



impact^{IP}

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Highlights from the 2005 “Special 301 Report” from the U.S. Trade Representative— *A key source for global IP strategy information*

by William A. Barrett

In this edition of impact^{IP}, we briefly review a useful source of information about global intellectual property challenges: the U.S. Trade Representative’s (USTR) 2005 “Special 301 Report.” Published annually, the report is based on extensive information-gathering and analysis. It provides a relatively detailed examination of the adequacy and effectiveness of IP protection in 90 countries, categorizing countries based the adequacy of their IP protection, enforcement, and market access for persons relying on IP protection. While the purpose of the report is to encourage other countries to live up to their international IP obligations, it also serves as a useful source for identifying potential IP issues and opportunities for companies developing global business and IP strategies.

The 2005 report identified 52 countries with significant problems and placed each of these countries in one of four categories:

- **Section 306 Monitoring** – countries with specific problems raised in earlier reports that resulted in bilateral agreements with the United States to address the problems
- **Priority Foreign Countries** – countries pursuing the most onerous or egregious policies that have the greatest adverse impact on U.S. right holders or products
- **Priority Watch List** – countries that do not provide an adequate level of IPR protection or enforcement, or market access for persons relying on IP protection
- **Watch List** – countries meriting bilateral attention to address the underlying IPR problems

Counterfeiting and Piracy

The 2005 report devotes special attention to counterfeiting and piracy. The economic damage caused by counterfeiting is enormous. Losses to

U.S. industries alone are estimated at \$200-\$250 billion per year.

In particular, the USTR reports that significant problems continue in the production of unauthorized copies of optical media products such as audio and video compact discs, as well as counterfeit trademarked goods. Optical media piracy and trademark counterfeiting are increasing problems in many countries including Brazil, Bulgaria, China, India, Indonesia, Lebanon, Mexico, Pakistan, Paraguay, the Philippines, Russia, Thailand, Venezuela and Vietnam. The report singled out India, Pakistan, Russia, Ukraine, Thailand and Bulgaria for failing to make sufficient progress in protecting optical media production. Governments in these countries appear to lack the political will to effectively address piracy and counterfeiting.

On the other hand, the report commended the Philippines, Poland and Indonesia for taking important steps toward implementing much-needed controls on optical media production in order to address and prevent future pirate activity. Hong Kong and Macau, which implemented optical media controls in previous years, were also commended for their commitment to continued enforcement. Malaysia is steadily improving its enforcement efforts, and Taiwan continues to make significant progress in providing improved enforcement.

Like optical media theft, global theft and trade in fakes have grown to unprecedented levels, threatening innovative and creative economies around the world. Counterfeiting has developed from a localized industry concentrated on copying high-end designer goods into a massive, sophisticated global business involving the manufacture and sale of counterfeit versions of a vast array of products including soaps, shampoos,

razors, batteries, cigarettes, alcoholic beverages, golf clubs, automobile parts, motorcycles, medicines and health care products.

Internet Piracy

The global spread of the Internet coupled with the increased availability of broadband connections has created an extremely efficient global distribution network for pirated products. The 2005 report cited the explosive growth of copyright piracy on the Internet as a serious

problem. The World Intellectual Property Organization (WIPO) has concluded several treaties to raise the minimum standards of IP protection around the world, with particular respect to Internet-based delivery of copyrighted works. They clarify exclusive rights in the on-line environment and specifically prohibit the devices and services intended to circumvent technological protection measures for copyrighted works. Even more countries have implemented key provisions of these treaties in their national laws - even without formal ratification.

Data Protections

Most countries impose stringent regulatory testing requirements on companies seeking to market a new drug or agricultural chemical product. TRIPS requires World Trade Organization (WTO) members to protect test data submitted to satisfy testing requirements. Abbreviated procedures are typically available for later applicants seeking to market a product identical to one that has already been approved. Rather than repeating all of the expensive and laborious clinical tests conducted by the first company to prove the safety of the product, these second applicants are permitted to rely on the test data generated by the first company.

Because of the considerable effort involved in being the first applicant, TRIPS requires that the original applicant must receive protection for that data against unfair commercial use. Accordingly, countries typically provide a period of protection during which second applicants may not rely on the data submitted by the first applicant. During this period of exclusivity, regulators cannot rely on the first applicant's data to approve similar products. The period of protection is five years in the United States and six to 10 years in the EU Member States.

The China Problem

The 2005 report focused significantly on China as the only country in the Section 306 Monitoring category. The 2005 report indicated that China's poor IP record extends to *virtually every form of IP*. It points to the rampant counterfeit and piracy problems that plague China's domestic market and China's status as a leading exporter of counterfeit and pirated goods. The report acknowledged that China has expended significant effort to improve the protection of IP rights, resulting in progress in some areas. However, the report concluded that China has not resolved critical deficiencies in protection and enforcement and, as a result, infringements remain at epidemic levels.

Priority Watch List

The following countries were included on the Priority Watch List for pursuing the most onerous or egregious policies that have the greatest adverse impact on U.S. right holders or products: Argentina, Brazil, Egypt, India, Indonesia, Israel, Kuwait, Lebanon, Pakistan, Philippines, Russia, Turkey and Venezuela. Some highlights include:

Argentina. Copyright piracy remains a significant problem, including video and sound recordings, entertainment software, business software and books. Lacks effective protection against infringement of patented pharmaceutical products.

Brazil. One of the world's largest markets for pirated products. Optical media and Internet piracy rates are increasing with estimated U.S. industry losses exceeding \$931 million in 2004. Significant backlog of pending patent applications.

Egypt. Approves marketing of patent-infringing pharmaceutical products. U.S. copyright industry estimates \$72.5 million in 2004 losses in Egypt. Copyright and trademark cases move slowly and collecting judgments is difficult.

India. Amended its current Patent Act in 2004 to satisfy TRIPS commitments, but implementation remains unpredictable.

Indonesia. Passed Optical Disc Regulations in 2004, which took effect in April 2005, demonstrating, on paper, commitment to improvement. Serious concerns remain over lack of effective IPR enforcement, inadequacy of new regulations to reduce the production, distribution and export of pirated optical media products, trademark infringement and deficiencies in its judicial system. U.S. copyright industry estimated 2004 losses at \$197.5 million.

Israel. New legislation would curtail existing pharmaceutical patent term adjustments granted to compensate for delays in obtaining regulatory approval of a drug. Administrative requirements in the current draft legislation would make it very difficult for U.S. companies to obtain any patent term extension.

Pakistan. Leading producer/exporter of pirated optical media, pirated apparel and pharmaceuticals with counterfeit trademarks.

Philippines. Significant progress in 2004 could lead to the elimination of optical media piracy. Notable single seizure of optical discs (valued over \$8 million) in December 2004. Levels of illegal production and consumption of optical media nevertheless remain consistently high. U.S. copyright industry estimated its 2004 losses due to copyright piracy at \$139 million.

Russia. Amended laws on patents, protection of layout designs for integrated circuits, plant varieties and protection of computer software and databases. Enforcement in Russia remains weak and caused substantial losses for the U.S. patent industries in the last year.

While the 2005 "Special 301 Report" could benefit from more specific examples and case studies of specific IP protection and enforcement scenarios, it includes extremely helpful information to guide the business and IP strategies of companies doing business globally. For a complete copy of the report, please email the author at barrettw@mvalaw.com.

DIRECTORY OF IP ATTORNEYS

William A. Barrett (Bill) T 919 286-8128
barrettw@mvalaw.com F 919 416-8337

Dominic J. Chiantera (Dom) T 919 286-8169
domchiantera@mvalaw.com F 919 416-8369

Dale J. Davis T 919 286-8151
daledavis@mvalaw.com F 919 416-8351

Arthur J. DeBaugh (Art) T 919 286-8065
artdebaugh@mvalaw.com F 919 416-8365

Charles L. Evans T 919 286-8028
chuckevans@mvalaw.com F 919 416-8328

Edward T. Fenno T 843 579-7040
edwardfenno@mvalaw.com F 843 579-8712

Thomas E. Graham T 704 331-3581
thomgraham@mvalaw.com F 704 339-5881

Arlene D. Hanks T 919 286-8078
arlenehanks@mvalaw.com F 919 286-8199

Joyce W. Jenzano T 919 286 8088
joycejenzano@mvalaw.com F 919 416-8388

Michael G. Johnston T 919 286-8037
mikejohnston@mvalaw.com F 919 416-8337

Erin S. Lenhardt T 919 286-8032
erinlenhardt@mvalaw.com F 919 416-8332

Charles L. Moore Jr. T 919 286-8012
chuckmoore@mvalaw.com F 919 416-8312

Steven B. Phillips T 919 286-8124
stevephillips@mvalaw.com F 919 416-8324

Ellen A. Rubel T 919 286-8041
ellenrubel@mvalaw.com F 919 416-8341

Jennifer L. Skord T 919 286-8097
jenniferskord@mvalaw.com F 919 416-8397

John E. Slaughter T 919 286-8049
johnslaughter@mvalaw.com F 919 416-8349

Gregory Stephens T 919 286-8093
gregstephens@mvalaw.com F 919 416-8393

Dennis J. Williamson T 919 286-8188
denniswilliamson@mvalaw.com F 919 416-8318

Matthew W. Witsil T 919 286-8034
mattwitsil@mvalaw.com F 919 416-8334

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OFFICE LOCATIONS

430 Davis Drive, Suite 500
PO Box 13706
Research Triangle Park, NC 27709
T 919 286-8000
F 919 286-8199

100 North Tryon Street, Suite 4700
Charlotte, NC 28202
T 704 331-1000
F 704 331-1159

40 Calhoun Street, Suite 300
Charleston, SC 29401
T 843 579-7000
F 843 579-7099

VISIT US ON THE WEB AT:
mvalaw.com