

**THE FTAA AND THE CLASH OF IDEALS: The Future of Intellectual Property Rights in Hemispheric Integration**

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## INTRODUCTION

In early 2001, the United States lodged a complaint with the WTO over Brazil's alleged violation of intellectual property rights (IPR). The source of the United States' contention with Brazil was the fact that, since 1996, Brazil had been providing anti-retroviral (ARV) drugs free of charge to Brazilians with HIV. Although the WTO complaint was dropped by the Bush administration in 2001 before it could be adjudicated, the issue is far from being settled, and ongoing FTAA negotiations could potentially bring it to the fore once again. The US has shown a tendency to press for a "TRIPS-Plus" regime of IPR enforcement that, while offering enhanced protection for patentholders, would potentially impair countries' ability to produce cheaper generic medicines for themselves and other less-developed countries (LDCs).

As many of the major players in the international pharmaceutical industry are headquartered in the United States, they form a powerful domestic lobby applying pressure to maintain strict IPR rules regarding drugs. The issue has been highly divisive, with a flurry of accusations coming from both sides. Brazil, for example, has been a world leader in producing cheaper generic medicines, and has generally championed the right of states to promote public health objectives; on the other hand, the United States and the major pharmaceutical companies claim that production of generic drugs undermines the development of new medicines. This paper aims to examine these divergent and opposing viewpoints on the issue, and seeks to answer the following questions:

1. What exactly is the nature of the conflict between those who favor strict IPR rules and those who favor the current rules, or relaxed rules? What factors motivate them to uphold these positions?
2. Is there potential for an FTAA section on IPR that will satisfy both camps? If so, what form will it likely take?

This paper will argue that this issue is much bigger than the Brazil-US standoff, and has implications for the future and spirit of the FTAA agreement itself. Further, solutions to this impasse exist within the current TRIPS framework, and, indeed, the tentative text of the FTAA itself, that could potentially satisfy the needs of both developed and developing<sup>1</sup> countries, but only if these parties can reach some sort of compromise as to what normative goals should be emphasized in the section on intellectual property.

### **THE DEBATE OVER IPR: THE CURRENT LITERATURE**

The subject of IPR in a general sense has a long history, and a voluminous literature exists on the topic. However, comparatively little has been written on the subject of IPR as it relates to the production of generic drugs. As IPR relating to pharmaceuticals is a highly contentious issue, especially for those involved in development, the literature that does exist generally falls into two highly polarized categories. One school of thought argues that the rights of patent-holders ought to take precedence, and that the current regime as manifested in international agreements such as TRIPS, and national legislation, promotes innovation, profit, and quality in pharmaceuticals for both developed and developing countries. A second school consists of those who argue that public health should take priority and fundamental change in the system is needed to guarantee affordable access to medication in developing countries. In many ways, especially among health professionals and political scientists, the latter school of thought has been able to argue its case more forcefully.

Caroline Thomas takes the latter view, and has written an excellent article which points out the problem of restricted access of developing countries to necessary drugs, arguing that fundamental changes in the global health governance regime are necessary if a

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<sup>1</sup> A note on usage: in this paper, the developing countries referred to are limited to those in Latin America and the Caribbean who may potentially sign on to the FTAA agreement.

sincere commitment to the global health crisis is to be made.<sup>1</sup> Focusing on access to ARV drugs, Thomas argues that “differential access to ARV drugs because of cost contributes to the uneven global experience of HIV/AIDS.”<sup>2</sup> She examines and attempts to debunk some of the most frequent arguments against looser IPR rules, making two important contentions. First, she argues that patents actually do not necessarily encourage innovation, since even in developed countries the pharmaceutical patent system was introduced fairly recently; second, companies set research priorities not according to health needs, but with an eye to maximizing shareholder profit; and third, that a great deal of R&D is actually financed by government grants, not by the companies themselves. Thomas sees potential in multilateral organizations such as the WTO to liberalize access to necessary medications by increasing affordability and availability. Sarah Joseph takes a similar point of view.<sup>3</sup> Adopting a stance similar to Thomas, she writes that “Access to essential medicines is a human right which is currently compromised by the high prices charged by pharmaceutical corporations, which are facilitated by the global protection afforded to pharmaceutical patents by...TRIPS.”<sup>4</sup> She identifies three major “interests” in the debate: first, the need of the sick to acquire necessary drugs; second, the need of companies to engage in an optimal level of research and development; and third, the need for companies to make a profit. She argues that all three are important, but so far the profit interest has been given more weight than the other two, and that a balance can and must be struck. With respect specifically to the Brazilian case regarding IPR and production of generic drugs, a fine overview of the issues has been written by Joao Guilherme Biehl.<sup>5</sup>

Another point of view is that the current system, with stringent IPR rights for pharmaceutical companies, actually benefits everyone, including developing countries. A good example has been developed by Keith Maskus, who claims that protecting IPR has a

number of salutary effects. Protection of IPR, he argues, encourages innovation—there is little incentive to bring a product to market if other producers can offer it generically for much cheaper, as profits will decrease. Further, it promotes R&D, for many of the same reasons—companies are more willing to incur the heavy costs of R&D if they know that their results will mean significant profits for them in the long run. Finally, Maskus sums up the arguments of many IPR supporters when he argues that it will be in the long-run interest of developing countries to submit to IPR rules for the same reason that it currently benefits developed countries. Once they are able to kick-start the innovation process and begin producing their own medicines, he argues, developing countries will reap the benefits in terms of profit. A further elaboration of this argument was presented by David Resnik and Kenneth De Ville, who argue that the current regime is not good enough, and should be amended to provide even more protection for patent-holders.<sup>6</sup>

This brief literature review demonstrates two things, both of which are equally important for this analysis, and both of which are interrelated. First, the debate surrounding IPR and pharmaceuticals is highly polarized; second, scholars and policymakers examining the issue often to address it from a tendentious point of view rather than attempting to theorize some common ground.

## **METHODOLOGY: HOW TO APPROACH THE ISSUES**

This paper seeks to arrive at a recommendation that can potentially satisfy both parties to the IPR issue within the FTAA ratification process—that is, those states that support strict IPR rules, and those who by and large would like to see more latitude for states to pursue public health objectives and the like. This is the only way that the section on IPR will ever move forward, and due to its importance within the whole of the FTAA text,

the agreement will likely continue to stall if a concrete resolution is not reached. To arrive at its recommendation, this paper will go through several concrete steps:

1. First, some basic data on the international pharmaceutical industry will be presented, with the objective of demonstrating that it is a critical component of Northern economies, and therefore a crucial pillar of the future FTAA agreement.
2. As the debate surrounding IPR and pharmaceuticals is theoretically complex, a brief summary and examination of the theoretical context will be provided.
3. Finally, the text of the FTAA will be examined to determine whether there is anything in the language of the document that would permit the objectives of both sides to be met—profit and innovation for those in favor of strict IPR rules, and public health and social justice for those who are not.

Special attention will be paid to Section A, Articles 1-4, which detail the general rights provided for under the agreement, and Section B, Article 7, which discusses the legal exceptions to these rights. The TRIPS document will be also be carefully examined.

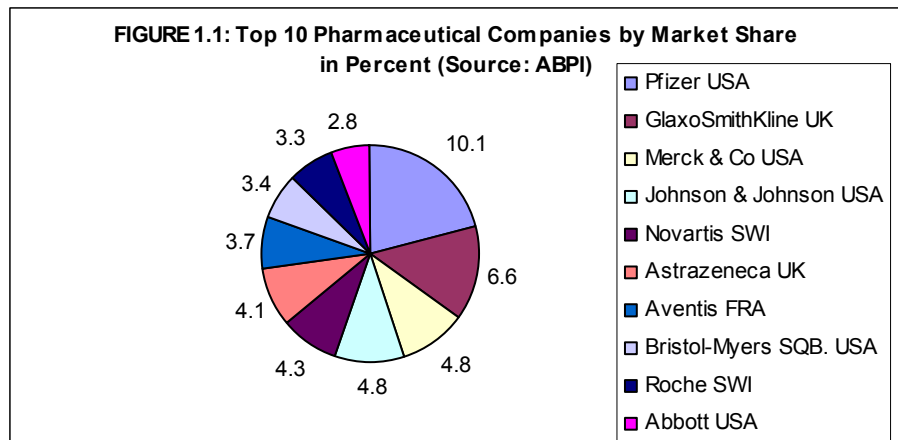
Evidence from these two agreements as well as examples of policy choices the major parties to this issue have made throughout the negotiating process will be compared to determine whether, as Section A, Article 5.6 of the FTAA draft agreement states, it is really true that “For all purposes, including the settlement of disputes, nothing...shall be construed as additional or higher levels of protection than the minimum standards established in the TRIPS Agreement.”

## THE IMPORTANCE OF THE PHARMACEUTICAL MARKET

### Statistics

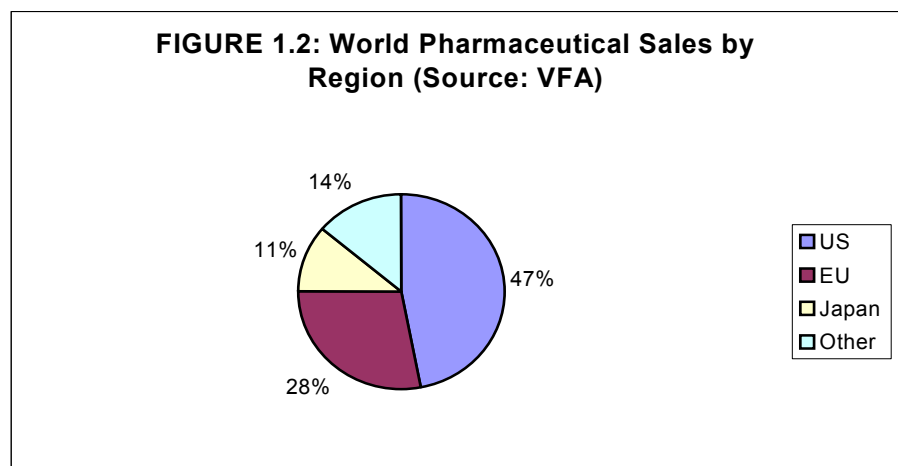
As Figure 1.1 shows<sup>7</sup>, developed countries comprise the top ten manufacturers of pharmaceutical products; these top 10 producers alone account for 47.8% of world market share. The five US companies on the list command a 25.9% market share. Figure 1.2<sup>8</sup> demonstrates further that these companies sell mostly to the US, EU and Japan; these countries taken together account for 86% of pharmaceutical sales, with “other” sources of revenue totaling only 14%.<sup>9</sup>

This demonstrates, first, that pharmaceutical sales mostly go to developed countries; and further,



mostly to the richest regions in the developed world (the US, EU and Japan). Nearly all of the top players in the international pharmaceutical industry are located in the US or UK.

Secondly, as the total proportion of sales coming from countries other than the US, EU and Japan is 14%, and as this figure undoubtedly includes



Asia and Africa, as well as many of the countries of the former Soviet Union (FSU), we can

assume that pharmaceutical sales to the developing-country parties to the FTAA agreement are small indeed. Despite this, there has been strong opposition to the measures taken by developing countries to secure affordable medication for their citizens. Many of those in need of drugs in these countries simply cannot afford them and are forced to go without. For example, a standard round of ARV drug treatment costs approximately \$4000-\$6000 US per person annually.<sup>10</sup> Even in the developed world, those costs are quite high, beyond the economic reach of some who have the disease. Yet it appears that pharmaceutical companies and developed-country parties to the FTAA are very concerned about this market. Why?

### *The Theoretical Context*

It would benefit us to examine the theory behind the arguments of both parties to the debate more carefully. It has been stated, for example, that developed countries believe that strict IPR rights are necessary to protect innovation, profit, and incentives for research. Pharmaceuticals are tremendously expensive to bring to market. Researchers must be well-paid; the cost of the necessary technology and equipment is high; drugs often require years, even decades of painstaking research to be made suitable for production; and quite often, a drug must go back to the drawing board after years of development, meaning that the process must start over, requiring further expenditures. Indeed, Pharmaceutical Research and Manufacturer's Association (PhRMA), an association representing "the leading research-based pharmaceutical and biotechnology companies in the United States,"<sup>11</sup> estimates that the cost of bringing a new drug to market is between \$500-\$600 million.<sup>12</sup>

However, these high costs generally only apply to the *initial* producer of a drug. As generic producers do not have to share in the costs of research, they can offer the same medications at lower prices with far lower inputs, and without endangering profits,



effectively becoming more competitive in world markets. From the perspective of the major developed-country pharmaceutical companies, this is why IPR rules need strict protection at the international level. In a situation wherein producers are permitted to manufacture patented medications on a generic basis at lower prices, patentholder profits will seriously decline. This will produce a peculiar variation of the “free rider” problem as each company, knowing that its new patents will inevitably be manufactured cheaper elsewhere, will have little incentive to continue creating new medicines. Indeed, the more practical plan under such conditions would be to wait for some other company to develop the drug, then produce it generically to avoid the associated R&D costs and maximize profits. High prices, the major pharmaceutical companies argue, are to offset the high costs of R&D, and pressure for enhanced IPR rights at the international level is merely an act of self-defense.

#### *Ramifications For The FTAA*

Regardless of the perspective one has on the normative issues surrounding pharmaceuticals, industry experts believe that “the fully integrated pharmaceutical company model will not work for much longer, as companies cannot produce enough blockbuster drugs to fuel long-term growth.”<sup>13</sup> According to Euromonitor International, the pharmaceutical industry today faces a daunting array of obstacles, including “unproductive pipelines producing few blockbusters, patent expirations and resultant generic competition that are leading to slowing sales, continued sales force expansion that delivers diminishing returns, health care economic change, manufacturing issues, drug importation...and more.”<sup>14</sup> Although it has been showing strong short-term growth in recent years, the pharmaceutical industry is believed by many to show poor potential for long-term growth for the reasons enumerated above, among others.<sup>15</sup> Nonetheless, the industry is worth approximately \$211.2

billion annually to the US economy, the main developed-country partner to the FTAA agreements.<sup>16</sup> Under conditions of global free trade, generic drug production has the potential to spill over into the US market: if consumers can buy generic drugs of equivalent value on world markets for a reduced price, many are likely to avoid purchasing more expensive “brand-name” alternatives, which will undercut profits, exacerbating and adding to the problems of an industry that already faces an uncertain future.

The final form of the FTAA text is similarly uncertain. The sections on intellectual property are heavily bracketed, with only the most basic principles being agreed upon. Section 1.1 states that “[1.1. Each Party shall [provide] [ensure] in its territory to the nationals of the other Parties adequate and effective protection and enforcement of intellectual property rights. Each Party shall ensure that measures to protect and enforce those rights do not themselves become barriers to legitimate trade [nor socioeconomic and technological development].]”<sup>17</sup> But what constitutes “adequate and effective” protection? This question is further problematized by Section 1.4, which allows for “measures to promote and protect public health” carried out “in a manner that takes into account each Party’s right to protect public health and, in particular, to promote access to [existing] medicines and to the research and development of new medicines.]”<sup>18</sup> Section 3.1 reiterates this ostensible commitment by stating that “Each Party may, in formulating or amending its laws and regulations, adopt measures necessary to protect public health and nutrition, or to promote public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Chapter.]”<sup>19</sup> So far, the FTAA text seems to approve the loosening of IPR rules not only for the purpose of protecting public health, but allowing growing industries in developing countries to “graduate” to fuller integration in world markets.

However, the language is really not as generous as it appears; it is subtly contradictory, apparently supporting two different visions of IPR at once. One asserts the rights of patentholders, the other governments to pursue policy goals. The former of these orientations is demonstrated by Section 1.2, which states that “Each Party may implement in its law [, although it is not obliged to do so,] more extensive protection of intellectual property rights than is required under this Chapter, provided that such protection is not [inconsistent with][contrary to] this Chapter.”<sup>20</sup> Interestingly, Section 1.2, which allows latitude for member governments to pursue stricter IPR policies, is one of the rare clauses in Chapter XX which is only partially bracketed. Section 1.2 provides textual support for the United States’ desire to enforce a “TRIPS-Plus” IPR protection regime which goes beyond WTO rules. Both have textual support, and, given the bracketed nature of most of the chapter, both are potentially subject to change. The negotiations now underway will determine which of these two potential normative orientations will be more strongly emphasized in the final text.

## **THE FUTURE OF THE FTAA: U.S. PRESSURE FOR A TRIPS-PLUS REGIME, AND POTENTIAL ALTERNATIVES**

As the previous section highlighted, the pharmaceutical industry is facing significant uncertainty. In the face of this uncertainty, the US government, as the largest player in the FTAA negotiations, and the actor with the most to lose if pharmaceutical profits plummet, has consistently been a strong advocate of tough IPR rules, and proposals throughout the process have consistently pushed for higher standards than those enforced by the WTO. For example, the US wants to include a provision in the FTAA that will render test data exclusivity to patentholders for a period of five years, a provision which does not exist in the

TRIPS.<sup>21</sup> The effect this will have is to make it essentially impossible for states to manufacture generic drugs without breaking FTAA regulations. It also means that scientific experimentation using data generated by companies in other states would be much harder to obtain, stunting the possibilities for scientific progress. In addition, the proposed IPR chapter in the FTAA text covers a wide variety of areas that are not covered by TRIPS, including encoded satellite signals, Internet domain names, genetic resources, traditional knowledge, and expressions of folklore.<sup>22</sup> While some of the new IPR regulations may benefit developing countries, most of them will act as de facto protectionist measures that will increase costs and make it difficult for them to compete with developed countries.

The United States seeks increased IPR protection, particularly in the pharmaceutical sphere, because it wants to preserve its dominance over an industry that brings hundreds of billions into the domestic economy each year, and because the industry is in many ways stagnating (although it shows strong short-term growth, it is unclear how much longer this can be sustained). The likely US position for the foreseeable future is to continue to use its economic muscle to goad smaller countries into signing bilateral agreements with it, as it has done with Chile.<sup>23</sup> Using this strategy, the U.S. could presumably isolate Brazil, which has consistently disagreed with it on numerous important aspects of southern integration, including agriculture, IPR, and trade in steel. Brazil could presumably counter by retreating into Mercosur and finding alternative trading partners (a less than optimal outcome).

The clash over IPR is a proxy for a number of essentially ideological differences between member states as to which goals should be emphasized under the new agreement—sustainable development, labour rights, and public health, or growth, profitability, and competitiveness. While may seem as if it is an insoluble issue, this paper will suggest a

number of potential solutions. They are presented in descending order,(from most likely to succeed to least).

### *1. Differential pricing.*

A differential pricing scheme could easily be worked into the FTAA agreement, which in theory makes provisions for special and differential treatment (SDT) for countries with smaller economies. Chapter V, Section 1.3, states that “[1.3 The differential treatment for countries with different levels of development and size of their economies is a fundamental principle of this Agreement. Both the Parties and the entities of the FTAA are obliged to abide by the provisions on the issue, found in all chapters of the Agreement.]”<sup>24</sup>

A differential pricing scheme would work well because it would enable the current system of IPR protection to continue unchanged, but would also make it easier for states whose populations cannot afford expensive medications to secure access to them. Developing countries would benefit from continued access to medicines at more reasonable prices, and patentholders would benefit by retaining control over their intellectual property, and deriving at least some revenue from them (as it stands, they are losing profits to generic production and outright piracy, which is a problem particularly in Brazil).<sup>25</sup> However, patentholders are likely to continue to be concerned, perhaps even more concerned, that drugs bought more cheaply in states benefiting from SDT will find their way back into the North American market at reduced prices.

### *2. Multilateral aid.*

This option would enable developed countries to provide medications to needy countries at their discretion, and could take place in the form of direct distribution of

medicines, or additional multilateral disbursement of official development assistance (ODA) that could be used to purchase the medicines from pharmaceutical companies. This solution would mostly be of benefit to developed countries and the pharmaceutical companies they represent, as it enables them to control the numbers of medicines made available to the developing-country parties to the agreement. It will, however, do little to help change the current IPR paradigm, and may in fact exacerbate existing problems, providing an excuse for the continuation of a system that often ignores legitimate public policy objectives in the name of protecting patentholder rights.

### *3. Reinstatement of TRIPS standards.*

The third, and least likely, option envisaged by this analysis is the return to TRIPS standards. Although theoretically TRIPS are the world standard on IPR in terms of international trade, the FTAA text goes beyond TRIPS in many areas, and once states sign on, the provisions will be binding, effectively rendering TRIPS legally null. Enforcing a TRIPS-compliant rather than a TRIPS-Plus regime of IPR protection would benefit developing countries most, as it would enable them to use discretion when making policy decisions with regard to compulsory licensing and parallel importing in order to meet public health objectives. However, history has shown this to be a divisive issue regionally, and unpopular with patentholders, and it is therefore highly unlikely that this policy will be entertained within the final text of the FTAA.

## **CONCLUSION: The Potential For Change**

The issue of IPR could be solved in any of the three ways laid out above; as has been shown, however, some are more likely than others. Given the intractability of major players

such as the US and Brazil, some sort of compromise in the form of a differential pricing scheme seems the most likely and workable option. In terms of flexibility for developing countries to pursue public health objectives it is not an ideal solution, but it is perhaps the most sensible way for the FTAA to go ahead while at the same time giving FTAA signatories some latitude to make policy choices. IPR is a hugely important issue to the FTAA, with many important dimensions—moral, ideological, and economic—and if negotiations continue on their current track, there is unlikely to be a resolution, or an FTAA.

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## NOTES

<sup>1</sup> Caroline Thomas, "Trade policy and the politics of access to drugs," *Third World Quarterly* 23(2): 251-264.

<sup>2</sup> Thomas, 252-253.

<sup>3</sup> Sarah Joseph, "Pharmaceutical Corporations and Access to Drugs: The 'Fourth Wave' of Corporate Human Rights Security," *Human Rights Quarterly* 25(2): 425-452.

<sup>4</sup> Joseph, 425.

<sup>5</sup> Joao Guilherme Biehl, "The Activist State: Global Pharmaceuticals, AIDS, and Citizenship in Brazil," *Social Text* 22(3): 105-132.

<sup>6</sup> M. Gregg Bloche & Elizabeth R. Jungman, "Patent Immorality?," *American Journal of Bioethics* 2(3): 48-49.

<sup>7</sup> Source: The Association of the British Pharmaceutical Industry (ABPI), <http://www.abpi.org.uk/statistics/section.asp?sect=1#6>.

<sup>8</sup> Source: Verband Forschender Arzneimittelhersteller (VFA), "The Pharmaceutical Market Worldwide," [http://www.vfa.de/download/SHOW/en/statistics/pharmaceuticalmarket/vfastat\\_41\\_en\\_fa\\_mt.pdf](http://www.vfa.de/download/SHOW/en/statistics/pharmaceuticalmarket/vfastat_41_en_fa_mt.pdf).

<sup>9</sup> Ibid.

<sup>10</sup> Thomas, 252.

<sup>11</sup> PhRMA, "Who We Are," <http://www.phrma.org/whoweare/>.

<sup>12</sup> PhRMA,

<sup>13</sup> Euromonitor International, "Pharmaceuticals in the USA (October 2004)," <http://www.euromonitor.com.proxy.lib.sfu.ca/gmid/default.asp>.

<sup>14</sup> Ibid.

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

<sup>17</sup> FTAA Draft Agreement 2003, Chapter XX. [http://www.ftaa-alca.org/FTAADraft03/ChapterXX\\_e.asp](http://www.ftaa-alca.org/FTAADraft03/ChapterXX_e.asp).

<sup>18</sup> Ibid.

<sup>19</sup> Ibid.

<sup>20</sup> Ibid.

<sup>21</sup> Ann Silversides, "New free trade agreement could make generic drugs less accessible in the Americas," *Canadian Medical Association Journal* 170(6): 935.

<sup>22</sup> Center for International Law, "Intellectual Property in the FTAA: Little Opportunity and Much Risk," [http://www.iprsonline.org/resources/docs/IP\\_FTAA\\_Oct03.pdf](http://www.iprsonline.org/resources/docs/IP_FTAA_Oct03.pdf), 3.

<sup>23</sup> NotiSur, "Chile: U.S. Congress Approves Free Trade Agreement," [http://ladb.unm.edu.proxy.lib.sfu.ca/prot/search/retrieve.php3?ID\[0\]=25418](http://ladb.unm.edu.proxy.lib.sfu.ca/prot/search/retrieve.php3?ID[0]=25418).

<sup>24</sup> FTAA Draft Agreement 2003, Chapter V, [http://www.ftaa-alca.org/FTAADraft03/ChapterV\\_e.asp](http://www.ftaa-alca.org/FTAADraft03/ChapterV_e.asp).

<sup>25</sup> Brazil-U.S. Business Council, "Counterfeiting and Piracy in Brazil: The Economic Impact," [http://www.brazilcouncil.org/usermedia/MediaLibrary/Counterfeiting\\_and\\_Piracy\\_in\\_Brazil.pdf](http://www.brazilcouncil.org/usermedia/MediaLibrary/Counterfeiting_and_Piracy_in_Brazil.pdf).