

## **The Global Evolution of Intellectual Property Rights**

September 20, 2007 2003 GMT

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The World Intellectual Property Organization (WIPO) will hold its annual meeting beginning Sept. 24, at which time representatives of its 184 member countries will likely endorse the so-called WIPO Development Agenda. WIPO rejected the ideas expressed in the Development Agenda just two years ago, but leading industrialized countries appear rather suddenly to have changed their positions. As a result, this agenda will reflect a fundamental change in how intellectual property rights (IPR) will be viewed globally in the coming decades.

For the past 40 years, the world's largest economies have enforced their position globally that intellectual property rights are sacrosanct. The 1994 World Trade Organization (WTO) agreement on Trade on Intellectual Property Rights (TRIPS) added some exclusions for emergencies, but in general WIPO and TRIPS rules have been reflexively protective of patents and copyrights.

In the past 10 years, however, this approach has come under increasing fire from governments in developing countries (including WIPO members), human rights and humanitarian groups, relief organizations and anti-capitalist groups. These entities argue that the system retards the economic growth of developing countries and even results in deaths because citizens cannot access medicines and other patented life-saving technologies. Most detractors of the current regime argue that the absolute protection of intellectual property rights is doing far more harm than good -- economically and socially -- and some of them are calling for a radical shift that would essentially do away with recognition of IPR entirely.

As production of goods becomes more and more efficient, especially with modern industrial processes reaching low-wage countries such as China, goods are becoming less expensive. Intellectual property, on the other hand, is coming to be seen as expensive. Whether in drugs, music, seeds or even designer handbags, the price gap between patented products and the raw cost of the materials -- that is, the price of the intellectual property -- is growing. With that growth, intellectual property rights are more frequently being abrogated. Any government tax authority will attest that the amount of cheating is directly related to the perception that the cost of a product is unfairly high.

Though change is afoot, the world is nowhere near doing away with intellectual property protection. Still, the tide has shifted the WIPO stance, as well as the outlook of a number of other players. Most important, the fairly absolute approach to intellectual property protection looks shaky. The coming regime will likely give corporations a rationale for protecting IPR in some cases, but not others. In doing so, it will force changes in a number of industries and business models.

## **IPR Fundamentals**

The global intellectual property system was designed to ensure a creator's monopoly on the use and sale of his or her invention. The inventor could be a writer or musician producing copyrighted material, or a chemist inventing a new paint color. Patents have been extended (with some controversy) to processes and to living organisms that have been developed through biotechnology. In all of these cases, the current legal structure allows the inventor to benefit from the monopoly for a certain amount of time, after which the property falls into the public domain.

Many advocates of changes to these laws argue that ownership of an idea is an absurd concept in many cultures -- and that it therefore is unfair to strictly enforce IPR protections in those cultures. They also argue that it is unfair to demand that people from these countries jump through the necessary hoops, such as hiring a patent lawyer, to secure patents on their own inventions (something they consider to be knowledge rather than property) -- particularly when the system requires that they buy from a company that has patented their traditional knowledge. For instance, they oppose allowing a foreign multinational to patent a seed that has been cultivated by indigenous groups for decades. (The United Nations on Sept. 13 adopted a declaration on the rights of indigenous peoples that mentions indigenous control over intellectual property, while WIPO has a separate working group on indigenous issues.)

In industrialized countries, meanwhile, patent and copyright protections are generally uncontroversial, and the patent system is long-standing and thoroughly engrained. The entry of the U.S. Patent Office, for example, bears a quote from Abraham Lincoln, who said the creation of the U.S. patent system "added the fuel of interest to the fire of genius, in the discovery and production of new and useful things." Even the most ardent supporters of reform are not calling for an end to IPR protections, but rather for changes, such as expanding the extraordinary circumstances under which protections can be abrogated or further limiting the time the creator enjoys a monopoly.

In 1967, WIPO was formed to centralize the world's patent and copyright information. It operates a database of patents and awards internationally recognized patents to inventors. More than any other body, WIPO ensures an invention receives global patent protection the first time it is patented anywhere in the world. In addition, WIPO promotes adherence to IPR among its member countries, and thus has come to be seen as the global champion of intellectual property protection.

WIPO's hand was strengthened by the 1994 TRIPS regime. In agreeing to TRIPS, countries acknowledged that the protection of intellectual property rights is central to free trade, and each agreed to combat piracy and respect patent and copyright protection.

## **The Coming Revolution**

Intellectual property protection has entered the public's mind through three very different spheres -- pharmaceuticals, expensive consumer products and media (especially music).

City dwellers come into contact with intellectual property violations every time they pass a street vendor selling knockoff Prada, Gucci or Louis Vuitton products for \$20 or pirated new-release DVDs for 75 cents or less. The designer bags look and feel very close to the "real" item, and the only thing their manufacturer failed to do was invent the style. The materials used in a Prada handbag cost a fraction of the bag's retail price.

Similarly, the music industry sells for around \$16 a CD that is available for free on the Internet, yet the actual material in the CD and its packaging cost pennies. The rest of the cost is in intellectual property, marketing and distribution.

Though the music and movie industries and luxury brand name goods are besieged by IPR problems, their global importance pales in comparison to that of the pharmaceutical industry. At the center of the pharmaceutical industry's problem is compulsory licensing. Under the compulsory licensing clause in TRIPS, member countries can break a patent and manufacture a drug themselves in emergency situations, such as a malaria outbreak. Using this clause, however, some governments have actively encouraged the copying and selling of patented drugs without the payment of a royalty to the drug's inventor. As a result of increasing episodes of compulsory licensing, the pharmaceutical industry's core business model is under attack.

The current business model is fairly simple. Drug patents give the inventor a monopoly on the drug for a set number of years, during which time the maker charges a high price for the drug. Only a small percentage of new drugs that begin safety trials make it to market, so the high price allows the company to recoup not just the development and production costs of the drug, but also the development costs of all the failed drugs in the manufacturer's pipeline. The high prices also provide for salaries for managers and sales staff, for advertising and for enough profit to encourage shareholders to keep the company open.

Once the monopoly period is over, the drug's inventor loses the patent and anyone can make and market the drug. Companies that specialize in making drugs, but not inventing them -- the generics manufacturers -- step in and sell the drugs for a fraction of the name brand cost.

For the pharmaceutical business model to work, then, a drug must make a lot of money in seven years to satisfy the company's needs.

### **Pressure to Change**

In the 1990s, the development of costly AIDS drugs initiated a chain of reactions that has led to changes in how IPR is viewed. These drugs severely stalled the outbreak of AIDS in patients who were HIV positive, and had an immediate impact on HIV mortality in the West. In part because they were expensive, however, they were slow to reach poorer countries, areas where AIDS happens to be more prevalent. As a result, countries began to demand access to free AIDS drugs. The pharmaceutical companies, however, hesitated. They had reasons beyond the IPR issue for not giving away AIDS drugs, but

the fear of setting a precedent should they do so was a major concern. When it became clear that they could either give away AIDS drugs or face compulsory licensing, they chose to protect the integrity of IPR and began to sell the drugs at greatly reduced prices. Many read the drug companies' hesitation as insensitivity, which paved the way for a wide open discussion on where pharmaceutical companies' social responsibility begins and ends.

This conversation has altered the pharmaceutical companies' leverage in certain places, most visibly in two developing countries that have an increasingly large middle class but a large poor population as well: Thailand and India.

In Thailand, the government and the U.S.-based pharmaceutical lobby PhRMA have launched a public war of words. The Thai government says that, under the compulsory license clause of TRIPS, it should be allowed to break the patent on "essential" AIDS-related drugs and have its government-backed pharmaceutical agency produce generic versions of them. PhRMA said the compulsory licensing step was unwarranted because it already has been providing low-cost drugs to Thailand voluntarily. The most controversial case involved Abbot Laboratories, which ended up pulling its top AIDS and heart-related drugs from the Thai market after Bangkok, enacting a compulsory license law, began production on generic versions. Even the U.S. government became involved, adding Thailand to its list of countries that do not abide by the intellectual property rights of U.S. companies.

In India, Swiss-based Novartis lost a patent suit over what constituted a new or improved drug under Indian patent law. Novartis said that an update to its leukemia drug Gleevec (also called Glivec) regarding how the drug is absorbed into the body represented a major improvement of the drug and that the drug therefore should be subject to patent in India (earlier versions of the drug, which were not subject to patent in India, are now made generically in India). An Indian court in Chennai ruled against Novartis' claim that Indian patent law, which disallows patents to be placed on drugs on which only minor modifications have been made, did not comply with TRIPS requirements. The Indian court instead referred the issue back to the WTO -- a time-consuming and costly maneuver that Novartis sought to avoid by keeping the issue local. Nevertheless, drug-focused nongovernmental organizations, including Doctors without Borders, hailed the court's decision as a victory for essential drugs in the developing world. Novartis is trying to overturn the original patent refusal through other means, but the company's problems in India likely foreshadow growing battles in the developing world that could make it harder for major pharmaceuticals to obtain patents.

The Indian court decision and the activities of the Thai government show that the essential drugs argument is gaining traction, and that developing countries are becoming critical players in shaping how the pharmaceutical companies will conduct business in the future.

## **IPR Going Forward**

The WIPO Development Initiative was born in 2005 with an eye toward addressing problems such as those raised by the patenting of drugs or living things. Most of the ideas expressed in the initiative were unobjectionable to IPR-dependent industrialized countries -- but some were very much objectionable. The plan, therefore, was twice scuttled by industrialized countries. Partly as a result of the recent spate of controversies surrounding pharmaceuticals, however, various industries dependent on IPR have come to see intellectual property in a different light.

WIPO's decision to give the new ideas a second look, then, reinforces a lesson the pharmaceutical companies learned in the AIDS-drug debate: maintaining the status quo will not work. The high cost of intellectual property is encouraging piracy and spurring resentment. The remaining question is how to find an intellectual property protection regime that will continue to add "the fuel of interest to the fire of genius," but remain flexible enough to restrain poorer countries from explicitly breaking it.

The corporations could have the answer, or at least part of it. The risk to a corporate brand from being seen as a bully or even a greedy killer is enormous. As the world increasingly demands that corporations be socially responsible, companies are under pressure to look at the social aspects of their businesses, including their patents. With this, they appear willing to endorse a WIPO initiative -- at least as a first step in exploring ways to protect IPR and avoid resentment.

The change that this portends is far more significant than the WIPO agenda suggests, however. The difficulty with IPR is that, for any system to work it must be absolute. Either an invention is property (and therefore patentable) or it is not. Once the ability to patent an invention becomes situational, the business models that depend on absolute protection of intellectual property rights are challenged.

This scenario could lead to dramatic changes in IPR-dependent industries, such as pharmaceuticals. Already the industry is finding ways to increase production in Asian countries, where costs are lower, and is developing the generic arms of their businesses so they can dominate the generics market once the drug is off patent. In the United States, the issue of universal health care coverage is gaining traction and insurance companies are successfully demanding that doctors prescribe cheaper generics rather than name brand drugs. Factor in the growing pressure from developing countries that have strengthening economies, and the playing field is ripe for change in how modern business deals with intellectual property rights on a global scale. The ideas behind the WIPO Development Agenda signal the changes to come.