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**FOREIGN INFRINGEMENT OF INTELLECTUAL  
PROPERTY RIGHTS: IMPLICATIONS FOR  
SELECTED U.S. INDUSTRIES**

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**Office of Industries**  
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**Amanda Horan, Christopher Johnson, and Heather Sykes<sup>1</sup>**

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**ABSTRACT:** The primary purpose of this paper is to review foreign IPR infringement issues affecting selected U.S. industries, with a particular emphasis on patent, trademark, and copyright infringement. Although the review is primarily based on qualitative information, some attempts to measure the effects of IPR infringement quantitatively also are reviewed. To provide background and context for the analysis, the authors discuss the problem of foreign IPR infringement for U.S. industry; describe certain U.S. trade laws and international agreements that attempt to address such infringement; review examples of inadequate foreign patent, trademark, and copyright protection and their implications for selected U.S. industries; and describe U.S. private and public sector efforts to address such problems. The paper finds that (1) intellectual property protection is essential to encouraging creative expression and the development of new products in a number of industries; (2) the development of intellectual property-based products is generally far more expensive than their manufacture or duplication; (3) inadequate IPR protection leaves firms vulnerable to infringement, causing them to risk their investment and reputations; (4) foreign IPR infringement results in billions of dollars in lost revenues for U.S. industries; (5) current estimates likely understate the actual cost of infringement; and (6) more rigorous empirical research is needed to confirm the actual amount of U.S. industry losses due to inadequate IP protection.

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# FOREIGN INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS: IMPLICATIONS FOR SELECTED U.S. INDUSTRIES

## Introduction

As tariffs are reduced and eliminated as a result of global trade liberalization, nontariff measures have become increasingly more visible as significant impediments to U.S. industry and trade. Among these nontariff measures (NTMs), foreign intellectual property right (IPR) infringement is responsible for billions of dollars in lost revenues for U.S. industries dependent on intellectual property. The purpose of this paper is to provide background on the issue of foreign IPR infringement and assess the implications for U.S. industry of inadequate protection of three of the most common intellectual property forms: patents, trademarks, and copyrights.<sup>2</sup> Although the assessment is largely a qualitative one, some attempts to measure the effects of IPR infringement quantitatively also are reviewed.

In this paper, we (1) discuss why foreign IPR infringement is a problem to U.S. industry; (2) describe certain U.S. trade laws and international agreements that deal with intellectual property and the problems of infringement; (3) discuss qualitatively the views of U.S. industry, government and academic representatives on the effects of foreign infringement of patents, trademarks, and copyrights on selected industries; (4) discuss some attempts to measure quantitatively the effects of IPR infringement on U.S. industry and trade; and (5) describe U.S. public and private sector efforts to counter such foreign IPR infringement.

## The Problem of Foreign IPR Infringement

### *Reasons for IPR Protection*

The costs of developing new products embodying intellectual property are high.<sup>3</sup> The greatest expense in bringing most intellectual property-intensive goods and services<sup>4</sup> to market is in development rather than manufacture or duplication. Developing a new software operating system, making a major motion picture, producing a new video game or recording album, writing a new software application program, or releasing fiction books and educational texts can cost millions of dollars. Pharmaceutical, agricultural, chemical, and biotechnology firms also spend large amounts in discovering and developing new products.<sup>5</sup> For example, U.S. pharmaceutical manufacturers report spending an estimated

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<sup>2</sup> Government Accountability Office (GAO), *Intellectual Property: U.S. Efforts Have Contributed to Strengthened Laws Overseas, but Challenges Remain*, Sept. 2004, p. 6.

<sup>3</sup> Pharmaceutical Research and Manufacturers of America (PhRMA) representatives, interview by USITC staff, Washington, DC, Feb. 25, 2004; Michael P. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Washington, DC: Brookings Institution, 1998), pp. 4-10; and Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (Washington, DC: Institute for International Economics, Aug. 2000), pp. 57-60.

<sup>4</sup> For the purposes of this study intellectual property-intensive goods and services include those “which are costly to produce and subject to considerable uncertainty in costs and demand but are often straightforward to produce in bulk,” and, thus, are often provided legal protection through such means as patents, trademarks, copyrights, and other methods of intellectual property protection. Examples include pharmaceuticals, software, motion pictures, and recorded entertainment. Maskus, *Intellectual Property Rights in the Global Economy*, pp. 2-3.

<sup>5</sup> PhRMA representatives, interview by USITC staff, Feb. 25, 2004; and “PhRMA, Health Care Advocates to Fight Efforts by Generic Industry to Jeopardize the Progress in Medical Research,” *PhRMA News Release*, Feb. 25, 2002, p. 1, found at <http://www.phrma.org>, retrieved Feb. 26, 2005.

\$38.8 billion in research and development (R&D) in 2004, representing 15.9 percent of their total sales that year.<sup>6</sup> Such investment often entails significant risk since the resultant products are not assured of success in the market place.<sup>7</sup> Only a small percentage of new drugs, software programs, books, or music recordings become financially successful for their producers.<sup>8</sup>

While the costs and risks involved in product development are high, the costs of product imitation or intellectual property infringement are generally low.<sup>9</sup> Once a successful book is published, it may be replicated with little effort by photocopying, commercial reprinting, or unauthorized electronic distributions.<sup>10</sup> A successful new software program may easily be copied by digital means and transmitted via the Internet. A drug approved by the government for marketing after extensive R&D and clinical testing by the developer may be duplicated with much less cost by others.<sup>11</sup>

Because individuals or companies developing new products usually do so in anticipation of having a good chance of receiving an adequate return on their investment, governments often provide a minimum level of market exclusivity to inventors or developers of products.<sup>12</sup> Nevertheless, there are diverse opinions<sup>13</sup> about the amount of exclusivity that should be provided to a protected product or process.<sup>14</sup> One result of market exclusivity is that it permits the intellectual property rightholder to demand higher prices than she otherwise could if she faced competition in providing the protected product.

In recent years, a number of developing country leaders have come to recognize the importance of intellectual property protection to the development of their economies.<sup>15</sup> However, especially in the patent area, other leaders and scholars believe that intellectual property protection could affect the global availability of advanced agricultural inputs and medicines.<sup>16</sup> Leaders of some developing countries also argue that their societies can never advance educationally or technologically if they do not have lower cost access to products stringently protected by developed countries.<sup>17</sup> That being said, U.S. industry representatives point to recent studies conducted by industry groups as well as new studies commissioned

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<sup>6</sup> PhRMA Annual Membership Survey 2005, found at <http://www.phrma.org>, p. 1.

<sup>7</sup> Maskus, *Intellectual Property Rights in the Global Economy*, pp. 57-60.

<sup>8</sup> *Ibid.*, pp. 52-54; and Ryan, *Knowledge Diplomacy*, pp. 4-5.

<sup>9</sup> International Anti-Counterfeiting Coalition (IACC) representatives, interview by USITC staff, Jan. 20, 2004.

<sup>10</sup> Association of American Publishers representative, U.S. Department of State, Foreign Service Institute (FSI) course, "Intellectual Property Rights," Arlington, VA, July 15-16, 2004.

<sup>11</sup> PhRMA representatives, interview by USITC staff, Washington, DC, Feb. 25, 2004.

<sup>12</sup> Robert W. Hahn, "An Overview of the Economics of Intellectual Property Protection," ch. in *Intellectual Property Rights in Frontier Industries* (Washington, DC: AEI/Brookings Center for Regulatory Studies, 2005), p. 11; and Bernard Hoekman and Michel Kosteci, "Intellectual Property," ch. in *The Political Economy of the World Trading System: From GATT to the WTO* (Oxford: Oxford University Press, 1997), p. 146.

<sup>13</sup> Washington International Trade Association (WITA), "You Must Be TRIPing!: What's All the Fuss About TRIPs?," Washington, DC, Mar. 2, 2005.

<sup>14</sup> One scholar states that "[there] is a sound justification for public interest in defining and sustaining [IPR] rights in order to overcome the natural failure of markets to encourage investment in new technologies and artistic works." But, he continues, "there is also justification for distributing the fruits of such invention and creation widely to consumers at relatively low cost." Maskus, *Intellectual Property Rights in the Global Economy*, p. 9.

<sup>15</sup> Hoekman and Kosteci, *The Political Economy of the World Trading System: From GATT to the WTO*, pp. 148-149.

<sup>16</sup> *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, Sept. 2002, pp. 57-69, found at <http://www.iprcommission.org/papers/pdfs/fullfinal.pdf>; Donald G. Richards, *Intellectual Property Rights and Global Capitalism* (Armonk, NY: M.E. Sharp, 2004), pp. 141-166; and Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (London and New York: Zed Books Ltd., 2000), pp. 35-37, and 167-202.

<sup>17</sup> WITA, "You Must Be TRIPing!," Washington, DC, Mar. 2, 2005.

by international organizations such as the World Intellectual Property Organization (WIPO). These studies demonstrate or aim to demonstrate that increased IPR protection in developing countries would lead to greater numbers of jobs, increased opportunities for foreign direct investment (FDI), and increased economic welfare in general.<sup>18</sup>

### *Importance of IPR-Intensive Industries to the U.S. Economy*

U.S. industries that are the most dependent on IPR are particularly important to the strength of the U.S. economy. They are characterized by their significant contributions to U.S. economic output, above average growth in employment, and higher than average wages and salaries. A study completed in 2004 shows that value added<sup>19</sup> in the core copyright industries (including the motion picture, recording, business and entertainment software, and publishing industries)<sup>20</sup> reached \$626.2 billion, or 6 percent of the U.S. economy, in 2002.<sup>21</sup> These copyright industries, meanwhile, accounted for employment of an estimated 5.5 million, or 4 percent of total U.S. employment of 136.5 million<sup>22</sup> in that same year. Foreign sales and exports by U.S. copyright businesses amounted to almost \$89 billion in 2002, exceeding those of several other major U.S. industry sectors (table 1).

**Table 1**  
**Estimated U.S. exports and foreign sales for selected industries, 2002**

<b>U.S. Industry</b>	<b>Billions of dollars</b>
Core copyright industries .....	88.3
Chemicals .....	83.6
Motor vehicles, parts, and accessories .....	50.4
Aircraft and associated equipment .....	43.9
Food and live animals .....	40.3

Sources: U.S. Department of Commerce and the International Intellectual Property Alliance.

<sup>18</sup> Sahid Alikhan, *Socio-Economic Benefits of Intellectual Property Protection in Developing Countries* (Geneva: World Intellectual Property Organization (WIPO), 2000), pp. 61-63; Betty Mould-Iddrisu, *Introduction to Intellectual Property Rights: A Developing Country's Perspective*, July 25, 2003, found at <http://usinfo.state.gov/products/pubs/intelprp/perspect.htm>; IIPA, *Initial Survey of the Contribution of the Copyright Industries to Economic Development*, Apr. 2005, pp. 1-10, found at [http://www.iipa.com/pdf/2005\\_Apr27\\_Economic\\_Development\\_Survey.pdf](http://www.iipa.com/pdf/2005_Apr27_Economic_Development_Survey.pdf); Edward Mansfield, "Intellectual Property Rights, Technological Change, and Economic Growth," in *Intellectual Property Rights and Capital Formation in the Next Decade* (Lanham: University Press of America, 1988), Charles E. Waler and Mark Bloomfield, eds., pp. 107-145; Maskus, "The International Regulation of Intellectual Property," 134 *Weltwirtschaftliches Archiv* (1998), p. 154; Maskus, *Intellectual Property Rights in the Global Economy*, pp. 45-46; Business Software Alliance (BSA), *Contribution of the Packaged Software Industry to the Latin American Economies* (New York: PricewaterhouseCoopers, Sept. 1999), pp. 1-53; and U.S. industry representatives, written communications to USITC staff, Jan. 2003.

<sup>19</sup> "Value added" refers to gross domestic product (GDP) by industry. It is an industry's gross output (sales or receipts and other operating income, commodity taxes and inventory change) minus its intermediate inputs (consumption of goods and services purchased from other industries or imported). The sum of the value added of all U.S. industries is equal to U.S. GDP.

<sup>20</sup> For purposes of brevity (and consistent with general U.S. industry usage), in this report, the "copyright industries" refer to those industries that manufacture and/or distribute copyright-protected products. Stephen E. Siwek, *Copyright Industries in the U.S. Economy* (Economists Inc.: Washington, DC, 2004), p. i., found at [http://www.iipa.com/pdf/2004\\_siwek\\_full.pdf](http://www.iipa.com/pdf/2004_siwek_full.pdf), retrieved May 31, 2005.

<sup>21</sup> *Ibid.*, pp. iii-vi.

<sup>22</sup> Estimated by U.S. Bureau of Labor Statistics.

For the pharmaceutical industry, total U.S. production amounted to an estimated \$100 billion in 2001, or 25 percent of global production of drugs and medicines of \$398 billion.<sup>23</sup> Further, while U.S. exports totaled \$32 billion, or less than 15 percent of world exports of pharmaceuticals in that year, U.S. pharmaceutical industry representatives estimate that total sales abroad, including those of U.S. foreign affiliates, amounted to \$48 billion.<sup>24</sup> According to the industry representatives, total estimated sales abroad reached \$81 billion in 2004.<sup>25</sup> They point out that the pharmaceutical industry directly employed more than 400,000 people in the United States and many more abroad in 2004.<sup>26</sup>

The importance of intellectual property to the U.S. economy is also reflected in the magnitude of U.S. receipts and payments of royalties and license fees in connection with both domestic and foreign transactions related to patent, trademark, copyright, broadcast, and other intangible rights; and the rights to distribute, use, and reproduce general-use computer software (see text box). Receipts of royalties and license fees by U.S. companies from foreign affiliated and unaffiliated firms increased by 9 percent to \$48.2 billion in 2003 from the previous year.<sup>27</sup> Meanwhile, U.S. payments of royalties and license fees to affiliated and unaffiliated firms overseas increased by 4 percent to \$20 billion in 2003, resulting in a U.S. surplus of \$28.2 billion in such transactions.<sup>28</sup>

#### Cross-Border Trade - Royalties and License Fees

U.S. receipts of royalty and license fees, and film and television tape rentals, reflect U.S. exports of intangible intellectual property, whereas U.S. payments of royalties and license fees, and film and television tape rentals, reflect U.S. imports of such property. Many transactions involving intangible intellectual property are intrafirm transactions, carried out between parent firms in the home market and foreign affiliates in host markets. In 2003, intrafirm trade of royalties and license fees accounted for approximately 74 percent of cross-border trade in intangible intellectual property rights.<sup>1</sup> Intrafirm trade offers additional protections, as foreign affiliates can monitor its use in host-country markets on behalf of the parent firm.

Source: U.S. Department of Commerce, Bureau Economic Analysis, *Survey of Current Business*, Oct. 2004, p. 54.

### *Industry Estimates of Costs of Foreign Infringement*

Because of the economic importance of intellectual property industries to the U.S. economy, mounting revenue losses due to foreign IPR infringement are of concern to U.S. industry and government officials. In a 2005 report to the United States Trade Representative (USTR), the International Intellectual Property Alliance (IIPA) estimated losses due to copyright piracy in 52 selected countries for 5 core copyright industries to be \$12.5 billion (table 2).<sup>29</sup> The business software and sound recording industries had the highest estimated losses cited. The Business Software Alliance (BSA) reports that losses due to

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<sup>23</sup> National Science Foundation (NSF), *Science and Engineering Indicators 2004*, Vol. 2, Arlington, VA, 2004, app. table 6-1.

<sup>24</sup> *Ibid.*; and *PhRMA Annual Membership Survey 2005*, table 8, p. 39.

<sup>25</sup> *PhRMA Annual Membership Survey 2005*, table 8, p. 39.

<sup>26</sup> Ross DeVol, and others, *Biopharmaceutical Industry Contributions to State and U.S. Economies* (Santa Monica: CA: Milken Institute), 2004, p. 1, found at <http://www.milkeninstitute.org>, retrieved Sept. 13, 2005.

<sup>27</sup> U.S. Bureau of Economic Analysis (BEA), "U.S. International Services," *Survey of Current Business*, Oct. 2004, pp. 32-33.

<sup>28</sup> Royalty and license fees for the use of general-use computer software and use of industrial manufacturing processes in the pharmaceutical and telecommunications industries were responsible for the largest portion of U.S. receipts from unaffiliated foreign companies in 2003. BEA, *Survey of Current Business*, pp. 32-33.

<sup>29</sup> IIPA estimates that total global losses due to piracy at \$25-30 billion annually, since losses in countries such as the United States and EU member countries are not included in the 52 selected countries for which estimates were made above. For further information on how these estimates were made, see *IIPA, 2005 Special 301 Report on Global Copyright Protection and Enforcement*, Feb. 11, 2005, app. A and pp. 1-5.

Internet piracy have been rising rapidly in recent years, and are believed to contribute to an increasing percentage of overall global piracy losses.<sup>30</sup> A survey conducted for the Business Software Alliance (BSA) in 2005 suggests that 35 percent of computer software installed worldwide in 2004 was pirated.<sup>31</sup> U.S. Government and industry sources estimate that by 2008 software piracy will annually cost the U.S. economy 175,000 jobs, \$4.5 billion in wages, and nearly \$1 billion in tax revenues.<sup>32</sup>

**Table 2**  
**Estimated 2004 U.S. sales losses due to copyright piracy in 52 selected countries**

U.S. Industry	Estimated losses (Millions of dollars)
Business Software Applications .....	6,155.0
Sound Recordings .....	2,437.8
Entertainment Software .....	1,743.9
Motion Pictures .....	1,635.5
Books .....	571.0
Total .....	12,543.2

Source: International Intellectual Property Alliance, 2005.

Losses to other industries are also believed to be substantial. The International Chamber of Commerce Commercial Crime Services Division reports that counterfeiting accounts for around 5-7 percent of world trade.<sup>33</sup> Counterfeit drugs alone are estimated to account for 10 percent of all pharmaceuticals.<sup>34</sup> Meanwhile, the cost to the U.S. automobile industry due to counterfeiting is estimated to be \$3 billion.<sup>35</sup> The value of imported goods seized by U.S. Customs and Border Protection for IPR infringement<sup>36</sup> in 2003 amounted to \$94 million, representing a decline of 5 percent over the previous year.<sup>37</sup> Among the imported goods seized most often by Customs in that year were cigarettes, wearing apparel, handbags, media, consumer electronics, watches, footwear, toys and electronic games, sunglasses, and headwear.<sup>38</sup>

<sup>30</sup> Business Software Alliance (BSA), "Enhancing Trade Opportunities," *Trade Policy News*, 2000-2002, p. 1, found at <http://www.bsa.org>, retrieved Apr. 13, 2005.

<sup>31</sup> BSA, *Second Annual BSA and IDC Global Software Piracy Study*, May 2005, pp. 1-13, found at <http://www.bsa.org/usa/press/newsreleases/Global-Piracy-Study-05-18-2005.cfm>, retrieved May 31, 2005.

<sup>32</sup> James Rogan, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office (USPTO), before the Subcommittee on Commerce, Justice, State and the Judiciary, Committee on Appropriations, U.S. House of Representatives, Apr. 23, 2002, found at <http://www.uspto.gov>, retrieved May 25, 2005; and BSA, "Software Theft - Stopping the Piracy of Intellectual Property," 2000-2002, *Copyright Policy News*, p. 1, found at <http://www.bsa.org>, retrieved Apr. 13, 2005.

<sup>33</sup> International Chamber of Commerce (ICC) Commercial Crime Services, "A Brief Overview of Counterfeiting," pp. 1-2, 2001, found at <http://www.iccwbo.org>, retrieved June 28, 2004.

<sup>34</sup> First Global Congress on Combating Counterfeiting, "The Impact and Scale of Counterfeiting," *Fact Sheet*, May 25-26, 2004, pp. 1-4, found at <http://www.anti-counterfeitcongress.org>, retrieved Oct. 27, 2004.

<sup>35</sup> Frank Giovinnazzi, American International Automobile Dealers Association, "Federal Government Announces New Anti-Piracy Initiative," found at <http://www.aiada.org>, retrieved Oct. 27, 2004, pp. 1-2.

<sup>36</sup> Although U.S. Customs and Border Protection data pertain to seizures for all types of IPR infringement, most of the goods seized consist of counterfeit and pirated products ("counterfeit" refers to trademark infringement and "pirated" refers to copyright infringement). U.S. Department of Homeland Security official, telephone interview by USITC staff, May 10, 2005.

<sup>37</sup> U.S. Customs and Border Protection, L.A. Strategic Trade Center, "FY 2002 and FY 2003 Top IPR Commodities Seized," found at <http://www.cbp.gov>, retrieved Apr. 1, 2005.

<sup>38</sup> U.S. Customs and Border Protection, "FY 2002 and FY 2003 Top IPR Commodities Seized," p. 1.

## U.S. Trade Laws and International Agreements Related to IPR

This section provides some general information on U.S. trade laws used to address foreign IPR infringement. It also describes some of the most prominent international agreements pertaining to intellectual property rights and the organizations that administer them, including WIPO and the World Trade Organization (WTO).

### *Major U.S. Trade Laws*

#### **Section 301 and Special 301**

The Trade and Tariff Act of 1984<sup>39</sup> amended Section 301 of the Trade Act of 1974,<sup>40</sup> the principal U.S. statute for addressing foreign trade barriers, to identify inadequate protection of intellectual property as an unreasonable trade practice. The amended law authorizes the President to impose sanctions, including removal of tariff preferences against foreign countries failing to meet their IPR obligations. USTR has used Section 301 provisions and the threat of sanctions to address copyright, patent, and trademark infringement with a number of countries.

The IPR provisions of the 1984 Trade and Tariff Act were strengthened by the passage of the 1988 Omnibus Trade And Competitiveness Act, which contains a provision referred to as “Special 301.”<sup>41</sup> Special 301 requires USTR to provide an annual report to identify countries that deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to U.S. persons or firms that rely on IPR. Countries with laws, policies, or practices that have the greatest adverse effects on relevant U.S. producers or products must be designated as “priority foreign countries” unless USTR finds that the countries are entering into good faith negotiations or are making significant progress in bilateral or multilateral negotiations to provide adequate and effective IPR protection.

Priority foreign countries are subject to investigation and, if necessary, trade sanctions or other actions by USTR under Section 301 provisions.<sup>42</sup> Ukraine was the only country designated as a “priority foreign country” in 2005.<sup>43</sup> USTR also created a “priority watch list” (table 3) and “watch list” for those countries that, while not considered to be as problematic as “priority foreign countries,” are still

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<sup>39</sup> P.L. 98573, 98 Stat. 2948.

<sup>40</sup> Section 301 of the 1974 Trade Act, as amended, is the principal U.S. statute for addressing unfair foreign practices affecting U.S. exports of goods or services. As such, the provision may be used to enforce U.S. rights under international trade agreements and respond to unjustifiable or discriminatory foreign practices that restrict U.S. commerce such as inadequate protection of intellectual property rights. United States Trade Representative (USTR), *2005 Trade Policy Agenda and 2004 Annual Report of the President of the United States on the Trade Agreements Program* (Washington, DC: U.S. Government Printing Office, Mar. 1, 2005), pp. 256-257.

<sup>41</sup> Trade Act of 1974, P.L. No. 93-316, as amended by the Omnibus Trade and Competitiveness Act of 1988, P.L. No. 100-418, 102 Stat. 1107. See 19 U.S.C. § 2242(a)(A)(2001).

<sup>42</sup> The range of actions that may be taken under Section 301 is broad and includes any action that is within the power of the President with regard to trade or other pertinent aspects of U.S. foreign relations. For instance, among other things, under such authority, the President, or the USTR as his representative, may (1) suspend trade agreement concessions, (2) impose duties or other import restrictions, or (3) enter into agreements with the subject country to eliminate the offending practice or to provide compensatory benefits for the United States. USTR, *2005 Trade Policy Agenda and 2004 Annual Report*, pp. 256-257.

<sup>43</sup> Ukraine, designated for the fifth year in a row as the only priority foreign country, is cited in the 2005 Special 301 review for, among other things, continued failure to implement necessary IPR laws and rules providing for effective protection and enforcement of IPR, and rampant optical disc piracy. USTR, *2005 Special 301 Report*, Apr. 29, 2005, p. 1, found at <http://www.ustr.gov>, retrieved Sept. 7, 2005.

determined to merit U.S. attention to address IPR problems. Countries can also be selected for out-of cycle reviews under the Special 301 process when warranted. (See text box below outlining the results of such a review completed for China in early 2005).

**Table 3**  
**2005 Special 301 Priority Watch List**

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Argentina	Kuwait
Brazil	Lebanon
China	Pakistan
Egypt	Philippines
India	Russia
Indonesia	Turkey
Israel	Venezuela

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Source: USTR, *2005 Special 301 Report*, Apr. 29, 2005.

### **Section 337**

Section 337 of the Tariff Act of 1930, as amended, addresses imported products or processes alleged to violate U.S. intellectual property rights. Specifically, the law provides for investigations to be conducted by the U.S. International Trade Commission (USITC) to determine whether foreign producers of goods imported into the United States are engaging in unfair trade practices.<sup>44</sup> Most of the cases brought under Section 337 involve claims of infringement of U.S.-held intellectual property rights such as U.S. patents, copyrights, trademarks, or registered semiconductor designs or mask works.<sup>45</sup> If a petitioner can show that infringement has occurred under Section 337, the USITC can issue orders that exclude the product from entry into the United States or direct offending parties to cease and desist from certain practices.<sup>46</sup>

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<sup>44</sup> U.S. International Trade Commission (USITC), *Understanding Investigations of Intellectual Property and Other Unfair Trade Practices in Import Trade*, found at <http://www.usitc.gov>, retrieved May 9, 2002.

<sup>45</sup> USTR, *2005 Trade Policy Agenda and 2004 Annual Report*, p. 267; and USITC, *Understanding Investigations of Intellectual Property and Other Unfair Trade Practices in Import Trade*, p. 1.

<sup>46</sup> Hahn, "Overview of the Economics of Intellectual Property Protection," p. 1; and Hoekman and Kostecki, *The Political Economy of the World Trading System*, pp. 144-158.

### China: Special 301 Out-of-Cycle Review

In early 2005, USTR conducted a Special 301 out-of-cycle review (OCR) of commitments made by China in 2004 at an annual meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT) to significantly reduce IPR infringements. Based on the review, the United States found that although China had made significant efforts to improve the protection of IPR, it had not resolved critical deficiencies in IPR protection and enforcement and, as a result, infringements remained at epidemic levels, and, thus, China did not meet its JCCT commitments.

Among the remaining IPR problems in China reported by USTR in conjunction with the OCR were (1) unacceptably high levels of infringement, (2) lack of transparency in the IPR regime, (3) insufficient deterrent effect in the IPR criminal enforcement system, (4) inadequate enforcement of IPR, (5) non-accession to WIPO Internet Treaties, (6) continued unauthorized use of software by certain government institutions, and (7) counterfeiting and patent infringement with respect to pharmaceuticals.

1. With regard to high infringement levels, estimated U.S. losses resulting from copyright piracy in China amount to between \$2.5 billion and \$3.8 billion annually. Meanwhile, trademark counterfeiting has not been significantly reduced. In 2004, the value of Chinese counterfeits seized by U.S. Customs increased by 47 percent from \$94 million to \$134 million, representing 67 percent of seizures in 2004.
2. Despite TRIPS requirements and JCCT commitments, lack of transparent information on IPR infringement levels and enforcement activities in China continues to be a problem. Further, transparency in rulemaking continues to be a problem as government regulatory agencies often refuse to make drafts of new rules widely available for public comment.
3. Criminal enforcement in China has not been shown to have any deterrent effect on infringers, as required by Article 61 of the TRIPS Agreement and by JCCT commitments made by China. Chinese authorities have pursued criminal prosecutions in a relatively small number of cases despite China's commitment to impose more criminal penalties with respect to copyright piracy and trademark counterfeiting activities. Further, by not holding Internet service providers liable for infringing material hosted on their networks, efforts to actually impose criminal liability is hindered.
4. The OCR review indicated that China's IPR enforcement efforts are hindered by inadequate coordination among Chinese Government agencies, local protectionism and corruption, high thresholds for initiating investigations and prosecutions, lack of training, and inadequate and non-transparent processes. Excessive reliance on administrative enforcement, as opposed to civil and criminal enforcement, is non-deterrent and, thus, not effective. There reportedly has been a decline in the number of cases forwarded for criminal investigation, even for commercial-scale piracy and counterfeiting.
5. Despite increased Internet and digital piracy, and despite a JCCT commitment, China has not yet acceded to the WIPO Internet Treaties.
6. Widespread use of unauthorized software continues in government offices in China. While some of the governments of major provinces have instituted measures requiring use of only legal software, many other provinces have not.
7. While China's patent laws largely comply with the TRIPS Agreement, OCR submissions indicate that patents for transgenic plants and animals are virtually unobtainable under Chinese law. Further, China has not yet implemented any meaningful data protections for pharmaceutical products, as required by TRIPS and China's JCCT commitments.

As China failed to significantly reduce IPR infringement levels, as required under the JCCT, the United States reported in the 2005 Special 301 Report that it will (1) use WTO instruments whenever appropriate to address its concerns about the unacceptable levels of counterfeiting in China, including the invocation of the transparency provisions of the TRIPS Agreement to request China to provide detailed documentation on aspects of IPR enforcement that affect U.S. rights under TRIPS; (2) elevate China onto the Priority Watch List on the basis of serious concerns about compliance with WTO TRIPS obligations related to IPR enforcement and three April 2004 JCCT commitments made by China to the United States, and also maintain Section 306 monitoring of China's implementation of 1992 and 1993 bilateral agreements with the United States; and (3) use the JCCT and IPR Working Group to secure new, specific commitments concerning additional actions that China will take that result in significant improvements in IPR protection and enforcement.

Sources: Adapted, with excerpts, from USTR, *2005 Special 301 Report*, Apr. 29, 2005.

### *International IPR Agreements*

The United States has signed a number of conventions related to IPR protection, including several international conventions and treaties that are now administered under the auspices of WIPO<sup>47</sup> (table 2) and the WTO. Two widely known international IPR agreements administered by WIPO are the Paris Convention and the Berne Convention (see table 4).<sup>48</sup> The Paris Convention deals with patent, trademark, and other industrial property protection and the Berne Convention addresses copyright issues. The Paris and Berne conventions provide both national treatment and most favored nation status for foreign countries, enabling inventors and other innovators an opportunity to apply for patents and copyrights in member countries on the same basis as nationals. A large number of countries, including the United States, have signed onto both conventions. Some other notable international intellectual property treaties are shown in table 2, including the WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT), together known as the WIPO Internet Treaties (text box).<sup>49</sup>

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was agreed upon by the United States and its trading partners in 1994 at the conclusion of the General Agreement on Tariffs and Trade (GATT) Uruguay Round of multilateral trade negotiations.<sup>50</sup> It is the only multilateral intellectual property agreement with a robust dispute resolution mechanism enforceable between governments. The TRIPS Agreement covers trademarks, patents, and copyrights (and related rights such as rights of performers, broadcasters, and producers of records, compact discs, and videos) (table 5). It also covers layout-designs of integrated circuits, geographical indications, and industrial designs. Generally, TRIPS (1) establishes minimum standards of protection of such rights, (2) prescribes procedures and remedies to be available in member states to enforce rights, (3) makes the WTO dispute-settlement mechanism available to address TRIPS-related disputes, and (4) extends basic WTO principles such as transparency, national treatment, and most favored nation treatment to intellectual property rights.

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<sup>47</sup> WIPO is part of the United Nations system. As administrator of the major international intellectual property treaties, its mission is to promote the protection of intellectual property throughout the world. As part of its responsibilities, WIPO helps member countries create multilateral norms, helps developing countries write and administer national laws and establish patent and copyright offices, and serves the member states through administration of the treaties. WIPO also provides a service to patent applicants from member countries under the Patent Cooperation Treaty (PCT), an international clearinghouse in which applicants may submit one patent application that may take effect in some or all (almost 100) PCT member countries. Ryan, *Knowledge Diplomacy*, pp. 125-139. For further information on WIPO, see its website at <http://www.wipo.int/about-wipo/en>.

<sup>48</sup> Maskus, *Intellectual Property Rights in the Global Economy*, p. 2.

<sup>49</sup> The WIPO Internet Treaties are discussed in more detail below in the copyright section of this study.

<sup>50</sup> The Uruguay Round Trade Agreements entered into force on Jan. 1, 1995, creating the WTO. See <http://www.wto.org>.

**Table 4**  
**Major international conventions, treaties, and other agreements on intellectual property**

<b>Agreement</b>	<b>Number of signatories</b>	<b>Objectives</b>	<b>Administrator</b>
Paris Convention (1883, revised in 1967)	129	Protection of patents, trademarks, and service marks, trade names, utility models, industrial designs, indications of sources or appellations of origin and the 'repression of unfair competition' based on principles of non-discrimination and national treatment. Allows for compulsory licensing.	WIPO
Berne Convention (1886, revised in 1971)	111	Basic copyright treaty based on principles of non-discrimination and national treatment.	WIPO
Madrid Agreement (1891)	31	Provides for the international registration of trademarks and service marks.	WIPO
Universal Copyright Convention (1952)	57	Copyright treaty accommodating U.S. statutory requirements and based on principles of non-discrimination and national treatment.	UNESCO
Lisbon Agreement (1958)	17	Protection of appellation of origin.	WIPO
Rome Convention (1961)	47	Protection of neighboring rights (performers, producers of phonograms, broadcasting organizations).	ILO, UNESCO, and WIPO
Geneva Convention (1971)	52	Protection of producers of phonograms against the making of duplicates in another country.	ILO, UNESCO, and WIPO
Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC) (1989)	8	Provides protection to semiconductor designs.	WIPO
WIPO Copyright Treaty (WCT) (1996)	52	Provides obligations for protecting copyrighted works in the digital environment.	WIPO
WIPO Performances and Phonograms Treaty (WPPT) (1996)	49	Provides obligations for protecting the rights of performers and producers of phonograms in the digital environment.	WIPO

Source: Adapted by USITC staff from Bernard Hoekman and Michel Kostecki, *The Political Economy of the World Trading System*, 1997; and other sources.

## The WIPO Internet Treaties

The WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) are often referred to as the "Internet Treaties" because they provide new international standards for the protection of copyrights and related rights in the digital economy. The two treaties entered into force on March 6, 2002, and May 20, 2002, respectively, once the required minimum 30 countries had ratified each.

- The WCT provides that traditional means for copyright protection (for such products as books, movies, and software) should apply to works transmitted on the Internet or otherwise using digital media, technology, and protections.
- The WPPT similarly provides intellectual property protections to producers of sound recordings, as well as performers, with respect to works on the Internet or in connection with use of digital technology and media.
- Both treaties clarify that traditional rights of reproduction continue to apply in the digital environment, including the storage of material in digital form in an electronic medium.
- The treaties establish the IPR holders' rights to maintain control of their works over the Internet and other digital transmission of their works.
- The treaties ensure that right holders can use digital rights management technology to protect their rights on the Internet. The treaties' anti-circumvention provisions address security and intellectual property infringement risks by requiring that signatories provide minimum levels of legal protection, including civil and criminal penalties, sufficient to deter the unauthorized circumvention of technical protective measures.
- Another provision in the treaties requires signatory countries to prohibit the intentional modification or removal of digital rights management information. This includes prohibitions against interfering with information and data that can be incorporated into the digital code of a protected work and used "to identify the work, its author, performer or owner, the terms and conditions for its use, and any other relevant attributes."
- Both treaties require signatory countries to impose penalties for circumventing technological protection measures that protect copyrighted works, and for tampering with or altering rights management information associated with a work. Such provisions are the principal means for providing copyright owners with security in making their works available in digital formats.
- The United States has ratified both treaties, and implemented them domestically via the Digital Millennium Copyright Act of 1998.

Sources: Adapted, and parts excerpted, by USITC staff from information provided in the following sources: WIPO, "WIPO Copyright Treaty (adopted in Geneva on Dec. 20, 1996)" and "WIPO Performances and Phonograms Treaty (WPPT) (adopted in Geneva on Dec. 20, 1996);" and Chris Gibson, *WIPO Internet Copyright Treaties Coming Into Force*, 2002.

**Table 5**  
**TRIPS requirements for WTO members**

Area	Requirements
Patents	Patents must be granted for at least 20 years from the date of filing. Pipeline protection must temporarily be granted to pharmaceutical and agricultural products in countries that are allowed to delay implementing full patent protection.
Copyrights	Copyright obligations are based on the Berne Convention for the Protection of Literary and Artistic Works (1971) and the Rome Convention (1961). Computer programs, databases, sound recordings, movies, and performances must be protected for 50 years. Broadcasts receive 20 years of protection. Rental rights (the rights to authorize or prohibit commercial renting) are provided for performers, producers, and broadcasting companies.
Trademarks	Trademarks must be made available for 7 years initially, and renewed indefinitely thereafter.
Semiconductor Layouts	Semiconductor design obligations are based on the Treaty on Intellectual Property in Respect of Integrated Circuits (1989). Owners of semiconductor layout designs must receive 10-year protection. Compulsory licensing is not allowed.
Geographic Indications	Use of indications that mislead consumers as to the true origin of a product, or that constitute unfair competition, must be prohibited.
Industrial Designs	Unauthorized making, selling, or importation of copies of new or original industrial designs must be prohibited for 10 years.
Trade Secrets	Trade secrets and other types of "undisclosed information" that have commercial value must be protected against breach of confidence and other acts contrary to honest commercial practices. But reasonable steps must have been taken to keep the information secret. Test data submitted to governments to obtain marketing approval for new pharmaceuticals or agricultural chemicals also must be protected against unfair commercial use.

Source: Adapted with excerpts from World Trade Organization, "Understanding the WTO: The Agreements: Intellectual Property" (2005); and Benedicte Callan, *Pirates on the High Seas: The United States and Global Intellectual Property Rights* (1988).

TRIPS is primarily structured around the main international conventions administered by WIPO. For instance, with respect to copyrights and neighboring rights,<sup>51</sup> WTO members are required to comply with the provisions of the Berne and Rome Conventions for copyright protection (with some important distinctions). Further, as in U.S. law, computer software is to be protected as a literary work under the Berne Convention and the conditions under which databases are to be protected by copyright are clearly specified. WTO members are also required to comply with the most important provisions of the Paris Convention (1967) on patents; at least 20-year patent protection must be provided by members for almost all inventions, including both products and processes.

An important feature of TRIPS is the obligation it places on WTO members to adequately and effectively enforce IPR.<sup>52</sup> While previous international agreements on harmonizing standards for IPR protection contained provisions on enforcement, it is the strength of the dispute settlement mechanism

<sup>51</sup> Neighboring rights (also called related rights) protect the rights of performers, producers of phonograms (sound recordings), and broadcasting organizations. Phonograms are sound recordings such as audiotapes, records, or music CDs. Jaleen Moroney, *Intellectual Property: Principles and Practice* [undated], p. 1, found at <http://www.sis.gov.eg/intellectual/html/716.htm>, retrieved May 31, 2005.

<sup>52</sup> IIPA representative, e-mail dated May 25, 2005, to USITC staff.

under the WTO that sets TRIPS apart. The enforcement provisions of the TRIPS Agreement (Articles 41-61) provide the basis under the WTO for determining whether individual countries are adequately able to fight IPR infringement within and at their borders. These provisions oblige WTO member countries to provide enforcement procedures, including civil or administrative remedies, as well as criminal penalties, that permit effective action against any act of IPR infringement (including acts of copyright infringement that occur in the online environment) and that constitute a deterrent to further infringements. In addition, enforcement provisions on IPR, crime, customs, taxes, and communications must effectively reduce high levels of commercial copyright piracy and trademark counterfeiting both domestically and at the borders of all WTO member countries.

### **Patents, Trademarks, and Copyrights**

Patents, trademarks, and copyrights are among the most common forms of intellectual property protection. Following are discussions of each of these three forms of protection, including definitions; brief summaries of relevant U.S. legislation and international treaties applicable to each; reviews of the different means by which patents, trademarks, and copyrights are infringed overseas; and discussions of the costs such infringement entails. Several other forms of intellectual property protection including *sui generis* means of protection for biotechnology, geographical indications, and semiconductor layout designs will also be discussed as they relate to the major forms of protection mentioned above.

#### ***Patents***

Patents play an important role in economic development by encouraging technology transfer and investment, R&D, and the discovery of new technologies.<sup>53</sup> Patents permit incremental innovation and expand the public stock of technical knowledge, as there is a disclosure requirement.<sup>54</sup> In addition to providing patent-holders with exclusive rights, which can result in higher prices and revenues from sales of patented products, many firms obtain significant revenues from the licensing or sale of the patent rights themselves for products and processes. Licensing transactions generate revenues in the form of royalties and license fees.<sup>55</sup>

Violations of patent laws are known as patent infringement. In the United States, civil remedies are available for patent infringement. However, foreign laws and enforcement of patents often are not sufficient to protect U.S. firms' patent rights.<sup>56</sup> According to U.S. industry and trade officials, if the patent system or judicial institutions for enforcing patent rights in a country are ineffective or nonexistent, U.S.-and other foreign-patented inventions can be imitated with impunity by competitors in that country.<sup>57</sup> As a result, the patent owner can be deprived of revenues and profits from his or her product or process.

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<sup>53</sup> USPTO official, FSI IPR course.

<sup>54</sup> Maskus, *Intellectual Property Rights in the Global Economy*, pp. 40-41.

<sup>55</sup> Further discussion of the use of licensing by firms in certain industries is provided in the next section.

<sup>56</sup> U.S. industry and trade officials, FSI IPR course.

<sup>57</sup> Biotechnology Industry Organization (BIO), Special 301 submission to Office of the United States Trade Representative, Feb. 11, 2005, found at <http://www.bio.org>, retrieved Feb. 17, 2005; and U.S. industry and trade officials, FSI IPR course.

## Some U.S. Industries Affected by Inadequate Patent Protection

Patents are widely used in both manufacturing and agriculture. According to the National Science Foundation, in 2001, “corporate patent activity indicated U.S. technological strengths in business methods, medical and surgical devices, electronics, telecommunications, and biotechnology” (see table 6).<sup>58</sup> Some industries take advantage of patents and related IPR protection in somewhat different ways for different purposes and thus are affected in a variety of ways by inadequate foreign protection of their rights.

**Table 6**  
**Technical Fields Favored by U.S. and Leading Foreign Inventors, as of 2001**

Country	Industries
France . . . . .	Manufacturing applications, biotechnology, and aeronautics
Germany . . . . .	Motor vehicles, printing, switches, and material-handling equipment
Japan . . . . .	Photocopying, photography, office electronics technology, communication technology, information storage
South Korea . . . . .	Television, information storage devices, data generation and conversion, error detection devices, display systems
Taiwan . . . . .	Testing and measuring equipment, semiconductor manufacturing processes, electrical systems, semiconductors, and computer hardware
United Kingdom . . . . .	Traditional manufacturing, biotechnology, chemistry
United States . . . . .	Business methods, medical and surgical devices, electronics, telecommunications, and biotechnology

Source: National Science Foundation, *Science and Engineering Indicators 2004*, Vol. 1, Arlington, VA, 2004.

Strong patent protection is a high priority trade issue for the pharmaceutical and chemical industries because their fixed costs of R&D are relatively high while imitators of patented drugs and chemicals generally do not incur such high costs in those two industries.<sup>59</sup> Several academic studies suggest that just under one-third of the inventions in those industries would not have been developed

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<sup>58</sup> The patent activity information examined by the NSF is based on USPTO’s classification system, which divides patents into roughly 400 active classes. Using the system, comparisons are made using an activity index. For a given year, the patent activity index consists of the proportion of patents in a specific class granted to inventors resident in a particular country divided by the proportion of all patents granted to inventors resident in that country. Since U.S. patenting data reflect a larger share of patenting by individuals without corporate or government affiliation than do data on foreign patenting, only patents granted to corporations are used by NSF to construct the U.S. patenting activity indices. NSF, *Science and Engineering Indicators 2004*, Vol. 1, Arlington, VA, 2004, pp. 6-25 and 6-26.

<sup>59</sup> Maskus, *Intellectual Property Rights in the Global Economy*, p. 43.

without potential protection.<sup>60</sup> However, in other patented industries, such as the electronics and telecommunications equipment industries, with complex products bearing multiple technologies, imitation is generally more difficult, and patents are not viewed as marginally significant in encouraging R&D.<sup>61</sup> Surveys have suggested that less than 20 percent of inventions in those industries would not have been made without patent protection.<sup>62</sup>

Patenting may be particularly effective in the pharmaceutical and chemical industries due to the discrete nature of products in those industries. New drugs or chemicals typically are made up of a relatively discrete number of patentable elements.<sup>63</sup> Manufacturers may find it easier to defend such products against infringement since relatively clear standards can be applied to assess a chemical products' validity. According to some economists, the "uniqueness of a specific molecule is more easily demonstrated than the novelty of, for example, a new component of a complex electrical or mechanical system."<sup>64</sup>

.....it is easy to determine whether an allegedly infringing molecule is physically identical to a patented molecule: it is more difficult to determine whether comparable components of two complex systems "do the same work in substantially the same way."<sup>65</sup>

That is not to say that patenting is not important for other industries, such as the electronics, telecommunications, and medical equipment industries. It is, but for different reasons than for primarily recouping fixed R&D costs.<sup>66</sup> Patenting for firms in these industries enables them to engage in strategic patent activities, including using patents to enhance a firm's reputation, increase licensing revenues, block rivals from patenting related inventions, protect themselves against infringement suits, and improve their

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<sup>60</sup> In one survey, Edwin Mansfield sampled 100 companies in 12 US manufacturing industries in an attempt to ascertain the relative importance of patents in their decisions on investment in R&D. The survey results suggested that only in the pharmaceutical and chemical industries were patents considered essential; more than 30 percent of the inventions would not have been developed without patent protection. In the petroleum, machinery, and fabricated metal products, patents were viewed as important in the development of 10-20 percent of inventions. Meanwhile, in the other 7 industries surveyed, patents were viewed as unimportant or only marginally significant in inducing R&D. Such results are consistent with results reported in several other studies. Maskus, *Intellectual Property Rights in the Global Economy*, pp. 42-43; Edwin Mansfield, "Patents and Innovation: An Empirical Study," *Management Science* 32, no. 2, pp. 173-181; and Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, and Sidney G. Winter, "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity*, SP ISS: pp. 783-820.

<sup>61</sup> Maskus, p. 43.

<sup>62</sup> Levin, Klevorick, Nelson, and Winter, "Appropriating the Returns from Industrial Research and Development," *Brookings Papers*, pp. 783-820; and Maskus, *Intellectual Property Rights in the Global Economy*, p. 43.

<sup>63</sup> Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions, and Why U.S. Firms Patent (or Not)," *National Bureau of Economic Research (NBER) Working Paper 7552* (Cambridge, MA: NBER, Feb. 2000), p. 19, found at <http://www.nber.org>, retrieved Jan. 8, 2005.

<sup>64</sup> Levin, Klevorick, Nelson, and Winter, "Appropriating the Returns from Industrial Research and Development," *Brookings Papers*, p. 798.

<sup>65</sup> Ibid.

<sup>66</sup> For example, according to two economists examining the patenting behavior of firms in industries characterized by rapid technological change and cumulative innovation, "recent survey evidence suggests that semiconductor firms do not rely heavily on patents to appropriate the returns to R&D, despite strengthening of US patent rights in the early 1980s. Yet the propensity of semiconductor firms to patent has risen dramatically over the same period." Bronwyn H. Hall, Department of Economics, University of California, Berkeley; and Rosemarie Ham Ziedonis, Wharton School of Business, University of Pennsylvania, "The Patent Paradox Revisited: An Empirical Study of Patenting in the US Semiconductor Industry, 1979-95," May 2000, p. 1, found at <http://www.nuff.ox.ac.uk/economics/papers/2000/w16/hzmay2000.pdf>, retrieved Sept. 26, 2005.

competitive positions in negotiations over technology rights.<sup>67</sup> For instance, the use of patents to improve firms' reputations often is used by smaller firms in some high technology industries, including the biotechnology industry, to assist them in obtaining financing and alliance partners. Meanwhile, a wide range of industries have reported that they use patenting for the purpose of obtaining licensing revenues. Included among these are the publishing, petroleum, steel, metal products, motors, semiconductors, telecommunications equipment, television, radio, and aerospace industries.<sup>68</sup> (Licensing revenues are also important to the pharmaceutical industry to supplement revenues achieved through commercial sales).

Prevention of rivals from patenting related inventions, or blocking, is another reason for patenting by firms in some industries. For instance, firms wanting to protect some patented core invention may patent substitutes to foreclose the possibility of competitors, by creating what some characterize as a "patent fence."<sup>69</sup> The firms creating these patent fences may have no intention of commercializing the patented substitutes. For instance, DuPont patented over 22 substitutes for Nylon to protect its core invention.<sup>70</sup> Other industries reporting that they have used blocking strategies in this manner include the textiles, paper, rubber/plastic products, mineral products, and electrical equipment.<sup>71</sup> However, patents by firms not intending to commercialize them have also been used to secure licensing revenues, as evidenced by efforts of U.S. semiconductor producer, Texas Instruments, to extract them first from Japanese producers, then from U.S. competitors, in the 1980s and 1990s.<sup>72</sup>

In the electronics, telecommunications, and medical equipment industries, as technologies mature, R&D at one company often parallels that of others in the same industry.<sup>73</sup> The mature products then tend to comprise a large number of patentable elements covered by different patents and, thus, are characterized as complex technologies.<sup>74</sup> A resulting "thicket" of overlapping patents, frequently leads to use of such means as cross-licensing and patent pools to avoid conflicts.<sup>75</sup> Cross-licensing can be used to "secure freedom of operation without running a risk of patent infringement litigation with other firms operating in similar markets."<sup>76</sup> An example of a patent pool is MPEG -2 video compression technology. The pool was created with patents from Fujitsu, General Instrument, Lucent, Matsushita, Mitsubishi, Philips, Scientific-Atlanta, Sony, and Columbia University. The patent pool permitted "one-stop shopping" for makers of televisions, digital video disks and players, and telecommunications equipment.<sup>77</sup> Patent pools sometimes raise complex anti-trust issues.

In the semiconductor industry the cumulative nature of the technology makes it almost impossible to effectively participate in the industry without access to the patents of many other firms, resulting in

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<sup>67</sup> Maskus, p. 43; Mansfield, "Patents and Innovation: An Empirical Study," pp. 173-181; and Levin, Klevorick, and Nelson, and Winter, "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity*, pp. 783-820.

<sup>68</sup> Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets," p.17, and table 8.

<sup>69</sup> *Ibid.*, "Protecting Their Intellectual Assets," pp. 22-23.

<sup>70</sup> D.A. Hounshell and J.K. Smith, *Science and Corporate Strategy DuPont R&D 1902-1980*, Science and Corporate Strategy (Cambridge: Cambridge University Press, 1988), pp. 183-90 and 249-286.

<sup>71</sup> Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets," pp. 22-23, and table 10.

<sup>72</sup> Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets," p. 22.

<sup>73</sup> *Ibid.* p. 19.

<sup>74</sup> *Ibid.*

<sup>75</sup> *Ibid.*; and Carl Shapiro, "Navigating the Patent 'Thicket: Cross Licenses, Patent Pools, and Standard Setting," in Jaffe, A. and others, Eds., *NBER Innovation Policy and the Economy* (Cambridge, MA: MIT Press, 2001), pp. 1-31, found at <http://www.nber.org/~confer/2000/ipess00/shapiro.pdf>, retrieved Sept. 15, 2005.

<sup>76</sup> *Ibid.*

<sup>77</sup> Shapiro, "Navigating the Patent Thicket," p. 17.

widespread cross-licensing.<sup>78</sup> However, established semiconductor firms will not issue a cross license to new entrants until they have established a significant position in the market. Thus, semiconductor companies will increase patenting activity in order to develop patent portfolios of their own, so that more established firms are compelled to negotiate cross-licensing agreements.<sup>79</sup> This permits the entrants to defend themselves against infringement suits, thereby enabling them to participate in the market.

The following discussion provides a summary of important patent and related IPR trends and issues in the biotechnology, pharmaceutical, electronic, telecommunications, and electromedical industries. The biotechnology and pharmaceutical industries, especially, in recent years, have provoked debate between (and among) many developing and developed WTO country members on the appropriate role of IPR protection.

### ***Biotechnology and Genetically Modified Plant Varieties***

The biotechnology industry consists of major pharmaceutical, chemical, and agribusiness companies, and smaller, independent firms that develop transgenic<sup>80</sup> strains of plants and animals, genetic research tools, pharmaceutical products, and biotechnology industrial processes.<sup>81</sup> Research in this area is conducted by small specialized firms, independent research institutes and organizations, and universities, as well as the major agribusiness, chemical, and pharmaceutical companies.<sup>82</sup> Because the section below on pharmaceuticals addresses many of the patent and related IPR issues pertaining principally to new drugs, including those drugs developed through biotechnology methods, this section will focus its attention on IPR issues related to food production, with a limited discussion of the use of biotechnology for medicines.

The United States and other advanced countries have moved toward strong and broad patent protection for biotechnology products and processes. Between 1990 and 1995, the United States and Japan each accounted for about 37 percent of global biotechnology patents, with the European Union accounting for another 19 percent.<sup>83</sup> Meanwhile, developing countries accounted for only 7 percent of biotechnology-related patents in that period.<sup>84</sup>

The TRIPS Agreement generally obliges WTO member countries to make patents available for any inventions, whether products or processes.<sup>85</sup> All WTO members must grant patents on microorganisms under TRIPS Article 27.3. TRIPS allows member states to exclude plants and animals other than microorganisms from patentability. However, it requires them to provide for the protection of

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<sup>78</sup> Eric von Hippel, "Appropriability of Innovation Benefit as a Predictor of the Source of Innovation," *Research Policy*, vol. 11, Jan. 1982, pp. 95-115, found at <http://web.mit.edu/evhippel/www/cvframe.htm>; Levin, "The Semiconductor Industry," in Richard R. Nelson, ed., *Government and Technical Progress: A Cross-Industry Analysis* (Pergamon Press, 1982), pp. 80-81; and Levin, Klevorick, Nelson, and Winter, "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity*, pp. 783-820.

<sup>79</sup> *Ibid.*

<sup>80</sup> This term describes an organism that has had genes from another organism put into its genome through recombinant DNA techniques.

<sup>81</sup> The broad definition of biotechnology (in the commercial sense) is the industrial use of living organisms (or parts of living organisms) to produce foods, drugs, or other products (such as environmental products). The oldest biotechnologies are plant and animal hybridization. The newest biotechnologies range from protein separation technologies to genomics and combinational chemistry. BIO, Special 301 submission.

<sup>82</sup> BIO, Special 301 submission; and Maskus, *Intellectual Property Rights in the Global Economy*, pp. 54-57.

<sup>83</sup> Maskus, *Intellectual Property Rights in the Global Economy*, pp. 173-174.

<sup>84</sup> *Ibid.*

<sup>85</sup> There are some exceptions to this obligation, such as for purposes of public morality.

plant varieties either by patents or by an effective *sui generis* (or unique) system, or by any combination thereof.

U.S. agricultural biotechnology interests are concerned that despite TRIPS requirements to provide adequate protection of IPR in new plant varieties, a number of countries' legal systems fail to provide such protection. The absence of effective mechanisms to enforce IPR in proprietary plants and plant varieties in some countries, reportedly, has led to a substantial number of unauthorized sales and uses of protected seed.<sup>86</sup> For example, losses by licensed U.S. producers of new plant varieties and seeds to unlicensed Argentinian producers are estimated to be in the millions of dollars.<sup>87</sup> Another, major concern of some U.S. industry representatives is what they believe to be unreasonable and burdensome requirements in some countries for patent applicants to disclose the source of all biological materials contributing to a biotechnology invention.<sup>88</sup> Some countries, such as India, require patent applicants to outline the history of all such materials even if they have been available from commercial suppliers for a long period of time. According to the industry representatives, such requirements can adversely affect U.S. biotechnology firms by increasing the costs of applying for a patent.<sup>89</sup>

On the other hand, a number of developing country proponents are concerned that overly broad patenting of biotechnology could primarily benefit major biotechnology research and corporate interests in developed countries, which, they allege, obtain many of their biological and genetic resources from the developing world.<sup>90</sup> Further, they fear that with stronger protection of life forms, including genetically modified plants and animals, only a handful of rightholders (mostly from the developed world) will control the production and marketing of seeds and farm inputs.<sup>91</sup> This, in turn, they believe, could lead to pricing beyond the reach of average farmers and make them dependent on the rightholders.<sup>92</sup>

The developing countries also are concerned about what they consider to be the misappropriation of traditional knowledge developed in communities over hundreds of years.<sup>93</sup> Such knowledge systems have made use of diverse biological and genetic resources for food and medicine, passing on the

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<sup>86</sup> BIO, Special 301 submission.

<sup>87</sup> Ibid.

<sup>88</sup> BIO, Special 301 submission.

<sup>89</sup> U.S. industry representatives, in-person and telephone interviews by USITC staff, Jan.-Aug. 2004.

<sup>90</sup> WITA, "You Must Be TRIPing!"

<sup>91</sup> Outside of the United States, new plant varieties are often protected by *sui generis* plant breeders' rights providing exclusive rights to produce, sell, and import seed varieties. However, one exception is the farmer's privilege, which allows farmers, after initially buying protected seeds, to keep for their own use sufficient amounts of seeds to plant the next year's crops. Another exception is the breeders' exemption, which allows competitors to use varieties freely in developing new strains. The International Union for the Protection of New Varieties of Plants (UPOV) is an example of a *sui generis* system that covers breeding options. The UPOV Convention was signed in 1961 and revised in 1972, 1978, and 1991. Franck Seuret and Robert Ali Brac de la Perriere, "No Patents on Biotechnology Products: Africa Defies Licenses for Life," *Le Monde Diplomatique*, July 2000, pp. 1-5, found at <http://www.biotech-info.net>, retrieved Jan. 27, 2004; "Right to Patent vs Right to Freely Use: TRIPS, UPOV and Farmers' Rights," *Conservation and Sustainable Use of Agricultural Biodiversity* (Lima Peru: CIP-UPWARD, 2003), pp. 514-521, found at <http://www.eseap.cipotato.org>, retrieved Apr. 13, 2005; and Maskus, *Intellectual Property Rights in the Global Economy*, pp. 56-57.

<sup>92</sup> *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, pp. 57-93; and "Intellectual Property Protection and Biotechnology: Issues and Processes for African Consensus," prepared for the African Policy Dialogues on Biotechnology—Southern Africa, Zimbabwe, Sept. 20-21, 2004, pp. 1-10.

<sup>93</sup> Ibid; and "Intellectual Property Protection and Biotechnology: Issues and Processes for African Consensus," pp. 1-10.

knowhow from generation to generation.<sup>94</sup> However, while developing countries are the sources of a number of valuable genetic resources, the technology, genome platforms, and patents are principally produced in developed countries.<sup>95</sup> To assure that communities in developing countries benefit from their biodiversity and traditional knowledge, developing country proponents believe that legal frameworks need to be established governing access and benefit sharing under mutually agreed terms and compensation arrangements.<sup>96</sup>

The United Nations Convention on Biological Diversity (CBD), adopted at the Rio Earth Summit in 1992, attempts to address some of these issues.<sup>97</sup> Among other things, the convention (1) reaffirms that nations have sovereign rights over their own biological and genetic resources, (2) stipulates that access to these is subject to prior consent of the countries concerned, (3) requires signatories to protect and support the rights of communities, farmers, and indigenous people over their biological resources and systems of knowledge, and (4) requires that benefits from the commercial use of biological resources and local community knowledge be shared in an equitable manner.<sup>98</sup>

The TRIPS Council, the WTO body responsible for monitoring the TRIPS Agreement, is currently undergoing a review of Article 27.3(b), which deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties.<sup>99</sup> Paragraph 19 of the 2001 Doha Declaration, made at the 2001 WTO Doha Ministerial, requires a broadening of the review, to consider the relationship between the TRIPS Agreement and the CBD, which addresses the protection of traditional knowledge and folklore.<sup>100</sup> Several general issues that have been raised in the CBD/TRIPS discussion are (1) whether or not there is a conflict between the TRIPS Agreement and the CBD; (2) whether something needs to be done with regard to TRIPS to ensure that they are both applied in mutually supportive, non-conflicting ways, and (3), if so, what this would be. With regard to these questions, views expressed by WTO members all fall into several broad categories:

- there is an inherent conflict between the CBD and TRIPS;
- there is no conflict between the two agreements, and they can be implemented by governments in a mutually supportive way through national measures; and
- there is no inherent conflict but there could be a potential for conflict depending on how both the CBD and TRIPS are implemented, and there is a need, or, at the least, a case for, action to ensure that the two agreements are implemented in a mutually supportive way.<sup>101</sup>

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<sup>94</sup> International Federation of Intellectual Property Attorneys (FICPI), FICPI 8<sup>th</sup> Open Forum, Session 1, Official Searching, Venice, Italy, Oct. 6-9, 2004.

<sup>95</sup> Seuret and Ali Brac de la Perriere, “No Patents on Biotechnology Products;” and “Right to Patent vs Right to Freely Use,” pp. 514-521.

<sup>96</sup> WTO, *Trips, Reviews, Article 27.3(b) and Related Issues*, [undated], p. 1, found at <http://www.wto.org>, retrieved Mar. 8, 2004.

<sup>97</sup> Seuret and Ali Brac de la Perriere, “No Patents on Biotechnology Products;” “Right to Patent vs Right to Freely Use,” pp. 514-521; *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, pp. 57-93; and Maskus, *Intellectual Property Rights in the Global Economy*, p. 225.

<sup>98</sup> *Ibid.* For more information on the CBD, see its website at <http://www.biodiv.org/default.shtml>.

<sup>99</sup> WTO, *Trips, Reviews*, p. 1.

<sup>100</sup> *Ibid.*

<sup>101</sup> WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), Article 27.3(B), *Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Made*, Note by the Secretariat, IP/C/W/368, Aug. 8, 2002, pp. 1-9, found at <http://www.wto.int> retrieved

(continued...)

Some developing countries, including Brazil, India, and a number of African countries, are proponents of the view that there is an inherent conflict between the TRIPS Agreement and the CBD. They state that “by requiring that certain genetic material be patentable or protected by *sui generis* plant variety rights and by not preventing the patenting of other genetic material, provides for the appropriation of such genetic resources by private parties in a way that is inconsistent with the sovereign rights of countries over their genetic resources as provided for in the CBD.”<sup>102</sup> Further, they argue that the TRIPS Agreement allows for patenting or other IPR protection of genetic material without respecting the provisions of the CBD, including those relating to prior informed consent and benefit sharing. The proponents of this view call for amending Article 27:3(b) of the TRIPS Agreement to require all WTO members to make life forms and parts thereof non-patentable.<sup>103</sup>

The United States, which is not a signatory to the CBD,<sup>104</sup> and some other developed countries, take the view that there is no conflict between TRIPS and the CBD.<sup>105</sup> They support their view by pointing out that (1) the TRIPS Agreement and the CBD have different purposes and deal with different subject matter; (2) that granting patent rights over inventions using genetic material does not prevent compliance with CBD provisions regarding the sovereign right of countries over their genetic resources, prior informed consent, and benefit sharing; and (3) no specific examples of conflict have been cited. The proponents of this view indicate that no change is needed in either the TRIPS Agreement or the CBD to accommodate implementation of the other and that each agreement should be pursued in separate frameworks. The United States suggests that implementation of the TRIPS Agreement actually supports implementation of the CBD.<sup>106</sup> For instance, it points out that TRIPS compliant patent system disclosure requirements and control provided to patent owners and licensees over manufacturing and distribution may facilitate sharing of technology, avoid anti-competitive secrecy agreements among commercial operators and the implementation of bio-safety rules, and be instrumental in encouraging benefit sharing and conservation of biological diversity based on voluntary contract.<sup>107</sup>

The EU, Brazil, and China represent proponents of a third category of views, which contend that while there may be no inherent conflict between the two agreements, there is considerable interaction and an overlap between their subject-matter.<sup>108</sup> As such, there may be a case for enhanced international action to ensure that the two agreements are implemented in a mutually supportive manner. China, among

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<sup>101</sup> (...continued)

Sept. 12, 2005.

<sup>102</sup> Ibid., p. 2.

<sup>103</sup> The Africa Group, for example, proposes amending the TRIPS Agreement “to prohibit patenting of all life forms (plants, animals, micro-organisms) and wants ‘*sui generis*’ protection for plant varieties to preserve farmers rights to use and share harvested seeds.” The group also proposes a draft decision on traditional knowledge designed to prevent what it considers to be “misappropriation.” WTO, *TRIPS: Reviews, Article 27(b) and Related Issues, Background and the Current Situation*, [undated], pp. 1-5, found at <http://www.wto.int>, retrieved Sept. 12, 2005.

<sup>104</sup> Although it is not a party to the CBD, the United States reports that it is “nevertheless taking positive steps to promote and encourage prior informed consent and equitable sharing of benefits on mutually agreed terms,” two of the objectives Members have raised in the TRIPS Council. WTO TRIPS Council, Article 27.3(B), *Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, Communication of the United States, IP/C/W/449, June 10, 2005, pp. 1-9, found at <http://www.wto.int>, retrieved Sept. 12, 2005, p. 2.

<sup>105</sup> Ibid., pp. 1-9.

<sup>106</sup> WTO TRIPS Council, *Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Made*, p. 2.

<sup>107</sup> Ibid.

<sup>108</sup> Ibid., and *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, pp. 57-93.

others, indicates that what is more important than considering whether there is a potential conflict between the two agreements is considering how the TRIPS Agreement may be implemented in a way supportive of the CBD. In this regard, Brazil has suggested that TRIPS might be amended to require that patent applicants disclose the origin of any genetic material or traditional knowledge used in inventions and to demonstrate that they have obtained prior foreign consent from appropriate authorities in the country of origin.<sup>109</sup> The EU proposes, however, that work on these ideas should first be pursued in WIPO, CBD, and the Food and Agriculture Organization (FAO), and “where and when relevant, in the TRIPS context.”<sup>110</sup>

Discussions in the TRIPS Council on the TRIPS/CBD issue continue. A steady stream of papers continues to be submitted both on the substance of the debate and how to proceed.<sup>111</sup>

### *Pharmaceuticals*

As previously indicated, U.S. pharmaceutical companies, including those that develop or acquire new biotechnology-based drugs, traditionally have placed a higher value on patents for protecting intellectual property than have firms in many other industries.<sup>112</sup> This industry has very high development costs, regulatory approval and testing requirements that significantly increase the time to market (and may reduce the effective term of the patent), relatively few R&D projects that result in a marketable drug, and liability concerns.<sup>113</sup>

The cost of pharmaceutical R&D is significant. As previously indicated, the U.S. pharmaceutical industry estimates that it spent over \$38 billion on R&D in 2004.<sup>114</sup> Average total drug development time has increased from 8.1 years to 14.2 years since the 1960s.<sup>115</sup> Meanwhile, the average cost to develop a new research-based prescription drug has reached more than \$800 million.<sup>116</sup> U.S. industry representatives contend that to continue developing advanced drugs, the costs of bringing them to market must be recouped.<sup>117</sup> According to them, strong patent protection is required for firms to recover these costs.<sup>118</sup>

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<sup>109</sup> Ibid.

<sup>110</sup> The EU's position "also includes a proposal to examine a requirement that patent applicants disclose the source or origin of genetic material as a subject in itself, with legal consequences of not meeting this requirement lying outside the scope of patent law." WTO, *TRIPS: Reviews, Article 27(b) and Related Issues, Background and the Current Situation*, pp. 1-5; and WTO TRIPS Council, *Communication from the European Communities and their Member States*, IP/C/W/383, Oct. 17, 2002, pp. 1-9.

<sup>111</sup> Ibid.

<sup>112</sup> Organisation for Economic Co-operation and Development (OECD), *Patents and Innovation: Trends and Policy Challenges* (Paris: OECD, 2004), p. 22, found at <http://www.oecd.org>, retrieved Feb. 10, 2004.

<sup>113</sup> Ibid.

<sup>114</sup> PhRMA, *PhRMA Annual Membership Survey 2005*, p. 1, found at <http://www.phrma.org>, retrieved June 14, 2005.

<sup>115</sup> U.S. Government official and industry representatives, FSI IPR course.

<sup>116</sup> PhRMA, *Pharmaceutical Industry Profile 2005*, fig. 1-1, p. 2.

<sup>117</sup> PhRMA representatives, interview by USITC staff, Washington, DC, Feb. 25, 2004.

<sup>118</sup> PhRMA, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights*, White Paper on the Intersection of Intellectual Property Law and Antitrust Law in the Pharmaceutical Industry, Apr. 22, 2002.

Compulsory licensing, marketing of generics prior to patent expiration,<sup>119</sup> patent term restoration, and disclosure of proprietary test data are all intellectual property issues that concern the U.S. pharmaceutical industry.

### *Compulsory licensing*

Compulsory licensing is sometimes used by governments to allow the production or sale of a product without the permission of the patent holder. TRIPS Article 31 allows compulsory licensing in certain instances, such as in the case of national emergency, but with strict limitations aimed at protecting the legitimate interests of the patent holder. Among these limitations are that compulsory licensing should be predominantly for the domestic market and not for export.<sup>120</sup> This is to limit the use of such licensing for the national health emergency purpose for which it is granted and prevent it from being used for commercial gain. As a result of concerns by a number of developing countries that such interpretations of TRIPS' compulsory licensing limitations could reduce access to medicines by people in poorer countries facing epidemics, the WTO clarified the issue in a statement made at the end of the 2001 Doha Ministerial (text box).

#### **Patents and Access to Medicines: Compulsory Licensing and the Doha Declaration**

Many developing countries argued that they could not benefit from TRIPS compulsory licensing provisions, even in cases of national emergency, because they lacked drug production capabilities. Because TRIPS stipulates that such licensing when permitted is to be predominantly for the domestic market, it was not clear that the developing countries could use the compulsory license privilege to authorize imports of cheaper generic drugs from other countries. This issue was addressed in the Doha Ministerial Declaration of November 14, 2001, in which ministers assigned further work to the WTO TRIPS Council to determine how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically could import patent drugs made under compulsory licensing. On August 30, 2003, WTO member governments agreed to waive the TRIPS Article 31(f) requirement that production under compulsory license be predominantly for the domestic market so that countries unable to manufacture the medicines themselves could import cheaper generics under such a license.

Sources: U.S. Government official and industry representatives, U.S. Department of State, Foreign Service Institute course, "Intellectual Property Rights," Arlington, VA, July 15-16, 2004; and WTO, "TRIPS and Public Health," TRIPS Issues, [undated], p. 1, found at <http://www.wto.org>, retrieved Mar. 8, 2005.

U.S. pharmaceutical industry representatives indicate that their industry is adversely affected by overly broad compulsory licensing provisions in some countries that do not meet TRIPS requirements and limitations.<sup>121</sup> According to them, countries that provide too much latitude in the area of compulsory licensing make it easier for generic producers to obtain permission to copy U.S. patented drugs.<sup>122</sup> They contend that without patent protection, research-based pharmaceutical companies lose sales to generic firms, which can produce the drugs more cheaply since they do not have to undergo the expensive development process of the research-based firm.

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<sup>119</sup> See subheading below under "marketing of generics" for information on some of the major drugs about to go "off patent" in the near future.

<sup>120</sup> U.S. Government official and industry representatives, FSI IPR course.

<sup>121</sup> PhRMA representatives, interview by USITC staff, Washington, DC, Feb. 25, 2004.

<sup>122</sup> Ibid.

### *Marketing of generics prior to patent expiration*

The FDA projects that “more than 200 brand-name medications will come off patent over the next several years.”<sup>123</sup> As this occurs, many pharmaceutical market analysts project that there likely will be a speedup in the generic drug approval process. According to U.S. Government and industry sources, popular drugs due to lose patent protection before the end of 2006 include such brand names as Flovent, Flonase, Cipro, Diflucan, Lamisil, Xenical, Zocor, Prevacid, Zoloft, Pravachol, and Zithromax.

Although pharmaceutical manufacturers can do little to prevent the marketing of generic versions of branded products that have gone off patent, they have expressed concern that some countries continue to provide marketing approval to drugs that are still under patent.<sup>124</sup> They believe that it is imperative that marketing approval officials consider the existence of patents before allowing infringing drugs to compete with patented drugs.<sup>125</sup> The U.S. industry would like to see foreign governments address this issue in a similar manner as has the United States in the U.S. Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act (1984).

For example, the Hatch-Waxman Act, which attempts to provide for safe and effective low cost drugs while protecting patented pharmaceuticals, enables generic companies requesting FDA approval to shorten the process required to get a new generic product on the market after a branded product’s patent expires. However, in return, the law requires that relevant detailed patent information be provided to the FDA in connection with generic producers’ applications for approval so the FDA can ascertain that the generic does not violate an existing patent. The Bolar Provisions to the Act permit generic manufacturers to experiment on and test drugs in order to file an abbreviated new drug application while the patents covering those drugs remain in force so that they may more quickly be placed on the market after the patents’ expiration.<sup>126</sup> Specifically, the new drug applications to FDA must include patent information about bioequivalent drugs<sup>127</sup> that the FDA must consider as part of the approval process for certain drugs.<sup>128</sup> U.S. pharmaceutical industry representatives believe that it is imperative that Bolar-type principles also be observed among foreign health care regulatory agencies, requiring such detailed patent information from generic applicants to make certain that infringing drugs do not get on foreign markets.<sup>129</sup>

### *Patent term restoration*

The effective length of a patent term is shortened by the amount of time taken by regulators to approve the patent or to provide marketing approval to a pharmaceutical.<sup>130</sup> Many countries have adopted systems of patent term restoration to give patent owners back some of the time lost due to regulatory

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<sup>123</sup> Michelle L. Kirsche, “Generics Watch,” *Drug Store News*, Nov. 17, 2003, found at [http://www.findarticles.com/p/articles/mi\\_m3374/is\\_16\\_25/ai\\_110533010](http://www.findarticles.com/p/articles/mi_m3374/is_16_25/ai_110533010), retrieved Sept. 22, 2005. See also FDA website, found at <http://www.fda.gov>, for further information on drug patenting trends.

<sup>124</sup> *Ibid.*

<sup>125</sup> *Ibid.*

<sup>126</sup> “Biosciences,” *Olswang News*, Jan. 26, 2005, found at <http://www.olswang.com>, retrieved Mar. 8, 2005, p. 1.

<sup>127</sup> For FDA purposes, in order to be considered “bioequivalent” to a branded drug, a generic copy must contain identical amounts of the same active drug ingredient in the same dosage form and route of administration and meet specified standards for strength, purity, quality, and identity. “Inactive ingredients” such as binders and fillers are allowed to differ but must occur in a ratio to the active compound similar to that of the reference drug. American Heart Association, “Issues in Bioequivalence and Generic Substitution for Antiarrhythmic Drugs,” p. 1, found at <http://www.americanheart.com>; and FDA official, telephone interview by USITC staff, Sept. 6, 2005.

<sup>128</sup> U.S. pharmaceutical industry representative, FSI IPR course.

<sup>129</sup> U.S. Government official and industry representatives, FSI IPR course.

<sup>130</sup> U.S. pharmaceutical industry representative, FSI IPR course.

delays. However, some countries have not adopted this practice although the United States is addressing this issue in some of its bilateral free trade agreements. The United States, the European Union, and Japan provide up to 5 years of restoration.<sup>131</sup>

### *Data exclusivity*

Data exclusivity is one of the most important trade issues to the pharmaceutical industry. Although data exclusivity is technically a trade secret or protection of undisclosed information issue rather than a patent issue, it is so often identified in tandem with patent protection by the U.S. pharmaceutical industry that it is important to discuss the issues together. U.S. pharmaceutical companies are concerned that there be sufficient protection of confidential clinical test data required for market approval of patented drugs.<sup>132</sup> Developing such data through clinical trials to prove the safety and efficacy of new drugs constitutes one of the most expensive elements of bringing such drugs to market.<sup>133</sup> Article 39.3 of the TRIPS Agreement requires WTO members to protect test data submitted by drug companies to health authorities against disclosure and against “unfair commercial use” of that data.

Most countries with advanced IPR regimes provide at least 5 years of exclusive rights to such data after approval of the drug by regulatory authorities even if the patent expires during the period.<sup>134</sup> During this period of data exclusivity, others may not use such data in support of their own applications for marketing approval of bioequivalent generic drugs. Data exclusivity recognizes the considerable effort needed to demonstrate the safety and efficacy of the innovative drug to regulatory authorities and the need for pharmaceutical and biotechnology firms to recoup investment. However, some countries with emerging pharmaceutical industries, such as China, Korea, India, and Poland, reportedly do not provide effective protection of data in compliance with TRIPS Article 39.3.

### ***Electronics, Telecommunications, and Medical Equipment***

The United States has among the most advanced electronics and telecommunications equipment industries in the world. Although outsourcing of manufacturing, especially to East Asian countries, has increased significantly in recent years, much of the research, design, and production of advanced electronics and telecommunications technologies continues to take place in the United States. Therefore, the patenting of such technologies and related manufacturing processes is of great importance to the U.S. industry.

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<sup>131</sup> In the United States, the Uruguay Round Agreements Act (Public Law 103-465) changed the patent term in the United States. Before June 8, 1995, patents typically had 17 years of patent life from the date the patent was issued. Patents granted after the June 8, 1995 date now have a 20-year patent life from the date of the first filing of the patent application. However, the effective patent term often is less than 20 years because patents are often obtained before products are actually marketed (largely due to the length of time it takes to obtain FDA marketing approval). Under Title II of the 1984 U.S. Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), a maximum of 5 years can now be restored to the patent because of such delays. In all cases, the total patent life for the product with the patent extension cannot exceed 14 years from the product’s approval date, or 14 years of potential marketing time. If the patent life of the product after approval has 14 or more years, the product would not be eligible for patent extension. FDA, Center for Drug Evaluation and Research, “Frequently Asked Questions on the Patent Term Restoration Program,” July 22, 2005, p. 1, found at [http://www.fda.gov/cder/about/smallbiz/patent\\_term.htm](http://www.fda.gov/cder/about/smallbiz/patent_term.htm), retrieved Sept. 22, 2005.

<sup>132</sup> Ibid.

<sup>133</sup> PhRMA representatives, interview by USITC staff, Washington, DC, Feb. 25, 2004.

<sup>134</sup> For instance, the period of exclusivity provided for pharmaceutical test data is 5 years in the United States and 5-10 years in the European Union. U.S. government and pharmaceutical industry officials, FSI IPR course.

Certain aspects of semiconductor topography used in chip design are required to be protected by a *sui generis* system under TRIPS.<sup>135</sup> This is because neither patent nor copyright protection is an appropriate means for protection. Infringement in this industry consists of the unauthorized direct optical copying of a chip protected by valid intellectual property rights, and the reproduction of a layout design based on the optical copying and then fabricating of a semiconductor based on this layout design. This form of infringement is harder to detect and has become a serious problem, especially with the advent of lower cost technology for optical copying.<sup>136</sup>

Some of the specific types of electronic products and components for which patents have allegedly been infringed by foreign companies include the following:<sup>137</sup>

Digital Processors and Components (Japan)	Encapsulated Integrated Circuit Devices (Malaysia)
Digital Processing Systems (Japan)	Data Storage Systems and Components (Japan)
Semiconductor Devices and Products Containing Them (China)	Semiconductor Timing Signal Generator Devices, Components (Philippines, Thailand)
Personal Computers, Monitors, and Related Components (China, Mexico, and Taiwan)	Programmable Logic Devices (Taiwan)
Disc Drives, Components, and Products Containing Disc Drives (China)	Plasma Display Panels and Products Containing Same (Japan)
Servers (China and Taiwan)	Synchronous Dynamic Random Access Memory Devices and Modules (Korea)

Some of the specific types of telecommunications products for which patents have allegedly been infringed by foreign companies include the following:<sup>138</sup>

Integrated Repeaters (Taiwan)	Dense Wavelength Division Multiplexing Systems and Components (Italy)
Integrated Switches, Transceivers, and Products Containing Them (Japan)	Digital Satellite System (DSS) Receivers and Components (Mexico)
WAP-Compatible Wireless Communication Devices and Components (Japan)	Self-Powered Fiber Optic Modems (Israel)
Telephonic Digital Added Main Line Systems and Components (Israel)	Coated Optical Waveguide Fibers (China)

<sup>135</sup> Joint Statement of the Eighth Meeting of World Semiconductor Council (WSC), Busan, Korea, May 13, 2004, found at <http://www.semiconductorcouncil.org>, retrieved Mar. 7, 2005.

<sup>136</sup> Ibid.

<sup>137</sup> Compiled by USITC staff from Section 337 Investigational History, found at <http://www.usitc.gov>; USTR, [2004 and 2005] *NTE*; and other sources, in-person and telephone interviews by USITC staff, Apr. 2004-May 2005.

<sup>138</sup> Compiled by USITC staff from USITC Section 337 Investigational History; and USTR, [2004 and 2005] *NTE*, Apr. 2004-May 2005.

Some recent surveys indicate that medical equipment (along with pharmaceuticals) had among the highest levels of patenting activity among industries, with two-thirds of innovations being patented.<sup>139</sup> Some of the types of medical and surgical devices and processes for which patents have allegedly been infringed by foreign companies include the following:<sup>140</sup>

Excimer Laser Systems for Vision Correction Surgery and Components (Japan)	Scanning Multiple Beam Equalization Systems for Chest Radiography (Netherlands)
Methods for Performing Excimer Laser Vision Surgery (Japan)	Processes for Manufacturing Artificial Breast Prostheses (Germany, France, and Ireland)
Mechanical Lumbar Supports (Austria, Canada, and Germany)	

In recent years, there has been an increase in medical equipment manufacturing and assembly activities in less developed countries such as the Dominican Republic, Costa Rica, and Malaysia. The production in these countries has primarily consisted of final assembly and packaging of commodity hospital supplies such as blood administration and infusion sets for large U.S.- based hospital supply companies.<sup>141</sup> However, increased manufacturing partnerships in China over the past decade by major U.S., European, and Japanese producers of more advanced x-ray, computed tomography (CT), magnetic resonance imaging (MRI) systems, and electronic patient monitoring systems, are resulting in higher levels of technology transfer to that country.<sup>142</sup> This has led to increased Chinese production of more advanced electromedical equipment.<sup>143</sup> To protect their technologies, U.S. medical device firms have indicated that they would like to see more vigorous enforcement of patent laws in China.<sup>144</sup>

### Estimated Costs of Inadequate Patent Protection

Royalty and license fees for the use of general-use computer software and use of industrial manufacturing processes in the pharmaceutical and telecommunications industries were responsible for the largest portion of U.S. receipts of such fees from unaffiliated foreign companies in 2003.<sup>145</sup> Thus, patent infringement and other problems in a foreign country's patent regime resulting in a loss of such fees can be costly to U.S. firms in those industries. Meanwhile, U.S. companies can also assume

<sup>139</sup> Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets;" Table A-1. Also see NSF, *Science and Engineering Indicators 2004*, Vol. 1, Arlington, VA, 2004, pp. 6-25 and 6-26.

<sup>140</sup> USITC Section 337 Investigational History; and other sources.

<sup>141</sup> U.S. industry representatives, in-person and telephone interviews by USITC staff, 2002-2005.

<sup>142</sup> "Philips Sets Up Medical Equipment Venture in China," *Appliance Magazine*, Feb. 10, 2004, pp. 1-2, found at <http://www.appliance-magazine.com>, retrieved Mar. 22, 2004; Kathryn Kranhold, "GE Pins Hopes on Emerging Markets: Strategy is Major Shift From Reliance on the West: Big Rivals Echo Approach," *Wall Street Journal*, Mar. 3, 2005, pp. A-3 and A-4; "Growth [in China]," *GE Medical Systems-Asia*, found at <http://www.savelives.gecareers.com>, retrieved Oct. 13, 2004; and Frost and Sullivan, "Chinese X-Ray Equipment Markets," *Market Research Report*, Feb. 1999, found at <http://www.mindbranch.com>, retrieved Mar. 2, 2004.

<sup>143</sup> Kranhold, "GE Pins Hopes on Emerging Markets," pp. A-3 and A-4.

<sup>144</sup> Advanced Medical Technology Association (AdvaMed), Dec. 21, 2004, letter to U.S. Department of Commerce in response to request for comments with respect to the *National Trade Estimate Report on Foreign Trade Barriers*, pp. 1-13, found at <http://www.advamed.com>, retrieved Feb. 8, 2004.

<sup>145</sup> BEA, *Survey of Current Business*, Oct. 2004, pp. 32-33.

considerable costs in having to hire additional administrative, legal, and investigative staff to pursue patent infringement cases in problematic countries.<sup>146</sup> Expending resources for staff can then lead to opportunity costs arising from not being able to fund other product development and marketing activities. Further, poor patent protection in some otherwise lucrative foreign markets causes some companies to ignore those countries completely. Finally, lost sales and revenues due to inadequate patent protection in foreign markets can cause financial problems for U.S. companies, leading to a loss in their global competitiveness.

Patent infringement cases in economies such as Japan and Europe are less problematic to U.S. producers since they have more effective institutions and means for settling patent disputes. Also, major Japanese and European companies with competing technologies often cross license with competitors in the United States or settle civil patent infringement cases before judgement,<sup>147</sup> which is consistent with findings reported by Keith Maskus in his review of several other research studies:

The industrial countries tend to have strong technological capabilities and might therefore represent a competitive threat through imitation. However, they also have strong patent rights that considerably dampen this effect...<sup>148</sup>

U.S. industry representatives are more concerned about inadequate patent protection in China and other less developed East Asian countries such as Thailand, Malaysia, and the Philippines that have less mature patent regimes.<sup>149</sup> Some of the costs to U.S. companies due to deficiencies in patent protection in those countries result from lost sales, loss of potential licensing income, the time and expense involved in registering patents, and costs involved in pursuing patent infringement cases.<sup>150</sup>

The U.S. pharmaceutical industry is the only industry known to estimate revenue losses in foreign countries due to inadequate patent protection. In 2005, it estimated direct and indirect losses of over \$7 billion in 22 selected countries due to inadequate patent and data protection.<sup>151</sup> As indicated in the following tabulation, inadequate patent protection in China, Korea, Turkey, and Poland reportedly caused the most damage to U.S. pharmaceutical companies in 2004, and China accounted for the highest percentage lost sales with 33 percent.<sup>152</sup>

Rank	Most patent damages	Most data damages	Most total IPR damages	Damages (percent of sales)	
1	China	China	China	China	33
2	Korea	Korea	Korea	Lebanon	26
3	Turkey	Turkey	Turkey	Poland	21
4	Poland	Poland	Poland	Korea	20
5	Canada	Venezuela	Canada	Turkey	20

<sup>146</sup> U.S. industry representatives, telephone interviews by USITC staff, Jan.-Mar. 2005.

<sup>147</sup> Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting," 1-31; and Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets," pp. 22-23.

<sup>148</sup> Maskus, *Intellectual Property Rights in the Global Economy*, pp. 116-118.

<sup>149</sup> Electronics industry representatives, telephone interviews by USITC staff, Jan.-Mar. 2004.

<sup>150</sup> Ibid.

<sup>151</sup> PhRMA, 2005 Special 301 submission, app. A.

<sup>152</sup> Compiled by USITC staff from data provided by PhRMA, 2005 Special 301 submission, app. A.

## *Trademarks*

A trademark or service mark<sup>153</sup> may be any word, name, number(s), letter(s), symbol, logo, slogan, package design, sound, color, smell, or other device, or combination thereof, whose purpose is to identify and distinguish particular products from others in the market.<sup>154</sup> Thus, the term Coca Cola ® is a trademark which differentiates that product from other cola products such as Pepsi Cola ® (which itself is a trademark). The shape of the original Coca Cola bottle is also a trademark. Trademarks serve a variety of functions for their owners and society. Some of these include helping consumers identify and purchase a product or service based on its nature and quality, eliminating confusion in the marketplace, and protecting an owner's reputation, or goodwill.<sup>155</sup> Trademarks also may reduce "consumers' search costs by providing them with valuable information about brands" while encouraging quality products.<sup>156</sup>

The Lanham Act<sup>157</sup> is the most important U.S. law used to protect trademark rights. This law permits civil suits against alleged trademark infringers in Federal courts. In addition, Section 42 of the Lanham Act<sup>158</sup> and Section 526 of the Tariff Act<sup>159</sup> prohibit imports of products bearing trademarks that have been registered at USPTO but not authorized to be used on the imported goods by the rightholder. Such goods are subject to seizure and forfeiture for trademark infringement and violation of U.S. customs laws. The U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement services of the U.S. Department of Homeland Security have the authority to (1) exclude from entry, (2) detain, or (3) seize imported counterfeit goods.<sup>160</sup> Other important U.S. trademark legislation includes the Trademark Counterfeiting Act of 1984,<sup>161</sup> the Anti-Counterfeiting Consumer Protection Act of 1996, and the Anticybersquatting Consumer Protection Act (ACPA) (table 7).

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<sup>153</sup> A service mark essentially serves the same purpose as trademarks do for manufactured products, but service marks apply to service products. Examples of three well-known service marks are Wal-Mart, the Rock of Gibraltar (symbol of Prudential Insurance Co.), and the Golden Arches (symbol of McDonald's).

<sup>154</sup> Under U.S. law, there are two other types of trademark and service marks: collective marks and certification marks. Collective marks are used to indicate goods or services that come from the members of the group or to indicate the members of the group or organization. An example of a collective mark is the American Dental Association, or its acronym ADA. Certification marks are used to certify the quality, method, or mode of manufacture of the goods, the origin of the goods or services, or that the goods or services were provided for by members of an organization. An example of a certification mark is Underwriters Laboratories, or its acronym UL.

<sup>155</sup> FICPI 8<sup>th</sup> Open Forum, Session 1, Official Searching (Trademarks), Venice, Italy, Oct. 6-9, 2004; and Lawrence R. Hefter and Robert D. Litowitz, "What is Intellectual Property?," *USINFO.STATE.GOV*, pp. 4-6, found at <http://www.usinfo.state.gov>, retrieved Aug. 16, 2004; and WIPO, "What is a Trademark," p. 1, found at <http://www.wipo.int/about-ip/en/trademarks.html>, retrieved Sept. 6, 2005.

<sup>156</sup> William M. Landes and Richard A. Posner, *Economic Structure of Intellectual Property Law* (Cambridge, MA: The Belknap Press of Harvard University Press, 2003), p. 173.

<sup>157</sup> 15 U.S.C. 1116-1118.

<sup>158</sup> 15 U.S.C. 1124.

<sup>159</sup> 19 U.S.C. 1526.

<sup>160</sup> Customs Directive No. 2310-008A, Apr. 7, 2000.

<sup>161</sup> 18 U.S.C. 2320.

**Table 7**  
**Other Important U.S. Trademark Laws**

<b>Law</b>	<b>Major Provisions</b>
Trademark Counterfeiting Act (1984)	Provides for criminal penalties for trafficking in counterfeit goods or services. First time offenders may be imprisoned for up to 10 years and fined up to \$2 million. Repeat offenders may be imprisoned for up to 20 years and fined a maximum of \$5 million. Corporate offenders may be fined up to \$15 million.
Anti-Counterfeiting Consumer Protection Act (1966)	Strengthened the Trademark Counterfeiting Act by providing law enforcement officials at the Federal level with the authority to seize and destroy counterfeit merchandise or give it to charities with the consent of the legitimate trademark owner. It also expanded Federal racketeering law, by amending the Racketeer Influenced Corrupt Organizations Act (RICO), to include trademark counterfeiting as a "predicate act."
Anticybersquatting Consumer Protection Act (1999)	Allows a trademark holder to sue an alleged cybersquatter in Federal court and obtain an order transferring the domain name back to the trademark holder, and, in certain instances, requires the cybersquatter to pay damages. A trademark holder may also fight cybersquatters by using an international arbitration system known as the Uniform Domain Name Dispute Resolution Policy (UDRP) created by the Internet Corporation of Assigned Names and Numbers (ICANN). This international system results in arbitration rather than litigation of the suit. If the complainant prevails, the domain name will be cancelled or transferred to the complainant, but no damages or other financial remedies are available under the UDRP.

Sources: 18 U.S.C. 2320; 18 U.S.C. 1961, et seq.; information provided by USPTO and U.S. State Dept. in e-mail and attachment dated July 8, 2005 to USITC staff; and Ellen Rony and Peter Rony, "Comparison of the Trademark Cyberpiracy Prevention Act and the Uniform Dispute Resolution Policy," *Domain Name Handbook: High Stakes and Strategies in Cyberspace*, 2000.

The United States participates in international IPR organizations and the WTO TRIPS Agreement to advance its own high standards of trademark protection worldwide.<sup>162</sup> Some international treaties related to trademark protection in addition to the WTO TRIPS Agreement, are the Paris Convention, Madrid Protocol, and Nice Agreement (text box).

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<sup>162</sup> USPTO and USTR officials, FSI IPR course; and U.S. industry representatives, in-person and telephone interviews by USITC staff, Washington, DC, Jan.-Aug. 2005.

### International Trademark Agreements

The earliest treaty addressing the protection of trademarks that is currently relevant, particularly by virtue of its incorporation by reference into the TRIPS Agreement, is the Paris Convention.<sup>163</sup> Paris Convention features benefiting trademark owners include the establishment of a U.S. priority date based on the filing date of a trademark application filed in a Paris Union country, provided an application is filed in the USPTO within 6 months of the foreign application. The Paris Convention also provides that Members must have effective protection against acts of unfair competition. Most notably, the Paris Convention provides protection for well-known marks, whether registered or not, against unauthorized use on similar goods.

The TRIPS Agreement outlines the minimum rights that WTO members must provide to trademark owners, including the exclusive right to prevent unauthorized uses of the mark when such use would likely cause confusion. The TRIPS Agreement builds on the Paris Convention by expanding the protection for trademarks in the Paris Convention to include service marks and increases the protection for well-known marks by including services, expanding to cover related goods, and by indicating that a mark may be well-known in the relevant sector of the public, rather than in the entire country or neighboring countries. A 1999 WIPO Joint Recommendation on Well-Known Marks goes even further and outlines a list of factors for countries to consider when evaluating whether a mark is well-known.

The other major international IPR treaties addressing trademarks deal primarily with (1) streamlining formalities in the trademark application process; and (2) simplifying the filing for trademark applications in multiple markets. The Protocol to the Madrid Agreement for the International Registration of Marks permits nationals of member countries to file one application in one language, with one set of fees in the country of origin and request extension protection in some or all Madrid Protocol Member countries. Additionally, trademark owners may file a single application for renewal and change in ownership, thereby simplifying the maintenance process for trademark owners who would have had to do so in each jurisdiction individually.<sup>164</sup> The Trademark Law Treaty, signed in 1994 by the United States and 34 other countries, is expected to further unify and simplify trademark application formality procedures in member countries, and gives service marks equal status as trademarks. The Nice Agreement, a trademark classification treaty, provides internationally accepted identifications of goods and services for which trademark protection may be obtained and provides 34 classes for goods and 11 classes for services.

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Sources: State Dept. and USPTO officials, e-mail communication to USITC staff, July 5, 2005; International Trademark Association, "Madrid Protocol," [undated]; Stanley Z. Goldberg, "Preserving Your Trademark-At Home and Abroad," *Global Treasury Management*, 2001; and Arnoud Engelfriet, "Crash Course on Trademarks: Trademark-Related Treaties," *Ius Mentis*, 2004.

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<sup>163</sup> U.S. State Dept. and USPTO officials, e-mail communication to USITC staff, July 5, 2005.

<sup>164</sup> International Trademark Association (INTA), "Madrid Protocol," [undated], p. 1, found at <http://www.inta.org>, retrieved July 12, 2004.

There are a number of different means by which trademarked products can be infringed. A common method is the production of unauthorized imitations of products with counterfeit trademarks. Such imitations are passed off as originals. Infringers sometimes use an otherwise legitimate trademark in an unauthorized manner. For example, less expensive substitute goods ranging from consumer goods to automobile parts may be placed in packages of used trademarked products and passed off as originals. Further, inexpensive substances may be used to refill used containers of branded products such as liquid detergents, shampoos, and motor oils.<sup>165</sup>

Digital and other advanced technologies have made it easier to produce and market counterfeits.<sup>166</sup> For instance, computers, scanners, and printers have enabled counterfeiters to more quickly and accurately imitate products, packaging, and documentation. Thus, technology has resulted in better copies “that are harder to detect, and “easier to slip into the ordinary trade channels used by legitimate commerce.”<sup>167</sup> Further, the Internet has resulted in an effective new distribution channel for counterfeit goods.<sup>168</sup> All of this has enormously increased the number of counterfeit products on the market.

Another form of trademark infringement is cybersquatting, which consists of the unauthorized registration and/or use of trademarks in Internet domain names.<sup>169</sup> This practice involves registering, selling, or using a domain name for the purpose of profiting from the goodwill associated with someone else’s name and trademark.<sup>170</sup> Some cybersquatters do this with the intent of selling the domain names back to the trademark owner. Others may engage in the practice to attract Internet users to their website for advertising or sales purposes.<sup>171</sup>

One other important issue related to trademarks is geographical indications (GIs) (text box).<sup>172</sup> GIs are indicators of origin used on goods or services that have a specific geographical origin and possess qualities or a reputation that are due to the place in which the goods or services originate. In the United States, a GI is considered a subset of trademarks, generally protected as certification and collective marks.<sup>173</sup> However, in other countries, such as France, GIs are protected in a registration system separate from the trademark system. Many U.S. companies are concerned that a number of countries are creating a “super-right” for GIs by canceling prior trademarks that conflict with later-established GIs in that territory, which they contend is in conflict with TRIPS Agreement obligations.<sup>174</sup>

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<sup>165</sup> Ibid.

<sup>166</sup> IACC representatives, interview by USITC staff, Washington, DC, Jan. 20, 2004; and USPTO and USTR officials, FSI IPR course.

<sup>167</sup> ICC, “A Brief Overview of Counterfeiting,” p. 2.

<sup>168</sup> Charles Hadda, “Fake Drugs, Real Disaster,” *Business Week*, Feb. 9, 2004, p. 44.

<sup>169</sup> USPTO official, e-mail dated June 10, 2005, to U.S. State Department official (related to review of this paper).

<sup>170</sup> “Cybersquatting: What It Is and What Can Be Done About It,” *NOLO Law for All*, 2004, found at <http://www.nolo.com>, retrieved Aug. 25, 2004.

<sup>171</sup> U.S. industry representatives, in-person and telephone interviews by USITC staff, Jan.-Oct. 2004.

<sup>172</sup> Bill Edgar, President FICPI Trade Committee, FICPI 8<sup>th</sup> Open Forum, interview by USITC staff, Oct. 9, 2004; and International Trademark Association (INTA), *Special Report on Geographical Indications*, Sept. 1, 2003, pp. 1-7, found at <http://www.inta.org>, retrieved Aug. 25, 2004.

<sup>173</sup> USPTO official, e-mail dated July 5, 2005 to U.S. State Department official (related to review of this paper).

<sup>174</sup> Ibid.

### Geographical Indications

Geographical indications are, for purposes of the TRIPS Agreement, a type of intellectual property. “Geographical Indications” (GIs) are defined, at Article 22(1) of the TRIPS Agreement, as “indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristics of the good is essentially attributable to its geographic origin.” (Examples of geographical indications from the United States include “NAPA VALLEY” for wine; IDAHO POTATOES” for potatoes; and “WASHINGTON STATE APPLES” for apples.)

Geographical indications are valuable to producers from particular regions for the same reasons that trademarks are valuable. First, they are source-identifiers—they identify goods as originating in a particular territory, or a region or locality in that territory. Geographical indications are also indicators of quality—they let consumers know that the goods come from an area where a given quality, reputation, or other characteristic of the goods is essentially attributable to their geographic origin. In addition, GIs are business interests—GIs exist solely to promote the goods of a particular area. Finally, GIs are intellectual property, eligible for relief from acts of infringement and/or unfair competition.

The TRIPS Agreement requires that WTO members provide the legal means for interested parties to prevent the use of a GI that: (1) indicates or suggests that a good originates in a geographical area other than the true place of its origin in a manner which misleads the public as to the geographical origin of the good; or (2) constitutes an act of unfair competition. For GIs on wines and spirits, the TRIPS Agreement also provides for a presumption of misleading use when a GI is used on wines or spirits and the goods do not come from the place identified by the GI.

Source: U.S. State Dept. and USPTO representatives, e-mail communication to USITC staff, July 5, 2005.

### *U.S. Industries Affected by Trademark Counterfeiting*

#### **Industries Affected**

Foreign trademark infringement affects a broad range of U.S. industries. Products affected range from counterfeit versions of apparel, leather goods, soaps, shampoos, razors, and batteries to cigarettes, alcoholic beverages, automobile parts, medicines, perfume, credit cards, PCs, toys, and tea bags (table 8).<sup>175</sup> Because trademark counterfeiting is so widespread and bears on so many industries, firms affected by such infringement reportedly often have a more difficult time organizing themselves to influence domestic and foreign trade polices on IPR compared to industries affected by patent and copyright piracy, whose common interests have enabled them to more effectively band together on IPR infringement issues.<sup>176</sup>

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<sup>175</sup> ICC, “A Brief Overview of Counterfeiting,” pp. 1-3; IACC, Inc., *Special 301 Recommendations*, Feb. 11, 2005, p. 4; and USTR, *2004 Special 301 Report*, pp. 24-26.

<sup>176</sup> IACC representatives, interview by USITC staff, Washington, DC, Jan. 20, 2004; and Maskus, *Intellectual Property Rights in the Global Economy*, pp. 63-64.

**Table 8**  
**Some types of products counterfeited worldwide in 2004**

Cell phone batteries	Power tools	Perfume	Crystal
Table salt	Christmas decorations	Toys	Olive oil
Paint	Body Creams	Steroids	Cars and autoparts
Power bar	Curling irons	Detergent	Pesticides
Contact lenses	Contraceptives	Sugar	Juices
Mineral water	Electrical cords	Alcohol	Baby formula
Air conditioners	Ovens	Canned goods and cream	Toothpaste
Soy sauce	Distilled water	Sesame Oil	Sweetened vinegar
Motorcycle chains	Maize seed	Diapers	Air Fresheners
Apparel	Shampoos	Razors	Soap
Leather goods	Batteries	Golf Clubs	Tea bags
Pharmaceuticals	PCs	Credit cards	

Sources: International AntiCounterfeiting Coalition, Inc. (IACC), *Special 301 Recommendations*, Feb. 11, 2005; and USTR, *2005 Special 301 Report*, Apr. 29, 2005.

The automotive parts industry has increasingly faced counterfeiting, especially in overseas markets. Among the products that have been counterfeited in foreign markets like Korea and China are brake linings made of wood chips and cardboard, oil filters made of old rags and perforated food cans, gasoline filters without check valves, and glass windshields.<sup>177</sup> Counterfeiters of well-known auto parts illegally copy the originals, including the brand logos and packaging, in an effort to pass them off as genuine original equipment manufacturer replacement parts.<sup>178</sup> Sometimes such counterfeiting occurs when a U.S. company provides its technology to a foreign manufacturer it contracts to make the genuine parts. After the foreign firm meets the U.S. company's request, it may produce additional inventory to brand and sell through its own underground distribution networks.<sup>179</sup>

Another industry beset by foreign counterfeiting in recent years is the pharmaceutical industry. There have been increases in reported instances in that industry of the use of counterfeit labeling on containers of inactive chemicals or other ingredients, passed off as branded prescription drugs (or active ingredients for other purposes than intended by the original drugs).<sup>180</sup> For instance, counterfeiters have used ingredients like aspirin in bottles bearing counterfeit trademarks, such as for the schizophrenia drug, Zyprexa.<sup>181</sup> In 2003, the FDA investigated counterfeiting of Lipitor, a cholesterol drug, and Procrit, used in treating anemia in Cancer and AIDs patients.<sup>182</sup> Counterfeiters may also purchase or steal legitimate

<sup>177</sup> Sativa Ross, "Parts Counterfeiting," *Aftermarket Business*, Oct. 6, 2004, pp. 1-7, found at <http://www.aftermarketbusiness.com>, retrieved Oct. 6, 2004.

<sup>178</sup> Jim Mele, "Counterfeit Parts: Buyer Beware—Counterfeit Truck Parts," *Fleet Owner*, Mar. 1, 2004, pp. 1-6, found at <http://www.fleetowner.com>, retrieved Oct. 5, 2004.

<sup>179</sup> Ross, "Parts Counterfeiting," pp. 1-7.

<sup>180</sup> The U.S. Food and Drug Administration (FDA) reports that its counterfeiting drug investigations increased to more than 20 per year during 2001-2003, after averaging only 5 per year during 1997-2000. The agency states that "although exact prevalence rates are unknown outside the U.S., drug counterfeiting is known to be widespread and affects both developing and developed countries." U.S. Department of Health and Human Services, *Combating Counterfeit Drugs*, Report of the Food and Drug Administration, Feb. 18, 2005, pp. i and 2 (fig. 1), found at <http://www.fda.gov>, retrieved Sept. 6, 2005.

<sup>181</sup> Charles Haddad, "Fake Drugs, Real Disaster," *Business Week*, Feb. 9, 2004, p. 44.

<sup>182</sup> "Protecting Consumers from Counterfeit Drugs," *FDA Consumer Magazine*, May-June 2004, p. 1, found at <http://www.fda.gov>, retrieved Sept. 6, 2005.

pharmaceuticals and repackage them to appear to contain higher dosages than the stolen drugs, enabling them to increase the price of the drugs.<sup>183</sup>

Drug counterfeiters often produce very good copies of labels, bar codes, and logos. Imitations of products containing such marks typically are sold through legitimate distribution channels or online drugstores.<sup>184</sup> Another means used by counterfeiters to deceive customs and other border enforcement officials is to export otherwise noninfringing generic products to a country, then attach a counterfeit brand name label on the product once it is inside the importing country.<sup>185</sup> Or they may place legitimate stickers over products to cover a counterfeit label, then remove the sticker once the product has cleared customs and is safely inside the intended market.

### **Estimated Costs of Trademark Infringement**

Foregone revenues to U.S. companies due to foreign trademark counterfeiting are difficult to quantify. However, they are believed to be considerable.<sup>186</sup> In 1995, the International Trademark Association (INTA) commissioned DRI/WEFA, a U.S. econometric firm, to conduct a study quantifying losses accruing to trademark owners as a result of counterfeiting and other trademark infringement. The study indicated that, in 1995, companies participating in the study lost an average of 22 percent of their total sales or \$2 billion as a result of such infringement. The International Chamber of Commerce Commercial Crime Services Division reported in 2001 that counterfeiting accounts for around 5-7 percent of world trade, and that the global counterfeit market is worth \$350 billion.<sup>187</sup> U.S. industry representatives state that because of the strengths of U.S. brands in global markets a significant portion of such revenue losses accrue to U.S. companies.<sup>188</sup> Meanwhile, the U.S. pharmaceutical industry has estimated that counterfeit drugs account for up to 40 percent of its sales in some countries.<sup>189</sup> Estimated trade losses due to counterfeiting to that industry in China, India, and Korea together amounted to \$3.5 billion in 2003; and Turkey and Poland accounted for another \$1 billion in losses in that year.

The U.S. Department of Homeland Security (DHS) collects annual information on top IPR products seized by U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement from foreign countries attempting to export them into the United States (table 9). Although the IPR seizures include those made for all types of IPR violations, in fact, virtually all such seizures involve counterfeits of trademarked products.<sup>190</sup> Cigarettes and wearing apparel; and handbags, wallets, and backpacks accounted for the largest portion of counterfeited products seized by DHS in 2003.

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<sup>183</sup> IACC representatives, interview by USITC staff, Washington, DC, Jan. 20, 2004.

<sup>184</sup> Hadda, "Fake Drugs, Real Disaster," p. 44.

<sup>185</sup> USTR, "Annual "Special 301" Report Finds Continued Progress on Strengthening Intellectual Property Protection, but Significant Improvements Needed," *USTR Press Release*, May 3, 2004, found at <http://www.ustr.gov>, retrieved June 24, 2004; and PhRMA, interview by USITC staff, Washington, DC, Feb. 25, 2004.

<sup>186</sup> INTA Bulletin, Oct. 2001, p. 3.

<sup>187</sup> ICC, "A Brief Overview of Counterfeiting," pp. 1-2, 2001.

<sup>188</sup> INTA Bulletin, Oct. 2001, p. 3.

<sup>189</sup> PhRMA representatives, interview by USITC staff, Feb. 25, 2004; and USTR, *2004 Special 301 Report*, p. 17, and pp. 24-26.

<sup>190</sup> Other IPR seizures principally consist of pirated copyrighted materials.

**Table 9**  
**Top Counterfeit IPR Products Seized by U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement, Department of Homeland Security, 2003**

<b>Product</b>	<b>U.S. dollar value</b>	<b>Percent of total</b>
Cigarettes .....	41,720,129	44
Wearing apparel .....	13,888,823	15
Handbags, wallets, backpacks .....	11,458,259	12
Media <sup>1</sup> .....	7,357,876	8
Consumer electronics <sup>2</sup> .....	3,779,736	4
Watches and parts .....	3,384,025	4
Footwear .....	2,555,386	3
Toys and electronic games .....	1,510,839	2
Sunglasses and parts .....	1,380,542	1
Headwear .....	1,286,198	1
All other commodities .....	<u>5,697,414</u>	<u>6</u>
Total .....	<u>94,019,227</u>	<u>100</u>

<sup>1</sup> Media includes motion pictures on tape, laser disc, and DVD; interactive and computer software on CDROM, CD-R, and floppy discs; and music on CD or tape.

<sup>2</sup> Consumer electronics includes cellular telephones and accessories, radios, power strips, electrical tools, and appliances.

Source: U.S. Customs and Border Protection, LA Strategic Trade Center, 2003.

As the following tabulation shows, in 2003, counterfeit products valued at over \$94 million were seized, representing a 5-percent decline from the previous year. Despite the 5-percent decline in value, the number of seizures increased by 12 percent in 2003, representing more than double the number reported in 2000. China accounted for well over one-half of the total value of products seized.

<b>Year</b>	<b>Total number of seizures</b>	<b>U.S. dollar value</b>
2003 .....	6,500	94,019,227
2002 .....	5,793	98,990,341
2001 .....	3,586	57,438,680
2000 .....	3,244	45,327,526
1999 .....	<u>3,691</u>	<u>98,501,594</u>
Total .....	<u>22,814</u>	<u>394,277,368</u>

Source: U.S. Customs and Border Protection.

Lost sales and lower profits are not the only costs accruing to trademark infringement. For instance, when a counterfeit product effectively passed off as an original is of lower quality, ineffective, or causes injury, the firms holding the genuine trademark are often open to law suits related to health and safety matters.<sup>191</sup> Firms also suffer economically due to the loss of good will and reputation of their company and products when problems caused by counterfeit products are attributed to the trademark holder and reported widely in the news media. Firms facing such infringement may have to expend resources to enforce their intellectual property by hiring lawyers, investigators, and other staff. The time

<sup>191</sup> IACC representatives, interview by USITC staff, Washington, DC, Jan. 20, 2004.

and resources diverted from other business activities when addressing IPR infringement constitute opportunity costs incurred by firms.<sup>192</sup> Companies may also face costs in having to purchase security technology and other measures to make it more difficult for their products to be imitated and successfully marketed.

### *Copyrights*

According to IIPA, in 2002, the total U.S. copyright industry,<sup>193</sup> which includes various supporting segments, contributed \$1.245 trillion in value-added to the U.S. economy, or 11.9 percent of gross domestic product (GDP); in addition, as indicated at the beginning of this report, “core” copyright producers contributed \$626.6 billion in value added or 6 percent of U.S. GDP.<sup>194</sup> Sales by U.S. firms in foreign markets and U.S. exports of core copyright products reached \$89.3 billion in 2002, up 1.1 percent over 2001 figures of \$88.3 billion. This slight increase is due primarily to gains by the motion picture industry, as most other core industries, including sound recording and music publishing, books and periodical publishing, and software all reported declines in foreign sales and exports for 2002, largely due to copyright piracy and economic downturns in key markets.<sup>195</sup> Piracy is the largest market access barrier to producers and distributors of copyright-protected products in foreign markets, reducing investment and employment opportunities.<sup>196</sup> However, these firms contend that improved enforcement methods and increased legal use of digital distribution of copyrighted materials could reverse these losses.<sup>197</sup>

Under U.S. law, a work is copyrighted immediately upon “fixation” in a tangible medium of expression.<sup>198</sup> A work is “fixed” when its embodiment in a copy is permanent or stable enough to allow it to be perceived for more than just a “transitory” period of time.<sup>199</sup> Fixed works receive protection regardless of whether they are published or unpublished. Publication of a work consists of distributing it either through sale, lease, or rental. Copyrights generally accrue to the author of the work and in cases where there are multiple authors, they share joint ownership of the copyright. In the case of “works for hire,”<sup>200</sup> the employer becomes the copyright holder.<sup>201</sup>

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<sup>192</sup> Kathleen Richards, “Global Market Strains IP Protection Strategies,” *Lightwave*, Sept. 2004, pp. 47-49.

<sup>193</sup> According to the IIPA, the copyright industry refers to firms that manufacture and/or distribute copyright-protected products. Siwek, “Copyright Industries in the U.S. Economy,” p. 1. The copyright industry also is often referred to as “the copyright industries,” taking into account the separate industries making up that industry. See footnote 20 of this paper.

<sup>194</sup> IIPA’s methodology meets international standards outlined by the WIPO. WIPO divides the industry into four categories: core, partial, non-dedicated support, and interdependent. Core industries are those that actually produce copyrighted products, such as book publishers or software manufacturers. Siwek, “Copyright Industries in the U.S. Economy,” pp. 5-6.

<sup>195</sup> Siwek, “Copyright Industries in the U.S. Economy,” p. vi.

<sup>196</sup> IIPA, “10 Years of the WTO TRIPS Agreement, Appendix to IIPA’s Press Release,” Oct. 7, 2004, found at <http://www.iipa.com/trips.html>, retrieved May 11, 2005.

<sup>197</sup> Siwek, “Copyright Industries in the U.S. Economy,” pp. vi, and 9-10.

<sup>198</sup> 17 U.S.C. §102(a).

<sup>199</sup> 17 U.S.C. §101 (see definition of “fixed”).

<sup>200</sup> Works for hire include works created by employees in the course of their job or works that are “ordered or commissioned.” U.S. Copyright Office, Circular 1, “Copyright Basics,” found at <http://www.copyright.gov/>, retrieved Oct. 21, 2004.

<sup>201</sup> U.S. Copyright Office, Circular 1, “Copyright Basics.”

The United States Copyright Act (title 17, U.S. code) provides protection for original authored works, granting the author exclusive rights to copy, license, distribute, perform (publicly or public via digital audio transmission), or display their work (table 10).<sup>202</sup> Examples of categories of products protected by copyright include literary works (including software); musical works; dramatic works; pantomimes and choreographic works; pictorial, graphic, and sculptural works; motion pictures and other audiovisual works; sound recordings; and architectural works.<sup>203</sup> Exceptions exist, including for (1) the affirmative defense of “fair use”<sup>204</sup> of the work;<sup>205</sup> (2) the first sale doctrine,<sup>206</sup> which limits the copyright owner’s right of distribution by authorizing the resale of lawfully acquired copies; (3) various exceptions for reproductions by libraries and archives;<sup>207</sup> and (4) certain exemptions for various performances and displays.<sup>208</sup>

Prior to 1978, authors were required to publish with notice and register their copyright in order to receive protection for their work. If these rules were not followed, a work could end up in the public domain.<sup>209</sup> Copyright notification includes a sign that the work is copyrighted, typically the word, “copyright” or the copyright symbol, “©,” the date of publication, and the name of the author. These requirements were removed when the United States ratified the Berne Convention, which does not allow such requirements in order to offer protection. Now, neither registration nor notification are necessary to obtain copyright protection. The registration process is a formality designed to create a public record outlining basic information about the copyrighted work. However, while optional, registration helps prevent infringement, since violators cannot claim they were unaware the copied work was protected.<sup>210</sup>

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<sup>202</sup> 17 U.S.C. 102(a).

<sup>203</sup> 17 U.S.C. 102(a). For more information, please see U.S. Copyright Office, Circular 2, “Copyright Basics,” found at <http://www.copyright.gov>, retrieved Oct. 21, 2004; and Legal Information Institute (LII), found at <http://www.law.cornell.edu/topics/copyright.html>, retrieved Oct. 21, 2004.

<sup>204</sup> Section 107 of the Copyright Act states that certain uses of copyrighted material, including “criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research,” are not necessarily a violation. Section 107 outlines four criteria used to determine if the use of the copyrighted material is in fact, fair. These include the type of use, i.e., whether a commercial benefit will accrue to the user, the nature of the work, the amount of the work used, and the effect the use may have on the value of the work. U.S. Copyright Office, Copyright Law of the United States of America and Related Laws Contained in Title 17 of the United States Code, Circular 92, Section 107, “Limitations on Exclusive Rights: Fair Use,” found at <http://www.copyright.gov>, retrieved Feb. 14, 2005.

<sup>205</sup> For additional exceptions, please see U.S. Copyright Office, Copyright Law of the United States of America and Related Laws Contained in Title 17 of the United States Code, Circular 92, found at <http://www.copyright.gov> retrieved Sept. 26, 2005.

<sup>206</sup> 17 U.S.C. §109(a).

<sup>207</sup> 17 U.S.C. §108.

<sup>208</sup> 17 U.S.C. §110.

<sup>209</sup> A work is said to be in the public domain when its copyright expires as the author ceases to have exclusive rights and the work is now freely available to the public.

<sup>210</sup> Legal Information Institute, “Copyright, An Overview,” found at <http://www.law.cornell.edu/topics/copyright.html/>, retrieved Oct. 21, 2004; U.S. Copyright Office, “In Answer to Your Query: International Copyright;” and “Copyright Basics,” found at <http://www.copyright.gov/>, retrieved Oct. 22, 2004.

**Table 10**  
**Copyright law**

<b>Legislation</b>	<b>Summary</b>	<b>Date of implementation</b>
United States Copyright Act (Title 17, U.S. Code)	Covers published and unpublished works; extends copyright term; establishes scope of protection for various works.	1976
Amendments to the Copyright Act		
<i>Berne Convention Implementation Act</i>	Brings United States into full compliance with the Berne Convention.	1988
<i>Digital Millennium Copyright Act</i>	Implements the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT); establishes liability limitations for ISPs; exempts computer program copies for maintenance and repair; provides protections for hull designs; outlines other miscellaneous provisions.	October 28, 1998
<i>Sonny Bono Copyright Term Extension Act</i>	Extends copyright protection for an additional 20 years after the death of the author, bringing total protection to the lifetime of the creator plus 70 years.	January 27, 1998
Fairness in Music Licensing Act	Extends pre-1978 copyright protection in the United States by 20 years to 95 years.	January 27, 1998
	Implements the provisions of the Uruguay Round, including TRIPS.	December 8, 1994

Source: U.S. Copyright Office, Circular 38b, International Copyright Relations of the United States, found at <http://www.copyright.gov/>, retrieved Oct. 25, 2004; S. 505 105<sup>th</sup> Congress 2<sup>nd</sup> session Jan. 27, 1998, Copyright Term Extension"; William M. Landes and Richard A. Posner, *The Political Economy of Intellectual Property Law*, 2004, AEI Press: Washington, DC, pp. 2-4, 13; and U.S. Copyright Office, "The Digital Millennium Copyright Act of 1998 - Summary," found at [http://www.copyright.gov](http://www.copyright.gov/), retrieved Oct. 21, 2004.

There have been three major amendments to the Copyright Act: the Berne Convention Implementation Act, the Digital Millennium Copyright Act, and the Sonny Bono Copyright Term Extension Act. Passage of the Berne Convention Implementation Act (BCIA) of 1988 was a crucial step in preparing the United States for participation in international copyright.<sup>211</sup> Congress undertook a full and complete analysis of whether the framework of legal protection in the United States complied with the BCIA, including the "moral rights" (see text box) requirements of Berne, and made additional changes to the Copyright Act to ensure compliance.<sup>212</sup>

<sup>211</sup> U.S. Copyright Office official, memorandum dated May 20, 2005, to USITC staff.

<sup>212</sup> Ibid.

### Moral Rights and the Berne Convention

Most commonly “moral rights” refer to an author's right to have his work identified as his own (the right of attribution), and an author's right to stop distortion or destruction of his work (the right of integrity). These rights remain with the author and cannot be transferred.

The Berne Convention provides for moral rights in article 6bis, which states:

“(1) Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honour or reputation.

(2) The rights granted to the author in accordance with the preceding paragraph shall, after his death, be maintained, at least until the expiry of the economic rights, and shall be exercisable by the persons or institutions authorised by the legislation of the country where the protection is claimed. However, those countries whose legislation, at the moment of their ratification of or accession to this Act, does not provide for the protection after the death of the author of all the rights set out in the preceding paragraph may provide that some of these rights may, after his death, cease to be maintained.”

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Source: Berne Convention, Article 6bis.

The United States passed the Digital Millennium Copyright Act (DMCA) in 1998. The DMCA, which addresses Internet and other digital piracy, implements the WIPO Internet Treaties in the United States, including its provisions relating to technological protection measures and rights management information protection.<sup>213</sup> Other core elements include liability limitations for Internet service providers (ISPs); exemptions for making copies of software in the course of maintenance or repair; and new protections for vessel hull designs.<sup>214</sup>

The Sonny Bono Copyright Term Extension Act of 1998 extends the term of copyright protection for original works by 20 years. Under this Act, works created post-1978 or works created pre-1978, but not published or registered until after 1978, are now protected for the lifetime of the author plus 70 years. For works created pre-1978 that currently enjoy copyright protection, the term has been extended to 95 years from the initial date of copyright.<sup>215</sup>

The Uruguay Round Agreements Act (URAA)<sup>216</sup> implements all of the agreements developed during the Uruguay Round of trade negotiations, including the TRIPS Agreement. The United States was obliged to amend its laws to incorporate the provisions of TRIPS. For example, section 109(b) of the Copyright Act was amended to eliminate the expiration of software rental rights. Now, under the URAA, software copyright holders enjoy these rights in perpetuity. The URAA also establishes civil and criminal penalties for unauthorized copying or “bootlegging” of music recordings or performances and provides for the restoration of copyright protection for foreign works that have fallen in the public domain in the United

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<sup>213</sup> See textbox on the WIPO Internet Treaties presented in the above section of this paper on international IPR agreements.

<sup>214</sup> U.S. Copyright Office, “The Digital Millennium Copyright Act of 1998, U.S. Copyright Office Summary,” Dec. 1998, found at <http://www.copyright.gov>, retrieved Oct. 21, 2004.

<sup>215</sup> U.S. Copyright Office, “New Terms for Copyright Protection,” found at <http://www.copyright.gov/legislation/dmca.pdf>, retrieved Oct. 21, 2004.

<sup>216</sup> Public Law 103-465.

States, but have not yet fallen into the public domain in the author’s home country through the expiration of the term.<sup>217</sup>

## International Copyright Agreements

A single international copyright designed to protect an authored work on a multilateral basis does not exist; in that regard there is no such thing as an international copyright. Authors instead must rely on the laws of individual countries, as well as multinational and bilateral copyright agreements, in order to secure protection for their works. The United States is a party to several international conventions that provide copyright protections, including the Buenos Aires Convention, the Berne Convention, the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of the Phonograms, the Universal Copyright Convention, the WCT, the WPPT, and the TRIPS Agreement (table 11).

**Table 11**  
International copyright conventions to which the United States is a party

Convention/Agreement	Date of U.S. implementation
Buenos Aires Convention, 1910	July 13, 1914
Berne Convention for the Protection of Literary and Artistic Works	March 1, 1989
Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of the Phonograms, Geneva, 1971	March 10, 1974
Universal Copyright Convention, Geneva, 1952 and as amended Paris, 1971	September 16, 1955 as amended July 10, 1974
WIPO Copyright Treaty 1996	March 6, 2002
WIPO Performances and Phonograms Treaty	March 20, 2002
WTO Agreement on Trade-Related Aspects of Intellectual Property Rights	January 1, 1995

Source: U.S. Copyright Office, Circular 38a, International Copyright Relations of the United States, found at <http://www.copyright.gov>, retrieved Oct. 25, 2004.

All of the agreements summarized in table 8 accord copyright protection on a national treatment basis. The TRIPS Agreement provides broad coverage and basic principles for copyright protection, and includes rules for the standard application of intellectual property agreements, enforcement, dispute settlement, and transition periods for implementation by developing member states.<sup>218</sup> Under TRIPS, authored works are protected for the author’s lifetime plus an additional 50 years. Works protected by copyright include literary works, such as books and software, and artistic works such as music, paintings, sculpture, and films.<sup>219</sup> The agreement treats existing international agreements as the baseline for protection and adds new standards of conduct for all countries where there are deficiencies. For example, since software is not covered by the Berne Convention, the TRIPS Agreement establishes software as a literary work, ensuring protection. TRIPS also grants authors of software and sound recordings rental

<sup>217</sup> U.S. Copyright Office, Circular 38a, International Copyright Relations of the United States, found at <http://www.copyright.gov>, retrieved Oct. 25, 2004; and Recording Industry Association of America (RIAA) representative, e-mail communication to USITC staff, May 6, 2005.

<sup>218</sup> WTO, “Intellectual Property: Protection and Enforcement,” found at <http://www.wto.org>, retrieved Oct. 21, 2004.

<sup>219</sup> WTO, “TRIPS: What are IPRs - What are Intellectual Property Rights?,” found at <http://www.wto.org>, retrieved Oct. 21, 2004.

rights and rights against unauthorized recording, copying, and broadcast of their works.<sup>220</sup> In terms of enforcement, TRIPS requires member states to make copyright violations an actionable offense under their domestic laws with penalties severe enough to deter similar actions. The agreement outlines enforcement measures necessary to protect the industry from copyright violations.<sup>221</sup>

TRIPS was finalized prior to consideration of such copyright issues as Internet and other digital piracy. The WIPO WCT and WPPT treaties, also referred to as the “Internet Treaties,” were established under the 1996 diplomatic conference because, as previously indicated, they provide new international standards for the protection of copyright and related rights in a digital environment.<sup>222</sup> The two treaties confirmed that copyright applies in the digital environment, significantly clarifying exclusive rights in the distribution of copies of works, and in the communication to the public of works, including the “making available” of works so they can be accessed at a place and at a time chosen by the user. Other key provisions of the Internet Treaties include protections against the unlawful circumvention of technical protective measures used to protect works, as well as protections against illegal tampering or altering of tags or codes that may be used to facilitate licensing (so-called rights management information). Additionally, both treaties contain provisions requiring signatories to impose penalties for such unlawful activities, which are the principal means for providing copyright owners with security in making their works available in digital formats.<sup>223</sup>

In addition to the multinational agreements, the United States has also completed a number of bilateral free trade agreements (FTAs) that provide copyright protection. Among other things, the FTAs include provisions that require ratification of the WIPO Internet Treaties and implementation of DCMA-like legislation.<sup>224</sup> These agreements offer the highest level of intellectual property protection of any international agreement,<sup>225</sup> and U.S. industry endorses the comprehensive treatment of intellectual property designed to protect copyrighted products.<sup>226</sup>

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<sup>220</sup> WTO, “Intellectual Property: Protection and Enforcement.”

<sup>221</sup> IIPA, “10 Years of the WTO TRIPS Agreement, Appendix to IIPA’s Press Release,” found at <http://www.iipa.com>, retrieved Oct. 18, 2004.

<sup>222</sup> Gibson, *WIPO Internet Copyright Treaties Coming Into Force* (London: Steptoe & Johnson, 2002), pp. 1-4.

<sup>223</sup> U.S. Copyright Office official, memorandum dated May 20, 2005, to USITC staff.

<sup>224</sup> U.S. Government official, AIPLA Annual Meeting, Washington, DC, Oct. 14, 2004.

<sup>225</sup> *Ibid.*

<sup>226</sup> IIPA, “10 Years of the WTO TRIPS Agreement, Appendix to IIPA’s Press Release.”

## *Effect of Copyright Piracy on U.S. Industries*

### **Industries Affected**

Copyright piracy is the most important challenge faced by U.S. copyright holders. U.S. industries most affected by such piracy include the book publishing, motion picture, music recording, entertainment software, and business software industries.

### **Reported Costs of Foreign Copyright Piracy to U.S. Industries**

The IIPA estimates that foreign copyright piracy cost U.S. industry over \$12.5 billion in 52 selected markets in 2004 (table 12), exclusive of Internet piracy such as illegal downloads.<sup>227</sup> The IIPA estimates that global losses for U.S. copyrighted materials range from \$25-30 billion each year (not including Internet piracy). Copyrighted materials may be simple and inexpensive to reproduce making illegal copying a lucrative endeavor for pirates.<sup>228</sup> Typically, the more developed a country, the more sophisticated the piracy. The IIPA equates piracy rates with the number of unauthorized units sold. For example, piracy of audiovisual products during 1997-1998 was approximately 15 percent. As a result of growing optical disc piracy, video piracy has increased to 50 percent currently.<sup>229</sup> Optical disc (CDs and DVDs, etc.) piracy is a particular concern as supply far exceeds demand for these products. The industry states that strict licensing laws are required to track production and Internet piracy is a critical concern. U.S. industry representatives believe that the secure transmission of copyright products over the Internet will lead to gains in economic growth and productivity in the United States. However, they caution that piracy can easily reverse these gains.<sup>230</sup>

According to a U.S. industry representative, unauthorized use of content is increasing dramatically, with illegal movie downloads estimated at 400,000 to 600,000 per day. Movies are often available on the street just hours after the films appear in theaters in Russia and China.<sup>231</sup> In addition, the Motion Picture Association of America (MPAA) estimates that a quarter of all Internet users worldwide have used the Internet to illegally download a movie, with the figure as high as 58 percent in Korea. Illegal downloading of movies is linked to a decrease in legitimate movie attendance and DVD/video purchasing, thus decreasing the revenues and profits of U.S. motion picture companies. Other digital piracy is also increasing rapidly, particularly in the case of illegally copied video,<sup>232</sup> sound, and other entertainment recorded on or copied from digital optical discs.<sup>233</sup> U.S. industry representatives report that strong enforcement is needed to prevent online and other digital piracy and encourage the legitimate sale of copyrighted materials and that implementation of the WIPO Internet Treaties will be instrumental in this regard.<sup>234</sup>

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<sup>227</sup> IIPA, "2004 Final Estimated Trade Losses Due to Copyright Piracy," June 4, 2005, found at <http://www.iipa.com/statistics.html>.

<sup>228</sup> IIPA representative, interview by USITC staff, Sept. 7, 2005.

<sup>229</sup> U.S. industry representative, interview with USITC staff, Washington, DC, Sept. 7, 2004.

<sup>230</sup> IIPA, "IIPA's New Economic Study Reveals the Copyright Industries Continue to be a Driving Force in the U.S. Economy," found at <http://www.IIPA.com>, retrieved Oct. 18, 2004.

<sup>231</sup> U.S. industry representative, AIPLA Annual Meeting, Washington, DC, Oct. 14, 2004.

<sup>232</sup> Refers to movies films.

<sup>233</sup> Also known as Digital Versatile Discs.

<sup>234</sup> U.S. industry representative, interview by USITC staff, Washington, DC, Sept. 7, 2004.

**Table 12**  
**Estimated trade losses due to copyright piracy in 52 selected foreign countries during 2000-2004**

Year	Motion pictures	Records and music	Business software	Entertainment software	Books	Estimated total losses
<i>In million dollars</i>						
2000	1,221.0	1,800.3	2,821.5	1,608.8	653.3	8,104.9
2001	1,288.0	2,034.7	2,653.5	1,767.1	636.4	8,379.7
2002	1,578.3	2,227.5	4,835.7	1,024.4	576.8	10,870.1
2003	1,671.7	2,777.6	6,728.0	1,686.8	535.6	13,245.1
2004	1,635.5	2,437.8	6,155.0	1,743.9	571.0	12,543.2

Source: Adapted with permission from IIPA, "2004 Final Estimated Trade Losses Due to Copyright Piracy;" June 4, 2005, found at <http://www.iipa.com/statistics.html>.

Software piracy sometimes takes the form of end user piracy, where entities or individuals make unauthorized copies of licensed software for their own use, and traditional counterfeiting, where pirated product is made to look like legitimate products or is bundled with other software packages to entice consumers. In 2004, approximately \$33 billion of personal computer software was pirated worldwide.<sup>235</sup> Internet piracy is a grave concern for the industry because millions of infringing copies can be downloaded online, instead of being sold one at a time.<sup>236</sup> Book publishers face more traditional forms of piracy, such as photocopying and illegal translations.<sup>237</sup>

Parallel import protection can also affect copyright-protected products. For example, through parallel imports, a movie could be released in theaters in one market at the same time the parallel imported video is already circulating for sale. Publishers who produce less expensive versions of textbooks for lesser developed countries are concerned that these cheaper books will be made available in larger markets, hurting sales of legitimate books.<sup>238</sup>

### **Measuring the Impact of Foreign IPR Infringement on U.S. Industry and Trade**

U.S. industry trade losses due to foreign infringement are believed to be substantial. However, hard data is lacking to substantiate the magnitude of such losses, and economists have found the economic effects of such losses difficult to quantify. This section briefly summarizes and critiques the existing research and data on IPR-related trade and the costs of foreign IPR infringement.

The chief sources of intellectual property data include (1) an annual article on U.S. international services published by the BEA, in its *Survey of Current Business*, which includes, among other things, U.S. trade data in intangible intellectual property rights; (2) U.S. foreign revenue loss estimates due to IPR

<sup>235</sup> BSA and IDC, "Global Software, Piracy Study," May 2005, p. 9. This figure is different from that shown for the types of software shown in the table 9 because it represents global software losses due to piracy for all types of PC software and is not limited to business and entertainment software. Further, the data is not limited to that for the 52 countries for which the data in table 9 is applicable.

<sup>236</sup> Robert Cresanti, BSA, statement to the House Committee on Government Reform, Sept. 23, 2004.

<sup>237</sup> IIPA, "Copyright Industry Initiatives and Challenges in 2004," found at <http://www.iipa.com>, retrieved Oct. 18, 2004.

<sup>238</sup> U.S. industry representative, interview by USITC staff, Washington, DC, Sept. 7, 2004.

infringement for certain countries provided annually by IIPA; (3) damage estimates of foreign IPR infringement provided by PhRMA for certain countries; and (4) data provided by the U.S. Department of Homeland Security on the value of counterfeits seized by U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement. In the past, the International Anti-Counterfeiting Coalition (IACC), representing numerous companies and associations dependent on trademarks, has also provided trade loss estimates in selected publications. The U.S. International Trade Commission published the last comprehensive U.S. Government analysis estimating U.S. revenue losses due to foreign infringement of U.S. IPR in 1988.<sup>239</sup>

In the annual BEA article, trade in intangible intellectual property rights is captured under the royalties and license fees line-item in the U.S. balance of payments. These fees are generated by sales of intellectual property or proprietary rights such as patents, trademarks, copyrights, franchises, broadcast rights, as well as the rights to distribute, use, and reproduce general-use computer software. These fees also include the right to sell a product under a certain brand name and management consulting fees.<sup>240</sup> Trade in intangible intellectual property rights is only reported on a cross-border basis, meaning the intellectual property, fees, and personnel are transmitted across national borders.<sup>241</sup> As indicated in table 13, U.S. receipts of royalties and license fees by U.S. companies from foreign affiliated and unaffiliated firms increased by 9 percent to \$48.2 billion in 2003 from the previous year.<sup>242</sup> Meanwhile, U.S. payments of royalties and license fees to affiliated and unaffiliated firms overseas increased by 4 percent to \$20 billion in 2003, resulting in a U.S. surplus of \$28.2 billion in 2003 in such transactions.<sup>243</sup> It should be noted that such trade accounts for only a small portion of total revenues derived by U.S. and foreign companies from their IPR, since many products dependent on such rights are sold by means other than through collection of royalties and licensing fees, such as through direct sales and exports.

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<sup>239</sup> USITC, inv. No. 332-245, *Foreign Protection of Intellectual Property Rights and the Effect on U.S. Industry and Trade*, Report to the USTR, USITC pub. No. 2065, Feb. 1988.

<sup>240</sup> BEA, "U.S. International Transactions in Royalties and Licensing Fees: Their relationship to the Transfer of Technology," *Survey of Current Business*, Dec. 1973, p. 15.

<sup>241</sup> For a more robust discussion of affiliate trade, please see USITC, *Recent Trends in Services Trade 2004 Annual Report*, USITC pub. No. 3703, June 2004, pp. 2-1 - 2-13.

<sup>242</sup> BEA, *Survey of Current Business*, Oct. 2004, pp. 32-33.

<sup>243</sup> Royalty and license fees for the use of general-use computer software and use of industrial manufacturing processes in the pharmaceutical and telecommunications industries were responsible for the largest portion of U.S. receipts from unaffiliated foreign companies in 2003. BEA, *Survey of Current Business*, Oct. 2004, pp. 32-33.

Table 13

**U.S. receipts (exports) and payments (imports) of royalties and license fees associated with affiliated and unaffiliated foreign companies: 1987-2003**

Year	U.S. receipts (exports)			U.S. payments (imports)			U.S. trade balance		
	All	Affiliated	Unaffiliated	All	Affiliated	Unaffiliated	All	Affiliated	Unaffiliated
1987	9,914	7,629	2,285	1,844	1,296	547	8,070	6,333	1,738
1988	11,802	9,156	2,646	2,585	1,410	1,175	9,217	7,746	1,471
1989	13,064	10,207	2,857	2,602	1,778	824	10,462	8,429	2,033
1990	16,634	13,251	3,384	3,135	2,206	929	13,499	11,045	2,455
1991	18,017	14,395	3,712	4,076	2,996	1,080	13,941	11,399	2,632
1992	19,715	15,718	3,997	5,074	3,381	1,694	14,641	12,337	2,303
1993	20,323	15,707	4,616	4,765	3,364	1,401	15,558	12,343	3,215
1994	26,712	20,275	6,347	5,852	3,934	1,919	20,860	16,341	4,428
1995	30,289	22,859	7,430	6,919	5,257	1,663	23,370	17,602	5,767
1996	32,470	24,556	7,914	7,837	5,406	2,431	24,633	19,150	5,483
1997	33,228	24,465	8,763	9,161	6,749	2,412	24,067	17,716	6,351
1998	39,626	26,313	9,314	11,235	8,547	2,688	28,391	17,766	6,626
1999	39,670	29,275	10,395	13,107	10,374	2,733	26,563	18,901	7,662
2000	43,233	30,479	12,754	16,468	12,536	3,932	26,765	17,943	8,802
2001	40,696	29,164	11,532	16,538	13,241	3,297	24,158	15,923	8,235
2002	44,219	32,658	11,561	19,235	15,084	4,151	24,984	17,574	7,410
2003	48,227	35,924	12,303	20,049	16,407	3,642	28,178	19,517	8,661

Note.—Details may not add to totals because of rounding. Affiliate refers to a business enterprise located in one country that is directly or indirectly owned or controlled by an entity in another country. Controlling interest must equal 10 percent or more of its voting stock or its equivalent.

Source: U.S. Bureau of Economic Analysis, *Survey of Current Business*, 80 (10): Oct. 2004.

Some analysts believe that IIPA has one of the most comprehensive and transparent methodologies for estimating revenue losses due to foreign IPR infringement, which it uses in support of its annual Special 301 submissions to USTR.<sup>244</sup> As previously indicated, in 2005, IIPA estimated that copyright industries represented by its organization amounted to over \$12.5 billion in 52 selected markets in 2004 (table 14).<sup>245</sup> However, other analysts point out that IIPA's estimates have certain limitations that affect the analysis of foreign copyright piracy.<sup>246</sup> For example, IIPA's estimates are limited to losses of companies represented by IIPA. Further, they do not include the costs of Internet piracy, which is fast becoming one of the principal means of piracy. Finally, in estimating copyright revenue losses by deriving estimates of additional revenues of copyright products (such as DVDs) could have been generated in a particular market or markets if pirate copies were not manufactured and distributed, it is not clear from the IIPA methodology how many people in a country that paid \$3 for an IPR infringing DVD would (or could) pay \$20 for a legitimately marketed DVD, if piracy did not exist.<sup>247</sup>

PhRMA estimates revenue losses in foreign countries due to inadequate patent and data protection for pharmaceuticals. In 2005, it documented losses of over \$7 billion in 22 selected countries in 2004 due to inadequate patent and data protection (accruing to both its U.S.- and non-U.S.-based member firms)

<sup>244</sup> IIPA's piracy estimate methodology may be viewed at <http://www.iipa.com/pdf/2005spec301methodology.pdf>.

<sup>245</sup> IIPA, "2004 Final Estimated Trade Losses Due to Copyright Piracy," June 4, 2005, found at <http://www.iipa.com/statistics.html>.

<sup>246</sup> U.S. academic and government economists, and U.S. industry analysts, in-person and telephone interviews by USITC staff, Aug.-Dec. 2004 and Apr.-May 2005.

<sup>247</sup> Ibid.

(table 15).<sup>248</sup> Previously, that organization had provided damage information in its annual Special 301 submissions to the U.S. Government, but had not separated out IPR-related damages from damages related to tariff and other nontariff issues (such as price reimbursement and regulatory issues). An important limitation of the PhRMA data is that it is confined to those countries for which PhRMA submits its annual Special 301 recommendations. Further, PhRMA has not yet been successful in documenting losses for one of its most important foreign markets, India. Thus the PhRMA data likely understate total losses due to inadequate patent, data, and other IPR protection. The lack of estimated revenue loss data due to inadequate patent and data protection in industries other than the pharmaceutical industry also limits the ability to analyze the effects of foreign patent infringement on the U.S. industry as a whole.

The IACC, representing a broad range of industries dependent on trademarks, also has commissioned studies in the past that included some overall revenue loss estimates affecting its members as a whole, but not broken out by country. But even these estimates have not been completed in recent years. IACC representatives indicate that they will not commission such studies in the future, since their limited resources are more effectively put to use in their other efforts to combat overseas counterfeiting and piracy.<sup>249</sup>

Although estimates of total revenues lost by U.S. companies are not available, data collected annually by DHS show the value of counterfeit products seized by U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement. In 2003, counterfeit products valued over \$94 million were seized by those agencies, with imports from China accounting for almost two-thirds of such seizures (table 16). Although such data is useful, it accounts for only a small portion of the billions of dollars in estimated losses to U.S. companies annually resulting from foreign trademark infringement from illicit sales in their U.S. and overseas markets. Further, a portion of the losses reflected in the DHS statistics represent losses to trademarked products of foreign companies, making it even more difficult to allocate foreign trademark infringement losses to U.S. industries.

The USITC completed the last comprehensive U.S. Government analysis estimating total U.S. revenue losses due to foreign infringement of U.S. IPR in 1988.<sup>250</sup> The study surveyed hundreds of U.S. firms, including all of the Fortune 500 companies and smaller firms believed to depend on royalties or sales of goods protected by intellectual property. Respondents estimated their aggregate worldwide losses as a result of inadequate intellectual property protection in 1986 at \$23.8 billion, or 2.7 percent of sales.<sup>251</sup> However, the USITC report pointed out a number of caveats with respect to its estimates, including statements that its figures represent estimates from a percentage of an unknown universe, and, likely substantially underestimate total losses experienced by U.S. industry. It should also be noted that the estimates were, at least partly, based on anecdotal responses of companies and associations to a USITC questionnaire.

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<sup>248</sup> PhRMA, 2005 Special 301 submission, app. A. The PhRMA damage estimate methodology may be viewed at [http://www.phrma.org/international/Appendix\\_A\\_Damage\\_Estimate\\_Methodology.pdf](http://www.phrma.org/international/Appendix_A_Damage_Estimate_Methodology.pdf).

<sup>249</sup> Such as working within the legal systems of problematic foreign countries to combat counterfeiting, and with international enforcement groups like Interpol, as well as with U.S. Government organizations such as USTR and USPTO. IACC officials, interview by USITC staff, Jan. 2004.

<sup>250</sup> USITC, *Foreign Protection of Intellectual Property Rights*, pp. vii and H-2.

<sup>251</sup> *Ibid.*, p. viii.

**Table 14**  
**Estimated trade losses due to copyright piracy in 52 selected foreign countries during 2000-2004**

Year	Motion pictures	Records and music	Business software	Entertainment software	Books	Estimated total losses
<i>In million dollars</i>						
Argentina	30.0	41.5	63.0	NA	NA	134.5
Azerbaijan	NA	12.0	NA	NA	NA	12.0
Bahamas	NA	NA	NA	NA	NA	NA
Belarus	NA	26.0	NA	NA	NA	26.0
Belize	NA	NA	NA	NA	NA	NA
Bolivia	2.0	16.0	5.0	NA	NA	23.0
Brazil	120.0	343.5	359.0	120.4	18.0	960.9
Bulgaria	4.0	6.5	18.0	NA	NA	28.5
Canada	NA	NA	560.0	NA	NA	560.0
Chile	2.0	24.8	49.0	37.9	1.0	114.7
Colombia	40.0	51.6	46.0	NA	NA	137.6
Costa Rica	2.0	NA	9.0	NA	NA	11.0
Croatia	2.0	NA	27.0	NA	NA	29.0
Dominican Republic	2.0	10.3	2.0	NA	1.0	15.3
Ecuador	NA	20.0	7.0	NA	2.5	29.5
Egypt	NA	7.5	28.0	NA	30.0	65.5
European Union	NA	NA	NA	NA	NA	NA
Guatemala	2.0	NA	6.0	NA	NA	8.0
Hungary	20.0	11.5	65.0	21.5	4.0	122.0
Italy	160.0	45.0	779.0	NA	23.0	1007.0
India	80.0	67.3	239.0	59.5	38.0	483.8
Indonesia	32.0	27.6	100.0	NA	32.0	191.6
Israel	30.0	34.0	30.0	12.4	1.0	107.4
Jamaica	NA	NA	NA	NA	NA	NA
Kazakhstan	NA	23.0	NA	NA	NA	23.0
Kuwait	12.0	8.0	26.0	NA	1.0	47.0
Latvia	NA	12.0	10.0	NA	NA	22.0
Lebanon	10.0	3.0	15.0	NA	3.0	31.0
Lithuania	1.5	15.0	11.0	NA	NA	27.5
Malaysia	36.0	55.5	73.0	12.9	10.0	187.4
Mexico	140.0	326.0	222.0	132.2	42.0	862.2
Pakistan	12.0	70.0	14.0	NA	52.0	148.0
Paraguay	2.0	127.8	6.0	NA	2.0	137.8
People's Rep of China	280.0	202.9	1,488.0	510.0	50.0	2,530.9
Peru	4.0	68.0	22.0	NA	8.5	102.5
Philippines	33.0	20.0	38.0	NA	48.0	139.0
Poland	30.0	36.0	197.0	109.3	5.0	377.3
Romania	8.0	18.0	32.0	NA	2.0	60.0
Russia	275.0	411.9	800.0	255.8	42.0	1,784.7
Saudi Arabia	20.0	15.0	73.0	NA	14.0	122.0
Slovakia	2.0	NA	26.0	NA	NA	28.0
South Korea	40.0	2.3	276.0	349.0	42.0	709.3
Taiwan	40.0	49.4	88.0	123.0	20.0	320.4
Tajikistan	NA	5.0	NA	NA	NA	5.0
Thailand	30.0	24.9	100.0	NA	30.0	184.9
Turkey	50.0	15.0	107.0	NA	23.0	195.0
Turkmenistan	NA	7.0	NA	NA	NA	7.0
Ukraine	45.0	115.0	63.0	NA	NA	223.0
Uruguay	2.0	NA	7.0	NA	NA	9.0
Uzbekistan	NA	31.0	NA	NA	NA	31.0
Venezuela	25.0	31.0	39.0	NA	NA	95.0
Vietnam	10.0	NA	30.0	NA	16.0	56.0
<b>Total</b>	<b>1,635.5</b>	<b>2,437.8</b>	<b>6,155.0</b>	<b>1,743.9</b>	<b>571.0</b>	<b>12,533.2</b>

Source: International Intellectual Property Alliance, 2005. [Data not available indicated by NA.]

**Table 15**  
**Estimated U.S. revenue losses due to inadequate foreign protection of pharmaceutical patents and clinical test data in 2004**

Country	Total sales	Patent Damages	Data Damages	Total Damages	Damages/sales
	<i>In thousand dollars</i>				<i>Percent</i>
Argentina	1,752,284	167,827	35,809	203,636	12
Canada	10,996,086	366,726	43,249	409,975	4
China	7,159,283	1,876,921	489,038	2,365,959	33
Egypt	661,565	77,344	43,505	120,849	18
Hungary	2,001,432	196,783	35,209	231,992	12
India	4,441,343	NA	NA	NA	NA
Israel	326,075	21,332	10,503	31,825	10
Korea	5,526,741	832,873	295,068	1,127,941	20
Lebanon	295,139	48,932	29,194	78,126	26
Malaysia	315,152	5,702	17,945	23,647	8
New Zealand	653,555	19,447	4,357	23,804	4
Pakistan	974,250	68,481	17,217	85,698	9
Peru	319,421	52,230	10,487	62,717	20
Philippines	1,287,040	50,226	10,518	60,744	5
Poland	4,009,913	707,289	137,693	844,982	21
Saudi Arabia	924,556	92,594	52,536	145,130	16
Slovenia	474,997	30,638	11,253	41,891	9
Taiwan	2,845,522	43,728	38,957	82,685	3
Thailand	1,061,310	89,206	40,333	129,539	12
Tunisia	321,205	31,811	24,088	55,899	17
Turkey	4,350,919	741,277	145,824	887,101	20
Venezuela	1,528,139	96,337	53,623	149,960	10
Total	52,315,927	5,617,694	1,546,406	7,164,100	14

Sources: Adapted with permission from Pharmaceutical Research and Manufacturers of America (PhRMA). [Data not available indicated by NA.]

**Table 16**  
**Top foreign sources of counterfeit products seized by U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement, Department of Homeland Security, 2003**

Country	U.S. dollar value	Percent of total
China	62,468,018	66
Hong Kong	8,236,507	9
Korea	3,219,268	3
Pakistan	2,010,465	2
Mexico	1,966,929	2
Malaysia	1,331,925	1
Philippines	1,224,058	1
Canada	1,189,160	1
Switzerland	676,197	<1
Thailand	662,112	<1
All other countries	11,034,588	12
Total	94,019,227	100

Source: U.S. Customs and Border Protection, L.A. Strategic Trade Center, 2003.

A number of economists, including economists at the USITC, are attempting to develop empirical techniques to identify, measure, and estimate the economic effects of nontariff measures, including intellectual property rights. However, the effects of IPRs and the effect on U.S. industry and economy of IPR infringement is likely to be among the most challenging of the NTMs to assess quantitatively. One scholar has reviewed the work of a number of economists in the areas of IPR measurement, determinants, and economic effects. Based on his review, he reports that “unlike tariffs and taxes, IPRs are not readily measurable; nor do they have obvious price-based equivalents like those used to assess the restrictiveness of quotas.”<sup>252</sup> “Complicating the picture,” he says, “is that, as fundamental rules governing behavior, IPRs surely interact in complex ways with other policies in reaching their full effectiveness. Thus, identical laws may have quite distinct effects in countries that differ in their market structures and preferences.”<sup>253</sup>

In sum, there have been few comprehensive empirical efforts in recent years to measure the impact of foreign infringement on U.S. industry. Those studies that have been completed suggest that due to various limitations in their assessments their revenue loss estimates likely significantly underestimate the total effects of foreign IPR infringement on U.S. industry as a whole. The most comprehensive effort to measure the economic impact of foreign IPR infringement was completed by the USITC almost two decades ago. Since that time, technological developments, such as the Internet and other digital technology, have increased the speed and ease with which the duplication and illicit file sharing of products protected by IPR can occur.<sup>254</sup> Thus, a number of industry and government leaders believe that revenue losses are likely much larger today than previously estimated in the ITC study and industry surveys, which do not include losses due to Internet piracy in their estimates.<sup>255</sup> Further research is needed to confirm these assumptions.

### **Addressing Foreign IPR Infringement**

There are various means available for addressing foreign infringement of IPR. Some of these are employed directly by U.S. companies affected by foreign counterfeiting, including the initiation of legal actions under the intellectual property laws of the country in question. Others are employed by the U.S. Government as a part of its official trade policy, and may include efforts to use trade laws and agreements to get countries to implement stronger IPR laws and enforcement procedures. Other means combine the efforts of U.S. private sector and public interests to address the challenges of foreign IPR infringement.

#### **Private Sector Efforts**

U.S. industries invest millions of dollars around the world to protect their products from infringement.<sup>256</sup> Intelligence gathering and analysis are among the more important tools that the private sector uses to combat intellectual property violations.<sup>257</sup> Some U.S. industries and individual firms affected by foreign trademark infringement employ private investigators and lawyers who sometimes work together

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<sup>252</sup> Maskus, *Intellectual Property Rights in the Global Economy*, p. 88.

<sup>253</sup> *Ibid.*

<sup>254</sup> For further information on the impact of Internet and other digital piracy on U.S. industries, see USITC, Office of Industries Working Paper, *Protecting U.S. Intellectual Property Rights and the Challenges of Digital Piracy*, ID-05, Mar. 2003.

<sup>255</sup> U.S. Government and industry officials, in-person and telephone interviews by USITC staff, Jan.-Oct. 2004 and June 2005.

<sup>256</sup> Testimony of Joseph Papovich, Senior Vice President International, Recording Industry Association of America, before the U.S. House of Representatives, Committee on Government Reform, Sept. 23, 2004.

<sup>257</sup> *Ibid.*

to detect counterfeiting and build legal cases for enforcing trademark law using the domestic legal systems of the foreign countries involved.<sup>258</sup> For instance, private investigators hired by companies whose trademarks are infringed often engage in evidence gathering through video and sound recordings and controlled purchases in countries where there is legal authority supporting the reliance on such types of evidence. The International Chamber of Commerce established its own counterfeiting investigative unit in 1985, the Counterfeiting Intelligence Bureau (CIB), to provide services to industries exposed to counterfeiting worldwide.<sup>259</sup> CIB gathers and analyzes intelligence, investigates sources and distribution of counterfeit products, provides expert advice and training, and provides sufficient evidence to police to enable them to arrest infringers and seize counterfeit goods.<sup>260</sup>

Private U.S. firms adversely affected by piracy and counterfeiting are also taking advantage of recent technical advances to counter such infringement in both the United States and important foreign markets. Some technological means developed and increasingly used by U.S. industries for detecting and impeding copyright and trademark infringement of their products include hologram and recognition software, security papers, security labels, radio frequency identification, and digital watermarking.<sup>261</sup> Such technologies enable private or government enforcement officials to more easily identify counterfeits. Private companies also are changing business strategies to address counterfeiting. For example, pharmaceutical companies are having hospitals and other healthcare providers order directly from them or through certified distributors.<sup>262</sup>

## U.S. Government Efforts

When private efforts to address IPR infringement fail or where infringement problems seem systemic in a country, the United States has a number of trade policy tools it can use to improve the IPR climate in countries of interest. These include bilateral consultations, FTAs, withdrawal of benefits under such programs as the Generalized System of Preferences (GSP),<sup>263</sup> the Caribbean Basin Economic Recovery Act (CBERA), the Andean Trade Preferences Act (ATPA), WTO accession negotiations, dispute settlement proceedings, technical assistance, and other official means. In using these tools, the United States tries to ensure that legislation, court decisions, and administrative bodies in foreign countries effectively address IPR problems. Recent efforts using U.S. trade policy tools have especially focused on encouraging other countries to make commercially based counterfeiting and copyright piracy criminal offenses, with increased levels of fines and imprisonment, and to ensure that equipment used to make counterfeits and pirated material is seized and destroyed.<sup>264</sup>

The annual Special 301 review is another tool for IPR enforcement, which requires USTR to identify foreign countries that deny adequate and effective protection of intellectual property rights or fair and equitable market access for Americans that rely on intellectual property protection. Besides serving as

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<sup>258</sup> Alana Sharenow and Patricia A. Wilcznski, "To Catch a Counterfeiter," *INTA Bulletin*, Oct. 2001, p. 1.

<sup>259</sup> ICC, "ICC Counterfeiting Intelligence Bureau," p. 2, 2001, found at <http://www.iccwbo.org>, retrieved June 28, 2004.

<sup>260</sup> Ibid.

<sup>261</sup> ICC, "A Brief Overview of Counterfeiting," p. 3.

<sup>262</sup> PhRMA representatives, interview by USITC staff, Feb. 25, 2004.

<sup>263</sup> According to some U.S. industry representatives, the possibility of GSP suspension is one of the most powerful tools available to the U.S. Government in terms of intellectual property protection. The law authorizes the President to suspend or revoke all or part of a country's GSP benefits if he determines that it denies adequate and effective intellectual property protection to U.S. rightholders. IIPA representative, interview by USITC staff, Sept. 7, 2004; and testimony of Joseph Papovich, RIAA, Sept. 23, 2004.

<sup>264</sup> USPTO and USTR officials, FSI IPR course.

a way to name foreign countries that do not protect intellectual property and possibly embarrass them into making changes to their intellectual property regime, it also allows the U.S. Government to set priorities and determine how to allocate its resources in combating global intellectual property problems.<sup>265</sup> The Special 301 process, including “out of cycle” reviews, also is an effective tool for industry to communicate its priorities for combating intellectual property problems to the U.S. Government.<sup>266</sup>

Trade sanctions against countries that fail to comply with the TRIPS Agreement are provided for under the WTO dispute settlement process.<sup>267</sup> The United States has been involved in 9 out of 10 total disputes regarding patents, but only once as a respondent. The most notable action of the United States in the area of trademark and related protections was the initiation of a WTO dispute settlement case against the EU, based on apparent TRIPS deficiencies in EC Regulation 2081/92, which relates to the protection of geographical indications for food and agricultural products in the EC.<sup>268</sup> Among the major issues of concern to the United States is the regulation allowing dilution and cancellation of trademarks when a GI is created later in time. In August 2003, the United States requested that a WTO dispute settlement panel review the consistency of the EU regulation 2018/92 with WTO rules. On March 15, 2005, the WTO released a panel report affirming the U.S. assertion that EC regulations discriminate against foreign owners of GI’s, and that the EC cannot deny the rights of trademark owners.<sup>1</sup> The United States expects the EC to adhere to the dispute settlement recommendation that it amend its GI regulation to come into compliance with its WTO obligations.<sup>269</sup> The United States will continue to monitor the situation and take stock of EU compliance before an out-of-cycle review to be held in December 2005.

Even with all of these tools to combat foreign infringement of IPR, strategic diplomacy is often the best way to get other countries to enforce intellectual property rights commitments.<sup>270</sup> Many foreign country leaders want to improve their intellectual property protection regimes to meet their trade agreement obligations and to establish a prosperous business climate for their own economies. U.S. Government agencies such as the U.S. Patent and Trademark Office, the U.S. Copyright Office, the U.S. Justice Department, the U.S. Agency for International Development, and other Federal agencies provide, coordinate, or fund education, training, and other technical assistance to help countries comply with implementation of the TRIPS Agreement and with other international agreements.<sup>271</sup> They also co-sponsor programs with WIPO and under WTO technical assistance and capacity building programs, or cooperate with private sector firms and organizations to provide such assistance.

## Summary and Outlook

The primary purpose of this paper has been to review foreign IPR infringement affecting selected U.S. industries, with a particular emphasis on patent, trademark, and copyright infringement. Although the review primarily has been qualitative, some attempts to measure the effects of IPR infringement quantitatively also have been reviewed.

The paper finds that (1) intellectual property protection is essential to encouraging creative expression and the development of new products in a number of industries; (2) the development of intellectual property-based products is generally far more expensive than their manufacture or duplication;

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<sup>265</sup> Ibid.

<sup>266</sup> Testimony of John G. Malcolm, MPAA, Sept. 23, 2004.

<sup>267</sup> Testimony of Joseph Papovich, RIAA, Sept. 23, 2004.

<sup>268</sup> USTR, *2005 Special 301 Report*, p. 8.

<sup>269</sup> Ibid.

<sup>270</sup> John G. Malcolm, MPAA, Sept. 23, 2004.

<sup>271</sup> USPTO and USTR officials, FSI IPR course.

(3) inadequate IPR protection leaves firms vulnerable to infringement, causing them to risk their investment and reputations; (4) foreign IPR infringement likely results in billions of dollars in annual lost revenues for U.S. industries; (5) current estimates likely understate the actual level of infringement; and (6) more research is needed to better ascertain both the qualitative and quantitative effects of foreign IPR infringement on U.S. industries and the economy.

As we have seen, a major obstacle in analyzing the quantitative impact of inadequate IPR infringement on U.S. industries is that, with few exceptions, hard data is lacking for many industries affected by such infringement. Further, data provided by other organizations or individuals on the impact of IPR infringement are neither comprehensive nor are they remotely comparable, limited often to (1) random single number estimates for an industry or product, (2) total revenues for an industry, or (3) the value of confiscated infringing goods imported into the U.S. market. No estimates are provided at all for most industries.

From an economic modeling point of view, the economic effects of IPRs have been found to be among the NTMs most difficult to measure, as they do not have obvious price-based equivalents like those used to assess the effects of such things as tariffs and quotas.<sup>272</sup> Moreover, whereas most research conducted on tariffs and NTMs is concerned with trade liberalization, research on IPRs is concerned with protection. Further complicating the situation is the fact that IPRs interact in complex ways with other policies, such as antitrust and competition policies, which can impede quantitative analyses of the overall economic impact of IPR protection policies.<sup>273</sup> Therefore, much more economic research and analysis of these complex interactions and how they might be measured needs to be undertaken before further progress may be made in developing quantitative estimates of the impacts of inadequate foreign IPR protection on U.S. industry.<sup>274</sup>

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<sup>272</sup> Maskus, *Intellectual Property Rights in the Global Economy*, p. 88.

<sup>273</sup> Ibid.

<sup>274</sup> The first phase of an OECD study on counterfeiting and piracy plans will include development and elaboration of a “methodological framework for assessing the effects of counterfeiting and piracy on stakeholders.” OECD, Directorate for Science, Technology and Industry Committee on Industry and Business Environment, *Counterfeiting and Piracy: Industry Survey*, DSTI/IND(2005)6, July 6, 2005, p. 9, found at <http://www.oecd.int>, retrieved Sept. 22, 2005.