedure suggests that the competent authority may be a governmental agency. If so, it appears imperative that the procedure still allow for ordinary legal activities in an IP infringement procedure. Should the rights-holder wish to instigate a civil procedure, he must be entitled to do so under ordinary rules and the Regulation cannot pre-empt this possibility. The Regulation provides that upon expiration of the ten-day period, the products shall be released, provided that all customs formalities have been satisfied.<sup>93</sup> The latter reference must open the way for ordinary civil procedures.

In contrast to the infringement procedure, which is normally carried out at the expense of the rights-holder, this procedure is carried out at the expense of the importer. The Regulation does not alter this fact in cases where the products are later released to the market, after scrutiny by the competent authority.<sup>94</sup>

If the products are tiered priced products, they shall be seized and disposed of in accordance with national legislation. Again, the procedure is carried out at the expense of the importer. Interestingly, the preamble mentions that seized products may be disposed of to the benefit of the developing countries should it be possible under national law, and only in the absence of such possibility should the products be destroyed.<sup>95</sup> This stipulation does not reappear in the operative part of the text and therefore has primarily a guiding force.

### *3.2. U.S. Restraints*

In the case of importation (or reimportation) of pharmaceuticals into the United States, the ambiguities in patent exhaustion

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.* art. 8(1).

<sup>94</sup> *Id.* art. 9.

<sup>95</sup> *Id.* pmb. ¶ 14.

may have limited relevance. The importation of pharmaceuticals is independently restricted by features of the U.S. pharmaceutical regulatory regime. All prescription pharmaceuticals that “move” in interstate commerce (which includes importation into the United States) must have a New Drug Application (“NDA”) approved by the Food and Drug Administration (“FDA”).<sup>96</sup> As NDAs apply to the source of a pharmaceutical (and involve manufacturing oversight), the existence of an NDA for a drug produced in the United States does not relieve the obligation to obtain an NDA for the identical drug produced in a foreign facility—whether by a generic producer, a compulsory licensee, or a third-party licensee of the U.S. patent holder.

The only situation where the absence of an NDA would not be problematic is in a true round-trip: a pharmaceutical produced in the United States under an NDA, exported for sale abroad, and then reimported. Even in this case, the importer may be asked to demonstrate that the imported pharmaceutical has not been adulterated or misbranded. After a spate of counterfeit importations in the 1980s, Congress amended the federal Food, Drug, and Cosmetic Act to prohibit the importation of prescription drugs made in the United States by anyone other than the manufacturer.<sup>97</sup> Under current law, therefore, only the manufacturer can lawfully complete a “round-trip” importation.

Thus, non-U.S.-origin pharmaceuticals are effectively prohibited without an NDA, except of course where the manufacturer reimports the good. There are no formal exceptions to these prohibitions, though as a matter of enforcement policy the FDA had permitted importation for personal use. This enforcement policy by its terms applies principally to pharmaceuticals treating conditions that have no effective treatment in the United States.<sup>98</sup> By implication then, any pharmaceutical available in the United States may not be imported under the personal use exception. Of course, the personal use exception is broader in practice than the FDA procedures suggest, as many U.S. senior citizens regularly visit pharmacies in Canada and Mexico and return to the United States with personal supplies of prescription drugs.

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<sup>96</sup> 21 U.S.C. §§ 331(d), 355(a) (2000)

<sup>97</sup> 21 U.S.C. § 381(d) (2000).

<sup>98</sup> See FDA Regulatory Procedures Manual, Ch. 9, available at [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html) (analyzing policies currently being reviewed).

Under current regulatory conditions, it is unlikely that significant parallel trade in pharmaceuticals will develop in the United States. HIV/AIDS drugs provided at low-cost to developing countries are unlikely to cycle into the United States, which would undercut high U.S. prices while denying the intended beneficiaries access to these medicines.

#### 4. CONCLUSION

New TRIPS Article 31*bis* marks a significant change in the overall “outlook” of TRIPS. Through its express endorsement of “anti-diversion measures,” it moves TRIPS from its declared “neutrality” on parallel trade (as expressed in TRIPS Article 6) to a position supporting the mandatory suppression of parallel trade. It remains to be seen whether this move is *lex specialis*—that is, applicable only to pharmaceuticals (or perhaps only to those pharmaceuticals produced and distributed in response to conditions that would justify compulsory licenses under Article 31 and 31*bis*)—or whether it reflects an overall shift. Viewing Article 31*bis* as a special rule acknowledges the abandonment of another primary TRIPS principle: neutrality to the technology field.<sup>99</sup> If the mandatory suppression of parallel trade grows into a general rule, exercise of exclusionary rights by IP-holders will lead to a world with fewer trade barriers.

That said, these doctrinal shifts do contribute to improving the condition of millions of people currently suffering from HIV/AIDS in LDCs. Pharmaceutical firms may supply these markets at low prices without exposing themselves to back-flow that would undercut higher prices in developed markets (thus maintaining their incentives to develop increasingly effective medicines). Or, rather, these companies may no longer use the specter of unfair competition from diverted products to justify ignoring the needs of the afflicted.

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<sup>99</sup> Article 27 of TRIPS provides that patents shall be available for any inventions “in all fields of technology.” TRIPS art. 27.