

# TACD

TRANS ATLANTIC      DIALOGUE TRANSATLANIQUE  
CONSUMER DIALOGUE      DES CONSOMMATEURS

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BRIEFING PAPER

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## **PRODUCING HIV/AIDS MEDICINES FOR EXPORT/IMPORT UNDER TRIPS, ARTICLES 31(F), (K), AND 30**

There is a massive disconnect between the perceived interests of countries and companies that research, develop and produce patented medicines, i.e., the U.S. and E.U., and the interests of the countries of the global South that desperately need such medicines to fight infectious and tropical diseases for their poverty-stricken populations. This disconnect occurs at the intersection of three separate systems: national and international intellectual property regimes, especially TRIPS, national and regional capacities to manufacture and market pharmaceutical products, and national and international patterns of income inequality and poverty.

The necessity of increasing access to life-saving medicines for tropical and infectious diseases, such as the HIV/AIDS pandemic in Africa, is undeniable.<sup>1</sup> Out of 36.1 million persons living with HIV/AIDS worldwide, 25.3 million, nearly 70%, live in sub-Saharan Africa; another 20-plus percent live in other developing countries. Out of the 3 million persons who died of AIDS in 2000, 2.4 million were from Africa and .47 million from Southern and Southeastern Asia. Out of the 5.3 million new HIV infections last year, more than 95% were in developing countries.<sup>2</sup> As the pandemic intensifies, it is estimated that 100 million persons will be HIV infected within twenty years and that the death rate could sky-rocket to 1 billion dead by the end of the century if treatment and eventual cures remain out of reach for the world's poor.

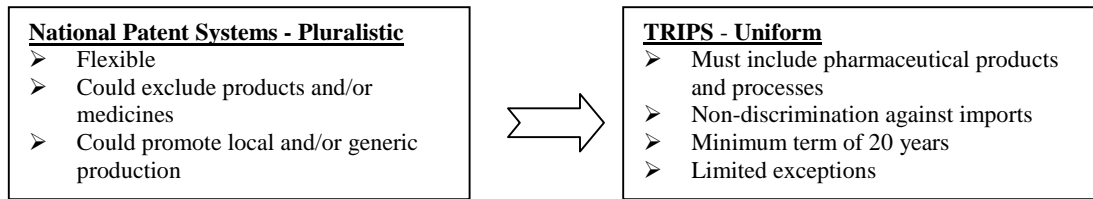
This paper describes the necessity and legality under TRIPS (the WTO Agreement on Trade Related Aspects of Intellectual Property Rights) of producing cheap, high-quality generic medicines in the countries that have pharmaceutical capacity so that they might be exported to extremely poor, and even middle-income, countries suffering a high burden of infectious disease, especially those countries that lack industrial capacity or market size to manufacture or market such medicines on their own. After examining the three systems that contextualize and complicate the delivery of high quality, affordable medicines to developing countries, this paper will analyze two mechanisms under TRIPS that permit the exportation of generic medicines from a country with productive capacity to those without. In particular, the paper analyzes compulsory licensing for export→import under Article 31(f) and (k) and a "limited" exception for export under Article 30.

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<sup>1</sup> AIDS is the prototypical example but the need for affordable medicines extends to other infectious and tropical diseases, including malaria, tuberculosis, sleeping sickness, Chagas disease, leishmaniasis, and other respiratory and intestinal infections. See MSF Campaign for Access to Essential Medicines and Drugs for Neglected Disease Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases* (Oct. 2001).

<sup>2</sup> UNAIDS (Dec. 1, 2000).

## 1.1 The Intellectual Property Regime



To understand the complications of getting needed medicines to developing countries, it is important to outline the intellectual property regime, both national and international, and the existing pattern of pharmaceutical patents. In the classic, “pre-TRIPS” era, patent law was essentially national. Each sovereign nation passed patent legislation designed to suit its own internal interests taking into account its stage of development, appropriate rewards for inventors/investors, and lower costs and increased availability for consumers and derivative users of intellectual property. During this classic era, countries could discriminate between fields of discovery and exclude patents for medicines, e.g., Brazil; they could decide to patent pharmaceutical processes but not pharmaceutical products, e.g., India; or they could decide to limit the duration or scope of medical patents. Accordingly, for example, prior to TRIPS, about 50 countries did not grant any patent protection whatsoever for pharmaceutical products, including both developed and undeveloped countries.<sup>3</sup>

Operating in this classic system, an inventor of a pharmaceutical product/process would ordinarily have to file relatively contemporaneous patent applications in each sovereign state in order to protect its intellectual property rights in each country. A product or process could not be patented in South Africa merely because a patent application had been filed in the U.S. Moreover, in filing a separate patent application in South Africa, the patent seeker would be bound to the local patent law of South Africa both procedurally and substantively. Thus, a poor country that wanted to make sure that it would have access to low cost generic medicines could have, and often did, exclude patents for pharmaceutical products.

At this point, it is important to acknowledge that HIV medicines have not been patented pervasively throughout the developing world, particularly in sub-Saharan Africa, even in countries that have pharmaceutical patent regimes.<sup>4</sup> The explanation for this pattern of non-uniform patenting is that smaller and poorer nations do not have markets that warrant the cost of patent applications. Despite incomplete patenting, however, there are multiple anti-viral patents in those few countries, South Africa, Kenya, and Nigeria, that have meaningful market size and some pharmaceutical capacity. Similarly, there is a pattern whereby some of the most important low-dose, low-cost anti-viral medicines are patented in countries where the disease is concentrated.<sup>5</sup>

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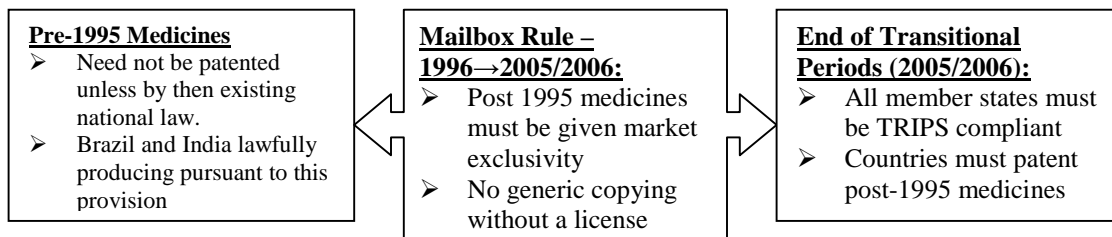
<sup>3</sup> Karin Timmermans and Togi Hutadjulu, *Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals*, 11(WHO 2000) (hereinafter, ASEAN Report). In fact, pharmaceutical patents were not uniformly recognized in the developed world until late in the 20th century: UK (1949), France (1960), Germany (1968), Italy (1978), Japan (1976), Sweden (1978), Switzerland (1977), and Spain (1992). *Id.* at 18.

<sup>4</sup> Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1888 (Oct. 17, 2001). This author strongly disagrees with the authors’ thesis that patents are not a significant barrier to treatment in Africa.

<sup>5</sup> Low-cost, front-line anti-viral therapies involving 3TC, d4T, AZT, Abacavir, and/or Nevirapine are significantly blocked by patents in countries containing 68% of HIV positive persons in sub-Saharan Africa. Consumer Project on Technology et als., *Comment on Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral drugs in Africa* (Oct. 16, 2001).

The pluralism of national patents systems under the classic regime was substantially undone by the introduction of the TRIPS Agreement, negotiated in the 1986-1994 Uruguay Round of the General Agreement on Tariffs and Trade. Instead of permitting pluralism, the TRIPS Agreement undertook to impose a substantially uniform system of intellectual property rights worldwide, with some flexibility for developing and least developed countries, which have transition periods within which to become TRIPS compliant.<sup>6</sup> The U.S. and E.U. pharmaceutical industry played a lead role in the negotiation of TRIPS,<sup>7</sup> not only by convincing trade representatives to champion its interests, but by direct lobbying during the negotiations. At the end of the day, the industry was ecstatic, with its principal negotiator boasting that the industry had achieved all of its aims, controlling the process and the result.<sup>8</sup>

The key features of the new agreement, from the industry's perspective, was that it was no longer possible for countries to discriminate against a field of technology, like medicines, in their patent rules.<sup>9</sup> Similarly, countries could no longer discriminate against imports in favor of locally produced products.<sup>10</sup> Finally, the length of patents was extended uniformly to 20 years,<sup>11</sup> far beyond the useful life of many patented medicines given rapid advances in product development.<sup>12</sup> Thus, the major producers had succeeded in consolidating their monopoly power internationally – they had exclusive rights to exclude others from “making, using, offering for sale, selling, or importing” patented pharmaceutical products or products made with a patented process.<sup>13</sup> Given its advantage in conducting research and development (96% vs. 4%), the developed world secured near absolute competitive advantage over the developing world in intellectual property rights via the TRIPS Agreement.



TRIPS delineates three time-frames that will have a dramatic impact on access to medicines. On the plus side, because TRIPS was not formally ratified until 1995, none of its provisions require that a country extend patent protections retroactively to products discovered before its enactment, unless that country's legal system already mandated such protection and patent applications had already been filed in a timely fashion. Thus, India, Brazil, and a number of other process-only or no-medical patent countries have continued to reverse-engineer pre-1995 AIDS medicines and to produce them generically. Moreover, India and Brazil could lawfully export these medicines to other countries where patents are not in force or where compulsory licenses (discussed further below) have been issued. Such manufacture and export/import would be fully TRIPS compliant.

<sup>6</sup> The transitional rules of TRIPS obligate most developing countries to become TRIPS compliant by January 1, 2000, and least developed countries by January 1, 2006. Articles 65 & 66.

<sup>7</sup> Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. Pa. J. Int'l Econ. L. 1069, 1075-1094 (1996). OXFAM Great Britain, *Fatal Side Effects: Medicine Patents under the Microscope*, 38 (2001).

<sup>8</sup> “In the words of Edmund Pratt of Pfizer, ‘Our combined strength enabled us to establish a global private sector-government network which laid the groundwork for what became TRIPS.’” OXFAM, *supra* note 7, at 38.

<sup>9</sup> Article 27.

<sup>10</sup> Article 27.

<sup>11</sup> Article 33.

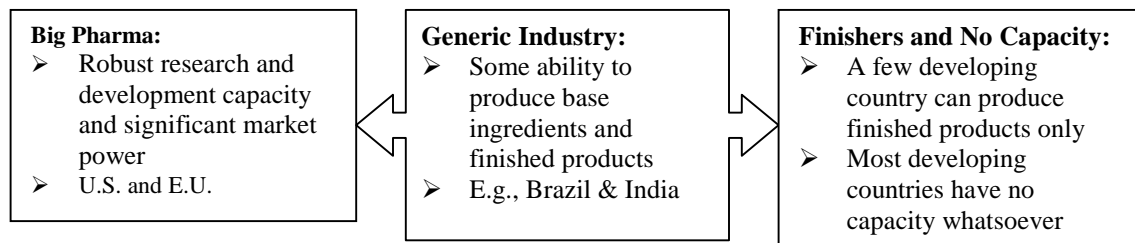
<sup>12</sup> ASEAN Report, *supra* note 3, at 19-20.

<sup>13</sup> Article 28.

TRIPS has complicated the future of producing medicines, however, even where productive capacity and sufficient market size exists and even in countries that are currently producing TRIPS compliant generic AIDS drugs, like Brazil and India, because of its “mailbox” and transitional timelines. Because of transitional periods running from 1996 to 2005/06,<sup>14</sup> TRIPS required a so-called “mail-box” rule whereby developing countries were obligated to establish mechanisms for receiving, processing, and establishing “priority-in-time” for pharmaceutical patent applications. Furthermore, the developing countries had to grant exclusive distribution rights to the patent applicant when certain prescribed conditions were satisfied.<sup>15</sup> Thus, the mailbox rule effectively precludes generic manufacturers in developing countries that do not recognize patents on medicines or product patents from producing “copies” of medicines described in “mailbox” applications. Stated differently, patent applicants have significant and exclusive market advantages with respect to post-1995 discoveries even before the full adoption of TRIPS in developing and least developed countries.

Even more dramatically, the window of opportunity for generic producers in developing and least developed countries to copy on-patent medicines without a license is rapidly closing. By January 1, 2005 or January 1, 2006, all countries seeking membership in the WTO must become TRIPS compliant with respect to their patent regime. By these dates, any generic copy of a post-1995, on-patent medicine must be produced pursuant to a compulsory license issued under Article 31 or as a limited exception, if applicable, under Article 30.

## 1.2 Pharmaceutical capacity and national markets



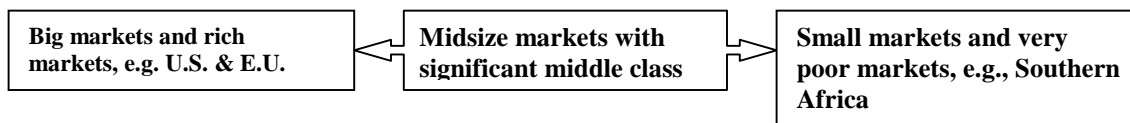
The capacity to produce pharmacological products varies greatly country by country and region by region, ranging all the way from highly sophisticated research-and-development capacities in the U.S. and E.U. to a total lack of capacity in most developing countries.<sup>16</sup> Before the passage of TRIPS, only ten developed countries had a sophisticated pharmaceutical industry with a significant research base. In the intermediate range, seventeen nations – twelve developed and five developing – had some innovative capacity and another fourteen – six industrial and eight developing – had the capacity to produce both therapeutic ingredients and finished products; eighty-nine countries, eighty-seven developing, had capacity to formulate finished products from imported therapeutic ingredients. At the far end of the incapacity spectrum, sixty countries, fifty-nine of which were developing, were without any pharmaceutical capacity whatsoever.<sup>17</sup> Obviously, this widespread lack of capacity has grave consequences on the ability of developing countries to manufacture generic medicines even when medicines are not patented within their borders or even when they might hope to produce medicines locally under a compulsory license.

<sup>14</sup> Articles 65 and 66.

<sup>15</sup> Article 70.

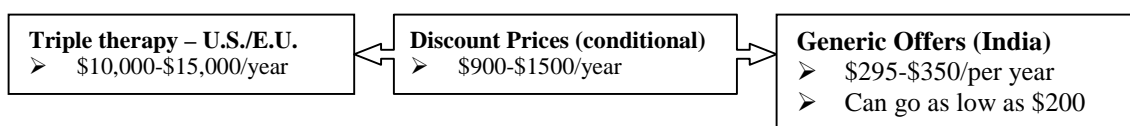
<sup>16</sup> OXFAM, *supra* note 7, at 10. In Africa, only Egypt can currently produce therapeutic ingredients and finished products, though several other countries, including South Africa, and perhaps Kenya and Nigeria, can produce finished products from imported compounds.

<sup>17</sup> ASEAN Report, *supra* note 3, at 20.



In addition to manufacturing capacity, the market size of a country and its access to other markets affects its ability to efficiently manufacture and market pharmaceutical products. Of course, market size is impacted in part by the population of the country – small population countries like Botswana have “small” markets. The markets in developing countries for pharmaceutical products is smaller yet when factoring in the purchasing power of consumers. Especially in countries with a small elite and a thin middle class, e.g., the poorest countries (where GDP/population is under \$400), there is little or no actual market for HIV/AIDS medicines in the absence of substantial foreign aid and/or cost subsidies. Thus, to achieve economies of scale vis-a-vis consumers who can actually afford to purchase even lowest cost generic drugs, it is important to aggregate regional markets including wealthier consumers using the private sector services.

### 1.3 The pricing system and the impact of poverty on purchasing power



Primarily as a result of publicly funded research into therapeutic compounds and subsequent drug patenting, development, registration, and production by the proprietary pharmaceutical industry, the industry has brought a range of anti-retroviral drugs to market. These medicines, typically in combination, dramatically extend the life of persons living with HIV/AIDS, but they have historically been priced at an extremely high level, such that the typical triple-therapy treatment regime costs between \$10,000 and \$15,000 per year in the U.S. and in Europe. These prices are certainly cost prohibitive for poor people in wealthy countries, but fortunately government subsidies, public health systems, and medical insurance schemes make these medicines available to many if not all people living with AIDS in the developed world.

In the developing world, however, the vast majority (99.9%) of people living with AIDS cannot afford anti-retroviral therapy nor can their cash strapped governments afford to subsidize care (with minor, pilot- program exceptions). The result is that in the year 2000, as few as 25,000 Africans were on triple-therapy out of 25.3 million HIV positive residents.<sup>18</sup> Despite this widespread unaffordability, until the very recent past patent holders offered their anti-retrovirals at the same monopoly price in Africa that they charged in the U.S.

Although pressure from the United Nations, developing countries, and treatment activists has recently resulted in highly conditional offers of steep price discounts for certain AIDS medicines, patented triple-anti-retroviral therapy still costs a minimum of \$900-\$1500 per patient per year.<sup>19</sup>

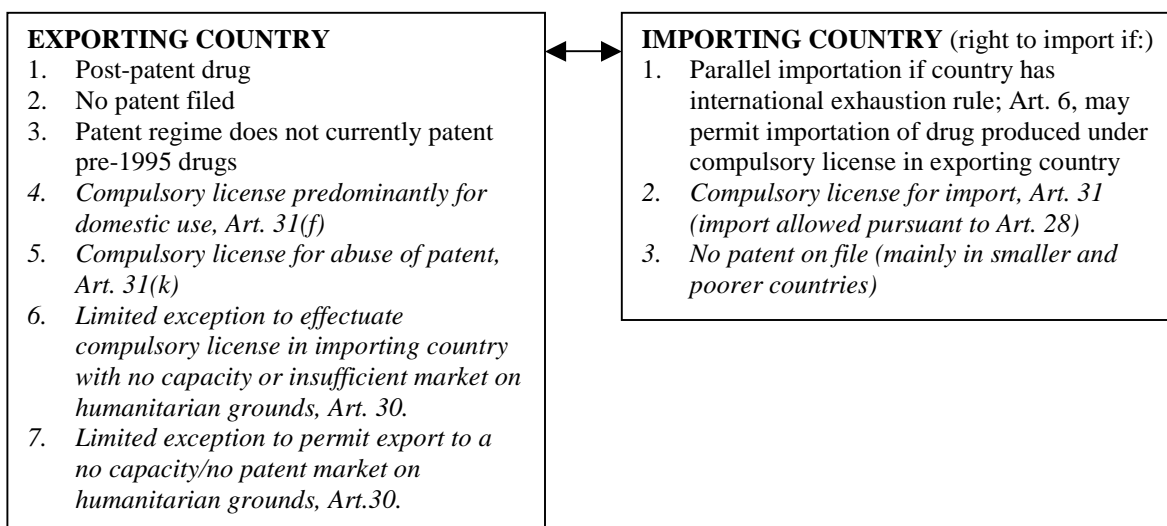
<sup>18</sup> Report on the WHO International Consultative Meeting on HIV/AIDS Antiretroviral Therapy (May 22-23, 2001). This figure may be considerably higher now, especially among private sector consumers, as the prices have plummeted over the past six months and as governments have expanded drug availability through agreements to import even cheaper generics.

<sup>19</sup> Offers are frequently time limited, use limited, and sector limited (usually public sector only) and often have stringent requirements on treatment regimes and medical monitoring. Carmen Perez-Casa et als., *Accessing ARVs:*

Even at these discounted or concessionary prices, essential AIDS medicines remain unaffordable for the vast majority of patients in the developing world. In contrast, generic triple-combo-therapy medicines have been offered by several Indian manufacturers, CIPLA, Hetero, and Ranbaxy, at dramatically lower prices, \$350, \$347, and \$295 respectively.<sup>20</sup> With sufficient economies of scale and secured sources of base ingredients, there are indications that standard triple therapy medicines could be provided for as little as \$200 or less per patient/per year.<sup>21</sup> It is because of the dramatic price advantages of high quality generic medicines over the current “rock bottom” prices of patent holders that strategies to export/import generic medicines becomes so important – every dollar or euro saved counts.

## 2. TRIPS compliant production of low-cost generic medicines for export→import

In order to keep track of the complications of satisfying the need for affordable medicines in the export/import context, it might be useful to map the alternatives that are currently available.



As the map above indicates, there are several options for exporting/importing generic medicines. Although this paper makes at least brief mention of all of them,<sup>22</sup> it primarily discusses the options shown above in *italics*.

### 2.1 TRIPS-free export/import of no patent, post-patent, and pre-1995 medicines

As previously discussed, in member states where a medicine is off-patent, either because the patent has expired or because the nation did not recognize pharmaceutical patents prior to 1995 or because a patent application was never filed in either country, it is completely lawful for a generic

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*Untangling the Web of Price Reduction for Developing Countries*, (MSF Campaign for Access to Essential Medicines, October 5, 2001).

<sup>20</sup> *Id.* at 3.

<sup>21</sup> Medecins Sans Frontieres, Campaign for Access to Essential Medicines, *HIV/AIDS Medicines Pricing Report. Setting Objectives: Is There a Political Will*, 18 (July 6, 2000).

<sup>22</sup> For example, although beyond the scope of this paper, there are arguments that drugs produced under a compulsory license, where a royalty has been paid, have “exhausted” the patent holder’s patent rights. Thus, if parallel importation rules survive, a country that recognizes “international exhaustion” would be permitted to import drugs produced under a compulsory license issued in another country. In this analysis, even if there is no compulsory licensing in the importing state, the parallel importation would be TRIPS compliant. Carlos Correa advocates this approach, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Section X.2 (2000).

manufacturer to export HIV/AIDS medicines. Pursuant to these rights, Brazil and India can lawfully export first and second generation AIDS medicines as could Namibia (assuming it had industrial capacity, which it does not) because it has no AIDS medicines under patent. Despite this theoretical possibility, only India is positioned to export significant quantities of anti-retroviral medicines; Brazil's generic production does not meet even its own internal needs.

## 2.2 Article 31: compulsory licenses – general provisions

If authorized by local law, Article 31 of TRIPS permits a competent government authority, including a health or patent department, to license the manufacture, sale, and use of an invention to an authorized third-party or government agency without the consent of the patent-holder. Although such licenses could stimulate price-lowering competition and ensure availability of needed medicines, no developing nation has yet issued a compulsory license for HIV/AIDS medicines, though an application is pending in South Africa. Complicating any such effort is the fact that few developing countries have comprehensive compulsory licensing clauses in their patent legislation. Even as developing countries amend their intellectual property regimes to become TRIPS compliant, many of them are not taking advantage of the TRIPS-compliant compulsory license provisions that exist.

The permissible grounds for compulsory licenses are not fully enumerated or delimited in the TRIPS Agreement, and thus developing nations have significant discretion in selecting health sensitive policies. Permissible grounds for compulsory licensing include public health and the public interest broadly defined,<sup>23</sup> national emergencies and matters of extreme urgency such as epidemics,<sup>24</sup> public non-commercial or governmental use,<sup>25</sup> and/or anti-competitive practices, including abusive pricing and non-working of the patent.<sup>26</sup> Some of these grounds justify expedited governmental action. For example, under Article 31(b), when the government declares an emergency or a matter of extreme urgency, such as the AIDS pandemic, it could seek a compulsory license for itself, or for an authorized third party, to begin commercial exploitation without first negotiating with the patent holder. Similarly, when the government is seeking a license for public, non-commercial use, the government or its authorized agent is not required to seek prior approval and it can limit the patent-holder's remedies to review of the amount of compensation.<sup>27</sup> Finally under Article 31(k), if the government acts to redress anti-competitive practices or abuse of patent, it can both reduce the amount of compensation to the patent holder and distribute the product without quantity restrictions outside the domestic market.

Although TRIPS is relatively indifferent about the grounds for issuing a compulsory license, it is relatively strict about the conditions that must be met in order for an ordinary license to be granted. Except in cases of governmental use, cases arising from abuse of patent rights, or cases involving emergency or extremely urgent conditions, the government is ordinarily required to seek a voluntary licensee on commercially reasonable grounds for a reasonable period of time.<sup>28</sup> In addition, as previously stated, the government or its authorized third-party is required to pay adequate compensation.<sup>29</sup> Even though the meaning of adequate compensation is not fully defined in TRIPS, the WTO will be certain to look at the process used to reach a particular result. Despite a requirement of case-specific determinations, however, it would be appropriate to set

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<sup>23</sup> Article 8.

<sup>24</sup> Article 31(b).

<sup>25</sup> Id.

<sup>26</sup> Article 31(k).

<sup>27</sup> Article 42.

<sup>28</sup> Article 31(b).

<sup>29</sup> Article 31(h).

forth factors affecting royalty rates including public expenditures, inventiveness, research and development costs, remaining life of the patent, purpose of use, etc. Fortunately, the companies cannot ordinarily insist on receiving their normal, extraordinary rates of profit. Instead, relatively small royalties in the range of 2-10% have become traditional in the pharmaceutical field.<sup>30</sup>

Even if a compulsory license is granted, the patent-holder retains its underlying intellectual property rights in the patent. The license granted is ordinarily non-exclusive, meaning the patent-holder and its other licensees can still compete;<sup>31</sup> moreover, the license is non-assignable.<sup>32</sup> More significantly, the license is revocable once the circumstances that led to its granting have ceased to exist, though some consideration must be given to the interests of the licensee who may have invested heavily in order to manufacture the licensed product.<sup>33</sup> This possibility of revocation creates barriers to entry in developing countries even in those rare circumstances where they have sufficient drug manufacturing capacity to produce drugs locally.<sup>34</sup>

### 2.2.1 Compulsory licenses for local production and use – an illusory right

Some developing countries that cannot produce base ingredients but have some “assembly” capacity may be able to import unpatented base ingredients and produce medicines pursuant to a compulsory license. However, compulsory licensing for local production is an illusory right for most African countries that lack any capacity whatsoever to produce HIV/AIDS medicines and for countries that have small markets. Admittedly a few larger and more industrially advanced countries, like South Africa, could make use of compulsory licenses to produce medicines internally and to satisfy their local market, though prosecuting a license, organizing production, and obtaining drug registration would obviously take time. Nonetheless, unless there are interpretations of TRIPS that permit export so as to aggregate a larger and more cost-effective market, the promise of the right to produce locally in TRIPS is meaningless to the poorest and smallest countries in the most desperate need of low cost medicines.

### 2.2.2 Compulsory licenses to import

If a country cannot manufacture generics on its own, then the obvious solution is to be able to import medicines under a compulsory license in the importing state. On its face, TRIPS seems to preclude the competing importation of a patent-infringing, non-licensed product because one of the exclusive rights given by Article 28 is the right of exclusive importation. On the other hand, TRIPS clearly authorizes the issuance of compulsory licenses and Article 27.1 provides for non-discrimination between locally produced and imported products. Article 27.1 surely justifies satisfying a compulsory license through import as well as by local manufacture. Thus, a compulsory license could be granted in the importing country that could in turn be satisfied by an exporting manufacturer producing its generic medicines, assuming its manufacture does not violate patent rights in the exporting state.

### 2.2.3 Production for export under 31(f)

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<sup>30</sup> James Love, *Access to Medicine and Use of Patents Without the Permission of the Patent Owner: Models for State Practice in Developing Countries*, ¶¶ 35-42.

<sup>31</sup> Article 31(d).

<sup>32</sup> Article 31(d).

<sup>33</sup> Article 31(c) and (g).

<sup>34</sup> As previously mentioned the vast majority of African countries have little or no pharmaceutical production capacity. See OXFAM, *supra* note 7, at 11.



For purposes of this analysis, the most problematic feature of the compulsory license regime in TRIPS is that compulsory licenses are authorized “predominantly for the supply of the domestic market” of the authorizing country, except in cases of patent abuse where the limit does not apply.<sup>35</sup> The meaning of this “domestic supply” requirement is inherently unclear as it might mean that “the predominant portion of products produced must be consumed domestically” or alternatively that “the license shall be predominantly for the benefit of domestic consumption.” With the latter interpretation, a country would be justified in exporting a major portion of its production if such export were necessary in order to have large production runs so as to efficiently supply the domestic market. This is the preferable interpretation of Article 31(f) because it could result in a regional manufacturer being able to supply several small markets in order to achieve cost efficient economies of scale.

#### 2.2.4 Production for export under 31(k)

Fortunately, there is a domestic-market exception in Article 31(k) when a patent-holder has been found to have anti-competitively abused its patent, by excessive pricing or otherwise, in the producing country. In these circumstances, a generic producer operating under a compulsory license could produce on a large scale for export to other countries, most obviously if a compulsory license had been granted on any basis in the importing country.

Unfortunately, TRIPS provides no definition of what might constitute an anti-competitive practice. Given the absence of guidance in TRIPS and given the directive in Article 1 that members states should “determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice,” it seems clear that individual countries are permitted to develop definitions of anti-competitive behavior so long as they are not transparently TRIPS-nullifying.<sup>36</sup>

By their very nature, patents are somewhat anti-competitive because they enable the patent holder to exclude other manufacturers and vendors. Although “normal” exploitation of patent rights would not constitute an anti-competitive practice, super-monopoly power, profits, and prices might be held anti-competitive in particular settings, particularly where a product dominates a therapeutic class. Another anti-competitive practice might be the now routine practice of patent holders discriminating between prices offered in the public and private sector and the practice of price differentiation among countries. Since price discrimination is frowned upon in many competition schemes, discriminatory pricing might justify the issuance of a license.

The most promising argument, however, is one that combines abusive pricing and a relative failure to work the patent. Given that many competition schemes are designed to prohibit excessive pricing or price gouging, it may be possible to argue that high prices are unwarranted even where there are multiple providers in the therapeutic class. This argument is bolstered when it can be shown that excessive pricing effectively eliminates product availability, producing a substantial failure to work the patent for the vast majority of consumers. If medicines are not being provided on a reasonably affordable basis, bearing some reasonable relation to the costs of production, then a country could issue a compulsory license under Article 31(k) on the basis of abusive pricing/non-working. Because anti-retroviral medicines have been largely discovered and developed with public money,<sup>37</sup> because industry profits have been so high,<sup>38</sup> and because the

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<sup>35</sup> Article 31(f),(k).

<sup>36</sup> Article 40 also empowers member states to address anti-competitive practices in licensing agreements.

<sup>37</sup> Consumer Project on Technology, *Additional Notes on Government Role in the Development of HIV/AIDS Drugs* (Feb. 23, 2000).

price of anti-retroviral drug have been grossly inflated until recent price discounts (and could become so again), there is a strong argument that patent-holders of essential anti-retrovirals have abused their market position and that an export promoting Article 31(k) compulsory license could be issued.

### 2.3 “Limited” exceptions for export under Article 30

A more coherent approach for expanding permission for export (under a compulsory license or otherwise) is to recognize “limited” Article 30 exceptions designed to address external public health crises on humanitarian grounds. Although the ultimate scope of Article 30 is unclear, particularly in its relationship to Article 31, although its language contains multiple interpretive ambiguities, and although its potential reach has been narrowly construed in at least one WTO decision, there are sound policy reasons and interpretive principles which support using Article 30 to prevent a Catch-22 that bars meaningful access to medicine for countries most in need of lowest cost generics exported from a producer nation.

The text of Article 30 certainly evidences enough flexibility to justify limited exceptions designed to address the dire public health crises of the developing world:

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

As a guiding interpretive principle, though this too is not free of dispute, it is important to recognize that Article 8 authorizes member countries to consider public health and public interests needs when drafting their patent laws “provided that such measures are consistent with the provisions of this Agreement.” Similarly, Article 7 provides that intellectual property rights “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” For these two provisions to mean anything, they must mean that member states can balance their public health, public interest, and consumer needs in some affirmative way that impacts the unfettered exercise of patent rights. Thus, given the extent of the AIDS pandemic in Africa and given the realities that many developing countries cannot produce medicines locally, it makes common sense under public health,<sup>39</sup> trade, and human rights principles to fashion limited exceptions that permit the export→import of AIDS medicines to those poor nations.

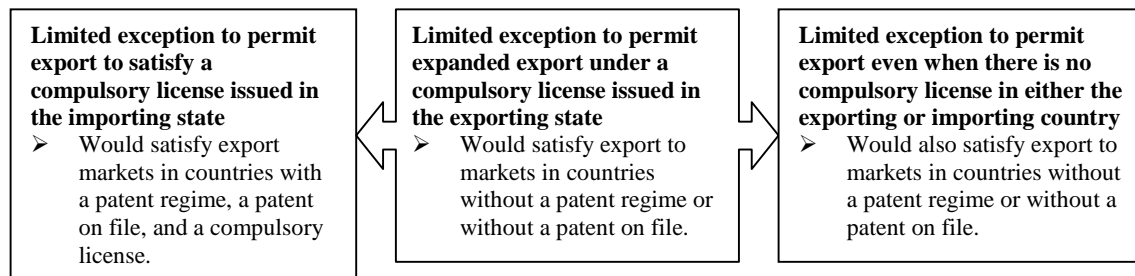
Some commentators express disagreement about the relationship between Articles 30 and 31 and about the use of Article 30 to limit one of the enumerated “exclusive” rights of the patent-holder under Article 28. These disagreements impact on whether Article 30 can ever be used so as to facilitate the operation of a compulsory license in either the importing or exporting country so as to permit export to developing countries that cannot manufacture medicines on their own. The better interpretation of the relationship between Articles 31 and 30, however, is that an Article 30

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<sup>38</sup> *Public Citizen’s Prescription Drug Update – Drug Company Profits* (Oct. 11, 2000) (a 38% return on equity, making the pharmaceutical industry the most profitable sector in the U.S. economy).

<sup>39</sup> The African Group, Brazil, India and other nations have proposed a clarification of TRIPS that “Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health.” Submission to the WTO TRIPS Council, Sept. 18, 2001. The U.S. has proposed a much more restrictive interpretation advocating use of “[existing] provisions in the TRIPS Agreement which provide flexibility to address public health crises such as HIV/AIDS and other pandemics . . . and in particular to secure access to medicines.”

limited exception can be used to augment or expand rights of exportation. In particular, Article 30 can be interpreted to support three highly important means of getting high quality, lowest cost generic medicines to developing countries suffering public health crises, most obviously HIV/AIDS, TB, and malaria.



First, Article 30 could justify manufacture and export of medicines to satisfy a compulsory license issued in the importing country/export market. Because such a license provides for a royalty payment to the patent holder, the patent holder's legitimate interests are fully protected. This limited exception, first proposed in the so-called Amsterdam Statement to WTO Member States on Access to Medicines,<sup>40</sup> has subsequently been endorsed by TACD in three separate documents: (1) ¶ 3 of TACD's Resolution on Global Access to Health Care,<sup>41</sup> (2) ¶ 5 of TACD's Access to Medicines in Developing Countries,<sup>42</sup> and (3) Pharmaceutical Doc. No. Health 11-01.<sup>43</sup> It is also endorsed by the Africa Group and its allies.<sup>44</sup> Although this option is critically important to countries where patents are on file and where national legislation authorizes compulsory licenses, this compulsory-license option does not address the needs of countries that lack compulsory licenses because no patents are on file. Fortunately, there are two other limited exceptions under Article 30 that address this other area of need.

Where a manufacturer is already producing medicines under a compulsory license issued in the country of manufacture, Article 30 could justify the expansion of that compulsory license to permit public-health oriented export, in effect creating a humanitarian exception to the domestic

<sup>40</sup> Increasing Access to Essential Drugs in a Globalised Economy Working Towards Solutions (Nov. 25-26, 1999) <http://www.cptech.org/ip/health/amsterdamstatement.html> (accessed Nov. 1, 2001).

<sup>41</sup> ¶ 3. The US and the EU should communicate to the WTO TRIPS council that they will support policies to ensure that compulsory licensing of medicines will also benefit small market countries. Specifically, that mechanisms to enable production of medicines for export markets will be supported where such exports benefit public health and where the legitimate rights of patent owners are protected in the markets where the products are used. <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=107> (accessed Nov. 1, 2001).

<sup>42</sup> ¶ 5. TACD asks the US and the EU to support patent exceptions for the export of medicines. The EU and the US should send communications to the WTO supporting interpretations of WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPs) provisions that would permit patent exceptions for production of medicines for export, when the legitimate rights of patent owners are protected in the export market. For example, patent exceptions should permit the production and export of a medicine to a country that had issued a TRIPs compliant compulsory license for medicine. A failure to address this issue will substantially undermine the usefulness of compulsory licensing of medicines in countries with small domestic markets. <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=34> (accessed Nov. 1, 2001).

<sup>43</sup> REGARDING PATENTS AND EXEMPTIONS FOR EXPORTS:  
Agree that a country may provide exemptions to patent rights to companies who are exporting the product to another country where patent rights have expired or where patent rights have been licensed under compulsory licensing and the legitimate interests of the patent owner has been protected under Article 31 of the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPs Agreement). <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=111> (accessed Nov. 1, 2001).

<sup>44</sup> Submission to the WTO TRIPS Council, *supra* note 39, at ¶ 5.

market rule in Article 31(f). In this instance, the patent holder's legitimate interests would be protected by a royalty paid by the compulsory licensee in the exporting state. Using this limited exception, if South Africa were to issue a compulsory license, it could expand that license to supply a regional African market, including countries with no patent in force.

An alternative limited exception under Article 30 would permit humanitarian production and export even in countries where a patent is in force and even if no compulsory license has been issued, but only if the market for those exports were to countries with no patent in effect.<sup>45</sup> This last exception provides even more access to medicines for the many smaller and poorer African markets where patent holders have not even bothered to file or prosecute a patent application and thus where there are no grounds to issue a compulsory license. This exception also expands the potential pool of supplier beyond those manufacturing under a local compulsory license. However, because the patent holder has no rights in the importing country, its legitimate interests there (in this case none) are being fully protected and it is entitled to no royalties with respect to these sales. Although manufacture and export might seem to technically violate the patent-holder's Article 28 rights in the exporting country, this limited exception does no real harm in the manufacturing market because the medicines cannot be sold domestically nor could they be sold anywhere else where a patent is on file.

The direct language of Article 30 supports an interpretation that *some* significant impact on patent rights is permissible. For example, the first requirement of Article 30 is that the exception must be limited. Although "limited" does not mean that total abrogation of patents would be permitted, it must mean that some impact is possible, such as the quite significant impact of the "Bolar" exception, which can accelerate approval of generic competition by as much as three years costing the patent holder millions, even billions, of dollars. Similarly, the second and third clauses of Article 30 permit some conflict with the normal exploitation of a patent, though not an "unreasonable conflict," and some prejudice to the legitimate interests of the patent owner, though not "unreasonable prejudice." Lawyers are used to talking about the meaning of what is "unreasonable," but once again the language necessarily suggests that some conflict and some prejudice is permissible – so long as the limited exception does not go too far.<sup>46</sup> In these last two exceptions, there is no real curtailment of the patent holder's rights in the consuming country. If that country had manufacturing capacity, it could produce medicines own its own. Since it doesn't, these two proposals simply give no-capacity countries a legal source of off-site manufacture leveling their playing field vis-à-vis countries with productive capacity.

As to the concern that a limited exception should not be used to "substantially curtail" an enumerated right,<sup>47</sup> it is important to emphasize that brand manufacturers have no patent rights in no patent countries. Moreover, in the AIDS context there is no real market for brand name medicines in disease burdened countries, even at discounted prices in the \$900-\$1500 range. These prices are totally beyond the reach of the poorest and smallest countries of Africa and the countries burdened by an astronomical rate of infection.<sup>48</sup> Thus, manufacturing medicines, with

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<sup>45</sup> The Africa Group and its allies have proposed this exception in ¶ 9 of their Submission to the WTO TRIPS Council, *supra* note 39. This interpretation is also being advanced by several NGOs, including James Love at the Consumer Project on Technology. Love, *supra* note 30, at ¶15-Four.

<sup>46</sup> Weissman, *supra* note 7, at 1096.

<sup>47</sup> *Canada—Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, March 17, 2000 [hereinafter *Generic Medicines*]. In *Generic Medicines*, the panel found that manufacture before patent expiration so as to register a medicine, the so-called "Bolar" exception was lawful, but that a six month stock-piling rule was unlawful. In particular to the point under discussion, *Generic Medicines* found that any exception which resulted in a "substantial curtailment of [any exclusionary right] cannot be considered a limited exception." *Id.* at paragraph 7.44.

<sup>48</sup> At present, pharmaceutical sales to Africa constitute only 1.3% of global sales for the proprietary drug industry. As previously stated, less than .1% of Africans with HIV are currently on anti-retroviral therapy.

or without a compulsory license, and supplying an export market with lower cost generic medicines does not “take” anything away from current patent holders, especially because they continue to retain the right to produce and sell their medicines.

Fortunately, the language of Article 30 does not suggest that only the patent holder’s rights be considered; it requires that the exception be judged “taking account of the legitimate interests of third parties” including presumably millions of poor people living with HIV/AIDS. There is no geographical scope given about “third parties” who count, and thus the legitimate interests of third parties living in the heart of the pandemic weigh heavily. This last proviso strongly suggests that Article 30 incorporates a principle of proportionality such that if the public health interests of third parties are substantial, then a more significant limitation on patent rights is permissible. In the real world, if these “third parties” in Africa do not get the lowest-price, highest-quality generics available (and foreign aid and debt relief as well), they *will* die.

In general terms, Article 30 should be understood as supporting public health exceptions with respect to medicines and other medical products. It could for example be used not only to expedite the distribution of essential medicines in response to existing patterns of infectious diseases like HIV/AIDS, TB, and malaria, it could also be used to justify export of medicines in response to bio-terrorism. In order for any of these Article 30 limited exceptions to be lawful, however, there must be enabling legislation in the exporting country permitting Article 31 and/or Article 30 manufacture for export. There must also be some provision for issuance of compulsory licenses in the importing nation, at least with respect to medicines under patent. Finally, there must be expedited processes for registration of medicines, including proof of bio-equivalence. This necessity should support an Article 30 exception to non-disclosure of clinical test information otherwise protected by Article 39.

### 3. Conclusion

Although it would be tempting to assert that the pro-export→import interpretations of TRIPS discussed above are the only plausible ones, in the real world of international trade negotiations, as this briefing paper is being written, some members of the E.U. and the U.S. are promoting much more stringent interpretations of international intellectual property rights for the upcoming Fourth WTO Ministerial Conference at Doha, Qatar. Developing countries, on the other hand, led by Brazil and the Africa Group, are urging that TRIPS be clarified to create an express public health exception that would ensure access to affordable medicines and life saving drugs for developing countries. Their proposal recognizes the permissibility of producing generic anti-retroviral medicines and other medicines for export to developing countries for use in both the public and private sectors and as such would greatly advance the fight against AIDS and other infectious diseases. Not only should TACD support the liberal interpretations of Articles 31 and 30 discussed above, it should also support the proposed clarifications and/or modifications of TRIPS that would allow member states to respond more proactively to genuine public health emergencies.