

FALL/WINTER 2005

# ipbusiness

MANAGING INTELLECTUAL PROPERTY AS A STRATEGIC ASSET

## IT'S YOUR MOVE



**Playing a critical position in a globalized world**

**Enforcing Cyber-borders • The Impact of Outsourcing  
The Patent Reform Act • ANDA Issues • Section 337 Revisited**

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## A Better, Flatter World

In his best-seller, *The World is Flat*, *New York Times* columnist Thomas Friedman reflects on a visit to Bangalore, an Indian boom town pushed into what Friedman calls Globalization 3.0 by outsourcing. “It is now possible,” he writes, “for more people . . . to collaborate and compete in real time with more other people on more different kinds of work from more different corners of the planet and on a more equal footing than at any previous time in the history of the world.” What Americans—and other residents of this flat earth—can learn from this, he concludes, is that “the most important attribute you can have is creative imagination—the ability to be the first on your block to figure out how all these enabling tools can be put together in new and exciting ways to create products, communities, opportunities and profits.”

The advantages of competing on this more level playing field are not difficult to grasp: Friedman’s visit to Bangalore exposed him not only to flourishing office complexes and thriving office workers, but also to shopping malls thronged with Bangalorians eager to spend their hard-earned cash in stores like The Gap. What’s harder is adapting systems, attitudes, and even laws developed during Globalization 1.0 and 2.0 to a suddenly brave new world. This issue of *IP Business* chronicles many of these adaptations—from legislation focused on smoothing the road to harmonization, to attempts to protect borders when harmonization fails, to some key IP issues posed by outsourcing such knowledge processes as R&D to other parts of this flattened earth.



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# harmonization

**In the US, pending legislation promises to reform the patent system—and eliminate some longstanding barriers to harmonization. By Peter Haapaniemi**

## ALL IN A ROW

Illustration by Richard Borge

This past June, US Congressman Lamar Smith introduced the Patent Reform Act of 2005, which he called “the most comprehensive change to US patent law since Congress passed the 1952 Patent Act.” The act is largely a response to a growing sense that the US patent system is flawed—and that IP litigation is becoming a serious problem. “The bill will eliminate legal gamesmanship from the current system that rewards lawsuit abuses over creativity,” said Smith. “It will enhance the quality of patents and increase public confidence in their legal integrity.”

At the same time, the legislation promises to be a leap forward in efforts to harmonize the international patent system. As it stands now, the proposal removes some fundamental differences between US patent law and that of most other countries—differences that have long been roadblocks to harmonization.

Harmonization is a complicated and slow process, and the new legislation will not usher in an era of international IP harmony overnight. Indeed, the legislation itself is still a work in progress and has not yet passed into law. But when it has—and most observers believe it will—it will quickly have an effect on the way companies get and defend patents, and executives should understand the changes that are coming and prepare for some new approaches to managing IP that will help them stay in sync with global business.

### **The End of First-to-Invent**

One of the most visible distinctions between the US patent regime and those of other countries is the first-to-file system. Under the US system, patents are given to the person who comes up with an invention first—the so-called first to invent—while

in most other countries, the person who first files a patent application gets the patent. The new legislation would convert the US to the globally accepted approach, so that the first inventor to file—whether in the US or in another country—would be entitled to the patent.

This will not just make US law consistent with other patent systems, it will also help simplify the US system significantly, proponents say. “The idea is to get rid of fights to determine who was the first to invent,” says James Lampert, chair of the IP Department at Wilmer Cutler Pickering Hale and Dorr. Under the current system, those fights take place in an “interference” procedure, in which the patent office pores over records to determine who in fact came up with an idea first—a slow, expensive and inexact process. With the first-inventor-to-file system, interferences would not be necessary.

The first-to-invent concept has been vigorously defended in the past and has been touted as part of America’s traditional emphasis on empowering the individual—that is, as a tool for protecting the small inventor who may not have the legal or financial wherewithal to file quickly. But in reality, the system has hardly offered foolproof protection to the little guy. “Even if you are first to invent, there are hurdles to proving it, and in reality, the first person to have invented something doesn’t always win,” says Lampert. “In fact, some recent research shows that small inventors don’t really benefit from the interference system.” What’s more, in a global economy, many small inventors today file overseas as well as in the US, meaning that the worldwide first-to-file system is already a fact of life for them.

The first-inventor-to-file concept seems likely to pass—although it has been proposed in the past and failed. But after

# harmonization



“Once you move from **first-to-invent** to first-inventor-to-file, you can remove some of the more subjective and **difficult issues**,” says the AIPLA’s Kirk.

years of operation, the first-to-file system has become a kind of proven global best practice, many observers note, and the US, they say, would do well to align its system with the rest of the world. As William L. LaFuze, chair of the ABA’s Intellectual Property Law Section, told Congress in April, “We believe . . . that there is one important step that the Congress could take now that would greatly advance the objective of greater international patent law harmonization. That step is the enactment of legislation that would institute a first-inventor-to-file rule.”

## A New Forum

The elimination of interferences does not mean that people can’t raise objections to patents. As in European law, the proposed reform legislation provides a “post-grant opposition proceeding,” in which third parties can challenge the validity of issued patents in the patent office. The proposed legislation provides two time periods during which an opposition may be requested: the first, within nine months of the patent’s being granted, and the second, within six months of receiving notice of

alleged infringement. The request will be reviewed by the patent office and, if a substantial new question of patentability is set forth, an opposition will be started and assigned to a panel of administrative patent judges. “Limiting the time for oppositions will help avoid possible harassment of patent owners and opposition proceedings that would overtax the [patent] office’s ability to handle the proceedings,” J. Jeffrey Hawley, president of the Intellectual Property Owners Association, told Congress in April.

The opposition procedure would provide a more viable alternative to the current reexamination process, which “has not worked very well and, in fact, hasn’t been used much—because people don’t trust it,” says Donna Meuth, an IP attorney at Wilmer Cutler Pickering Hale and Dorr. “Statistics show that the vast majority of patents survive reexamination, and in general, people feel the process is badly tilted in favor of the person who started on top.”

What’s more, many parties avoid the reexamination process because it can actually hurt their chances in any related litigation that may arise. “If the patent office has given a patent the stamp of approval during a reexam in which you presented all of the good prior art you can find, that prior art is not worth a whole heck of a lot in a later infringement suit,” says Lampert.

The opposition procedure attempts to avoid

## CONTINUATIONS, CONTINUED

**U**nlike patent offices in Europe, the US patent system lets applicants fine-tune their application claims extensively over time through a continuation process. The result at times has been much-publicized submarine patents, in which applicants keep changing their claims to cover evolving technologies in the marketplace.

“Some bad actors will try to follow the market and adjust their applications and then spring those applications on a mature market eight or 10 years out,” says Mike Kirk, executive director of the AIPLA. In a recent committee draft of patent reform legislation, lawmakers tackled that problem head-on and eliminated that broadening practice.

But things aren’t that simple, many observers note. When dealing with sophisticated, cutting-edge technology, “you may have an extremely valid basis for filing a continuation application,” Kirk says. A sophisticated, cutting-edge technology “may be something that the patent applicant and the examiner have not yet come to grips with in terms of exactly what the invention is and how it should be claimed,” he explains.

“Then, you’re just trying to get the patent rights you deserve.” In other words, there are good continuations and bad continuations, and writing a law to cover both is not easy.

As a result, lawmakers essentially decided not to decide. Instead, they empowered the director of the patent office to create regulations to control the continuations process. The idea and hope, says Kirk, is that “by allowing the director to do this, you can allow the promulgation of regulations that can be tailored to the real situation on the ground.” —P.H.

such problems by allowing parties to interact and exchange information with the patent office during proceedings and letting patentees adjust their claims based on challenges. This part of the legislation has been favorably received, with the only apparent controversy being whether to allow a second objection period for someone who is actually charged with infringement, allowing them to pursue the matter with the patent office before heading to court. Revised drafts of the legislation presented by various organizations have deleted this second time period as being unduly burdensome on both patentees and the patent office.

Overall, proponents of the new approach hope it will provide a mechanism for weeding out invalid and low-quality patents, while resolving issues early on to avoid lawsuits down the road. “If people trust it, it should work well,” says Lampert. “It won’t be cheap, but it will be a lot less expensive than a million dollars a year for a patent suit.”

### Staying Out of the Inventor’s Head

The rules around patents are often interrelated, and the proposed change to first-inventor-to-file has opened the door to other changes. “Once you move from first-to-invent to first-inventor-to-file, you can remove some of the more subjective and difficult issues,” says Mike Kirk, executive director of the American Intellectual Property Law Association. To a large extent, that means eliminating rules based on what the inventor thought or knew at certain times—the things that tend to complicate litigation. For example, the so-called best mode rule—which requires inventors to disclose their concept of the most effective way to practice an invention—would be eliminated.

Some changes in this area are subtle but important. For example, a revised definition of the prior art that can be used to invalidate a patent focuses on the information that is publicly known, often without considering what the patentee or some third party may actually have done before the application leading to the patent was filed. This changes some important policies reflected in current law and may lead to some unintended consequences, some observers say.

“Under current law, when you commercialize an invention, you can patent it or keep it as a trade secret. Either way, you have a one-year grace period from the point of commercialization, and then you lose the right to patent it,” says Lampert. “What you cannot do is keep your invention secret for many years, until you think somebody is about to discover it, and then patent it.”

Under the proposed legislation, however, it seems that you can do just that. There is no longer any loss of the right to seek a patent for an invention you may have commercialized but some-

## Still Talking...

Most of the proposals in the Patent Reform Act of 2005 have met with considerable agreement, but a few sticking points remain. These include:

**Raising the bar on willful infringement.** Some companies regularly send vague form letters to corporations claiming infringement, requiring those corporations to scurry around, research the issue and often, get an expensive written opinion. Otherwise, if the case ever goes to court, they run the risk of willful infringement and a trebling of damages. The proposed legislation requires much more specific notice of potential infringement before “increased” damages can be recovered.

**Softening injunctions.** Under current law, courts normally grant injunctions when patent infringement has been established and the case is through the judicial process. The new law initially proposed making it more difficult to get injunctions and encouraged courts to consider monetary damages first—a move that would weaken IP protection and have ramifications for international IP management, says AIPLA’s Mike Kirk. As the US tries to get China and other countries to strengthen IP protection, he says, “How can we say [that] even though we don’t always grant exclusive rights in the US on this widget, we want you to?” As a result of such objections, more limited proposals have been advanced; any eventual change seems likely to be limited to when an injunction should be granted pending appeal. —P.H.

how kept secret. That’s in line with European law, says Lampert, but it is likely to trouble some US observers. “The existing law gave you an incentive to disclose, which is a big part of what patents are all about,” he says. “Some of that idea appears to be gone now. Instead, we are providing protection for the person who made a private offer to sell a product or hid a process as long as they could, as opposed to making the invention public in exchange for patent protection. I wonder if that’s something we want to encourage.”

For US businesses, patent reform may require more proactive monitoring of the patent pipeline. But in the end, the most important advice is also the simplest, notes Lampert. “Getting that patent application on file early will be more important than ever,” he says. “You simply cannot wait.”

## Sheriff 337 Back on Border Patrol

**Dusting off an old Depression-era statute, an increasing number of companies with US operations are finding a quick means of protecting their patents from “foreign invaders.”**

**By Jeffrey A. Heilman**

While paging through a wholesale catalog back in 2003, a Wisconsin-based manufacturer of hand-crafted pool cues discovered an advertisement for imported cues that bore a striking resemblance to his patented products. Already facing decreasing market share from the flood of generic cues coming in from abroad, he realized that these apparent copycats, priced significantly lower than his customized, high-end products, represented a serious threat. Frustrated in his attempts to resolve the issue, he found his way to the US International Trade Commission, and, in turn, to Section 337 of the US Tariff Act of 1930, a Depression-era trade statute that offered a chance to address the problem when a District Court proceeding was out of the question.

Back in 1930, the world took a dark view of Section 337 and its parent, the US Smoot-Hawley Tariff Act, condemning the notorious law as a “virtual declaration of economic war.” Enacted to provide relief in the absence of effective remedies under the laws of exporting countries and in the lack of US jurisdiction over foreign manufacturers and distributors, 337 was and remains available to any company holding US intellectual property rights and engaged in exploiting those rights through manufacturing or research and development or other activities in the United States. As the US pursued a path of trade liberalization following the Depression, the statute evolved through a series of amendments, collec-

tively easing its statutory requirements and broadening its remedial powers.

While applicable to all IP infringements, 337 is primarily employed to block the unfair and unlawful importation of goods found to infringe patents. Procedurally, 337 patent cases resemble traditional federal court proceedings but move at hyper-speed and have fewer jurisdictional constraints. In short, 337 enables companies to legally cross borders and attack foreign infringers at the source. Remedy-wise, too, 337 is a powerful legal weapon. Upon a finding of infringement, 337 can permanently block the importation of infringing goods.

Internationally, 337 has spurred accusations of protectionism and unfair advantage from the European Commission as well as the governments of Japan and China. However, as William DiSalvatore, a litigation partner in Wilmer Cutler Pickering Hale and Dorr’s New York office, notes, the 337 story is not exclusively about the US versus the rest of the world. “Foreign companies have turned to 337 for years,” says DiSalvatore, “and you will also find US companies relying on 337 to take on their competitors here at home.”

### **New Shine on an Old Badge**

Initiated sporadically in the decades following the Depression, 337 investigations, as they are known, are currently on the rise. According to the online docket



of the US International Trade Commission (ITC), the independent, quasi-judicial agency responsible for administering 337 and other trade-remedy cases, 28 investigations launched in 2004—up from nine in 1999—and 20 new cases were initiated in just the first eight months of 2005. Michael Esch, a partner in Wilmer Cutler Pickering Hale and Dorr’s Trade Department, attributes the resurgence of this statute to the increasing globalization of the economy and the surging tide of foreign imports.

The use of 337 is seen by many as a departure from America’s call for free trade across open borders. Others distinguish IP enforcement from other types of trade remedy laws. “For many major US

companies,” says Esch, “competitive advantage lies in keeping at the cutting edge of technology in developing new products and improving on existing products. In this context, IP assets are at the core of the business, and enforcement of IP rights against infringing imports becomes a critical strategic priority.”

Oscillating lawn sprinklers, shirts with pucker-free seams and condoms join the pool cues as some of the more distinctive cases of late, but the majority of 337 investigations over the past four years reflect the dominant industries of global trade: semiconductors, life sciences, consumer electronics and computers. Drug-maker Pfizer is among the heavyweight combatants who have relied upon 337,

seeking exclusion of an infringing ingredient in its popular male impotence product, Viagra. As part of a wider dispute over competing patent rights, broadband semiconductor maker Broadcom recently used 337 against wireless technology maker Qualcomm, and computer manufacturers Gateway and Hewlett-Packard have traded blows over imported keyboards and other computer parts.

Companies initiate 337 actions by filing a complaint with the ITC (see sidebar, next page). As James Quarles, litigation partner and co-chair of Wilmer Cutler Pickering Hale and Dorr’s Appellate and Supreme Court Litigation Department explains, while the ensuing investigation mirrors traditional patent

ILLUSTRATION BY KEITH BENDIS



## SWIFT JUSTICE—AT A PRICE

**A**s Wilmer Cutler Pickering Hale and Dorr's William DiSalvatore cautions, companies should not just dive into a 337 action but should plan carefully for an intensive 12- to 15-month course of discovery, briefings and hearings. Here are key features of a proceeding that runs at triple speed with little margin for error:

- A complainant must show that it has an existing US "industry" related to the IP or an "industry in the process of being established." This can be met, for example, through R&D or licensing.
- Discovery can involve producing reams of documents under tight deadlines.
- The ITC often requires that all testimony be written. Accuracy suffers when depositions are recorded in foreign languages and translated.
- In countries where all depositions must be taken at a US Consulate, scheduling problems can arise.
- Protective orders mean that parties rarely see each other's confidential information.
- 337 cases can be very expensive; monetary damages are available via parallel District Court proceedings.
- While the losing party can appeal to the Federal Circuit, an exclusion order will normally stay in place pending appeal, subject only to Presidential veto. —J.H.

infringement litigation in US District Court, 337 offers unique procedural advantages. "The parties examine the same infringement, validity and enforceability issues," says Quarles, "but there is no risk of disappearing into a black hole in a 337 case. Federal cases can take up to five years, but 337 cases, by mandate, typically wrap within 12 months." For managers facing shrinking product lifecycles and "instant markets," as in the software

only a quarter of the cases; and the outcomes are not always onerous, with licensing or cross-licensing deals emerging post-suit. Nonetheless, 337 is seen in Europe and Asia as unfairly advantageous to US companies. In fact, Section 337 inspired international ire as far back as 1985, when Japan complained that US companies were unfairly blocking the importation of video recorders and other high-tech goods. In 1989, a GATT panel condemned 337

**"With no juries, compressed discovery deadlines and a speedy trial, 337 gives fast-evolving products room to breathe."**

and pharmaceutical sectors, speed is essential. "With no juries, tightly compressed discovery and motion deadlines, few limits on discovery and a speedy trial," says Quarles, "337 gives fast-evolving technology products room to breathe."

Section 337 remedies, in turn, give products room to grow. If the respondent can show that its accuser's patents are invalid or unenforceable, then the related goods are free to enter the US market. If not, and the respondent's products infringe, then the ITC orders the US Customs Service to permanently exclude the affected goods. Cease-and-desist orders are also available, stopping the sale of previously imported offending products; in some cases, the importation ban can extend to end products—regardless of the source—which incorporate the infringing article as a component. "In short," says Esch, "companies can engage the US government, through the ITC and the Customs Service, to freeze competitors out of the US market."

### **Bulls in China's (and Europe's) Shop**

Nearly half the 337 cases settle before a decision; patent infringement is found in

as a "less favorable" treatment of foreign nations, and to this day, dissatisfied with the US response to the panel's findings, the European Commission continues to challenge 337 as "protectionist."

And while the counterfeiting and piracy epidemic (see sidebar, page 9) gives the US plenty of reasons to lower its horns against China, China itself has been vocal in opposing 337—and has encouraged Chinese firms to "hit back."

While not as controversial an issue abroad as other perceived US trade abuses, such as the Byrd Amendment, which authorizes payment of the proceeds from antidumping and countervailing duty cases to US companies, 337 causes friction on the procedural and policy fronts.

"Foreign companies have long griped about the breadth of discovery in US patent cases," says DiSalvatore, "and they are upset by 337's hyper-accelerated schedule, especially when thousands, even millions of documents are involved."

Another source of irritation is the lack of similar legal mechanisms in Europe and Asia, says Esch. "With a single 337 complaint," he says, "US companies can simultaneously sue and, if successful, block multiple infringers in multiple

exporting countries. This power exceeds anything available to companies abroad and contributes to feelings of disadvantage.”

### Gunfights in the US Corral

IP and trade go hand in glove around the world, and international chagrin notwithstanding, says DiSalvatore, 337 is far from an exclusive weapon of unfair US advantage. “The twist is that almost anyone owning IP rights in the US and engaged in actively exploiting those rights in the US can invoke 337 against anyone making or selling products imported into the US,” he says, “and that naturally includes foreign companies.” For example, Japan-based Fuji Film sued 27 companies in China, Korea and Hong Kong for allegedly infringing 12 patents related to its single-use, disposable cameras, and in a case involving 3 million pages of documents and 60 depositions, Nikon, also Japanese, sued to protect its US-based R&D facility and its sales and technical support offices.

The adversaries are frequently both US companies, as in the Gateway-HP feud, with the battle involving the importation of parts and products made abroad. “Foreign-made,” says DiSalvatore, underpins many homegrown suits.

Similarly, patent holding companies in the US, formed solely for the purpose of acquiring, licensing and enforcing IP rights, often in concert with law firms, aggressively sue other US companies. “Knowing the ITC might take to heart a complaint dealing with the exportation of US jobs,” says DiSalvatore, “these ‘patent enforcers’ use 337 as a weapon against offshore manufacturers that diminish their inventor clients’ ability to compete.”

While efforts at IP harmonization may begin to reduce global disparities in IP law, managers will still “turn to 337,” notes Esch, “to defend what they see as inalienable IP rights” as they struggle to confront trade pressures due to lower

## The Global Battle Against IP Theft

**O**n the level field of the globalized economy, counterfeiting and piracy are running wild. Computers, brake liners, food and toys are among the countless illegitimate products flooding the world marketplace. Typically well-organized criminal enterprises, the malefactors are especially active in countries with lax intellectual property laws, with China regarded as the most notorious offender.

Marco Bronckers, a partner in Wilmer Cutler Pickering Hale and Dorr’s Brussels office, is no stranger to IP piracy, having figured prominently in a successful copyright action against the Indonesian government in connection with the 1985 Live Aid famine relief concerts. Belgium itself is familiar with fakes, with more than half of the counterfeit goods passing through Europe intercepted at its borders. “Counterfeiting is everybody’s problem,” says Bronckers, “costing companies billions in lost sales, introducing hazardous consumer goods into the marketplace, employing child labor and even financing terrorism.”

Bronckers sees varying degrees of success in global anti-theft efforts. “The US and the EU are vigilantly focused on the problem,” he says, “and most international governments take their IP protection obligations seriously, generally adhering to the provisions of the World Trade Organization’s TRIPS Agreement. France, for instance, has sharpened its focus on counterfeit luxury goods, including fining tourists.”

Complicating matters in the EU, though, is the expansion of its external borders via the recent addition of 10 new members, as well as differing attitudes on enforcement. “Some countries have poor IP protection records,” says Bronckers, “or are more concerned with policing illegal immigration and terrorism at the borders.” Nevertheless, EU seizures are on the rise, and IP rightholders, including US companies, have an advantage in being able to apply to one national customs authority covering the entire EU.

The picture elsewhere is less optimistic. Almost four years after joining the WTO, China’s progress in combating IP theft is overshadowed by still-ram-pant piracy. And other parts of Asia, Eastern Europe and Latin America remain serial infringers, as much poverty-driven as criminally driven. —J.H.



costs. Moreover, while illegal importations are threatening to the Pfizers of the world, small companies are especially vulnerable, with increasing numbers drowning in the flood of imports.

The Wisconsin pool cue manufacturer, for one, exemplifies US patent holders whose present is distracted and whose

future is threatened by having to confront alleged infringement from abroad. Already operating in a narrowing market space and unable to defend its patent in district court, the company at least has a fighting chance, courtesy of Section 337. Without that, its prospects for survival would likely be very bleak.

## FAQ: Challenging Pharmaceutical Patents

With ANDA litigation on the rise, generics are “getting a sense for the strength of their cases in the US courts, and then transporting those cases overseas.”

By Meryl Davids Landau

In the past few years, generic drug companies have found growing success overturning drug patents in US courts. Emboldened by these victories—and encouraged by reduced barriers-to-entry in the European Union—these generic firms are increasingly taking the lessons learned in US courtrooms and applying them overseas. Meanwhile, changes in US legislation, and recent court decisions surrounding them, aim to shift the balance between the big pharmaceutical companies that hold the patents and the generic marketers who seek to challenge them. All this action sets the stage for a global battle in the next few years between brand name drugs and generics that will be eagerly watched in both boardrooms and courtrooms around the world.

**Q: The first generic drug law is now more than 20 years old. How has this law played itself out in recent years?**

Approval of generic drugs in the US is governed under the 1984 law generally known as the Hatch-Waxman Act. The purpose of the law was largely to encourage generics onto the market. The law allows the manufacturer of a generic version of an approved drug to submit an Abbreviated New Drug Application (ANDA) to the FDA, demonstrating its

bioequivalence to an innovator drug rather than including its own animal and human studies establishing safety and effectiveness. The Act even gives generics that don't want to wait until a patent expires the opportunity to challenge that patent's validity without actually selling the potentially infringing product (known as Paragraph IV certifications). An added incentive: if successful in its challenge, the generic company is eligible for a 180-day period of market exclusivity before others can jump in.

“ANDA litigation has exploded in the past five or so years,” observes David Bassett, a partner in the Boston office of Wilmer Cutler Pickering Hale and Dorr. In Bassett's opinion, the reason for this is primarily that as some generics have had success, others have come to view litigation to invalidate patents as a viable business model. “Pharmaceutical companies put their focus on R&D; generics firms put theirs on litigation,” he says.

**Q: How has this litigation influenced Europe?**

Major drugs are sold in numerous countries with parallel patents protecting them. “What we are seeing is if a generic firm exploits a weakness in a patent in the US and wins, that can give it ammunition to go after similar patents in Europe,” says Robert Barry, a London-based partner of Wilmer Cutler Pickering Hale and Dorr. “Although the laws and incentives differ—for example, in Europe there is no

half-year exclusivity for the company that successfully challenges the patent—generics are increasingly getting a sense for the strength of their cases in the US courts, and then transporting those cases overseas.” Adds Bassett, “When we go to court now, we are very conscious of what evidence we are creating in the US that could impact European litigation.”

The more aggressive push by generics will expand in the coming years. In a recent report, the British research group Datamonitor forecast that by 2010, nearly 80 percent of 2003 blockbuster sales worldwide may be exposed to generics competition—a figure that equates to \$103.7 billion worth of products at the 2003 sales value.

**Q: What else is behind this push by generics in Europe?**

New directives from the European Union are making it easier for generics to enter the market as soon as patents expire. First, companies previ-



ously needed approval of their product from each separate country—one reason generics have been much slower to catch on in Europe than in the US. (The market share of generics in France, Italy and Spain is less than 10 percent each.) “Under the harmonization directive of the EU, it is now easier for companies to get market authorization and launch their product in numerous member states,” explains Yves Van Gerven, a partner in the Brussels office of Wilmer Cutler Pickering Hale and Dorr. The new directives also allow generics companies to get their product authorized for market more quickly once a drug’s patent expires, Barry says—about 10 years after the patented drug’s launch, versus 12 or 13 years previously.

Equally important, testing generic versions of drugs while they are under patent protection has been considered illegal in most European countries, in effect allowing the patent hold-

er several years of exclusivity once the patent expired, while the generic developed its manufacturing process, acquired and submitted data, and received approval from governmental authorities. (Some companies got around this by performing all studies and investing in manufacturing outside Western Europe.) “A safe-harbor provision will soon come into effect to exempt generics from patent infringement in relation to clinical tests and trials,” Barry notes.

**Q: What do the changes mean for name-brand companies?**

“Name-brand pharmaceuticals obviously still make massive investments in R&D, and new drugs are coming onto the market all the time,” Bassett says. “But it is a very different business model now than 20 years ago. Before ANDA, a branded pharmaceutical was virtually guaranteed to hold off generics until the patents

expired. Now these companies assume generics will try to come into the market more quickly, so we need a litigation strategy from the beginning.”

The enticement of the 180-day marketing exclusivity is increasingly proving irresistible to generics firms, requiring even more vigilance on the part of the branded pharmaceutical firm. As Datamonitor concluded, “The huge commercial rewards available . . . are leading generics companies to undertake increasingly speculative patent challenges . . . Paragraph IV challenges in the US are likely . . . to increase in importance.”

**Q: What other recent US court cases or legislation have impacted pharmaceuticals?**

One change that had been thought to favor generics was recently severely limited by a Federal Circuit Court. Prior to the Medicare Prescription Drug, Improvement and

Modernization Act of 2003, which included changes to the 1984 law, the legal status of a generics firm that served a Paragraph IV notice but was not sued within 45 days by the patent holder was unclear. “The ANDA mechanism is supposed to allow a generic to test whether its product will infringe a patent before it launches, without incurring devastating consequences,” Bassett explains. For example, he says, when a generic enters a market, the drug price typically drops as much as 80 percent within six months. So a drug selling \$100 million a year before a generic arrives could have \$80 million in lost profits to demand from a generic should it later be found to have infringed. The 2003 law allows the generic to bring a declaratory judgment action against the patent holder who does not sue.

“Many people assumed that meant a generic could always get a judge to determine whether the proposed product would infringe,” Bassett says. In *Teva Pharmaceuticals v. Pfizer*, however, the courts ruled that a declaratory judgment cannot be issued without the threat of imminent litigation, which an applicant who has not been sued by the patent holder often will not be able to demonstrate. “That returns generics to an uncertain position,” Bassett says. “It’s also causing pharmaceutical companies to consider not suing when they get a Paragraph IV notice, something they almost never considered before.”

ILLUSTRATION BY ELLEN WEINSTEIN

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## Offshoring's Hidden IP Risks

**Offshoring has become an important part of the business landscape as companies pursue low-cost labor—but it is also raising some critical new questions about the protection of intellectual property in global business.**

**By Peter Haapaniemi**

In the US, there has been a great deal of recent debate around the issue of offshoring—whether it's good or bad, harmful or healthy, fair or unfair. Even as that debate continues, however, one thing is clear—offshoring looks like it's going to be a vital part of the business landscape for the foreseeable future.

The business arguments for offshoring are compelling. Companies see it as a way to tap into lower-cost labor, handle work on a 24/7 basis and fill gaps in the workforce in the face of looming labor and skill shortages. According to consultants McKinsey & Company, about 1.5 million service jobs were outsourced abroad from developed countries in 2003, and that number is expected to reach 4.1 million by 2008. Similarly, the A.T. Kearney management consulting firm says that by 2009, 72 percent of companies plan to source from China, 59 percent plan to source from Eastern Europe, and about half plan to source from India.

But offshoring brings risks as well as benefits. Companies have to consider the issues associated with longer and more complex supply chains; changing regulatory and legal regimes across countries; the potential for domestic political fallout; and, increasingly, the vulnerability of intellectual property being shared with distant partners.

“There are a number of inherent risks in the transfer of valuable IP—secret processes and formulas, manufacturing know-how, and sensitive equipment—

overseas, to places where that IP may not be as well protected as it would be here in the US,” says Jorge Contreras, a partner at Wilmer Cutler Pickering Hale and Dorr. Today, many experts say, companies need to understand the nature of those risks and how to best manage them—because as offshoring becomes more and more common, the ability both to share and to protect IP will be critical to working effectively—and profitably—with overseas partners.

### **The Shift from BPO to KPO**

The issue of offshoring and IP protection is coming to the fore in part because of the rapid growth of the offshoring phenomenon. But just as important is the changing nature of the work that is being handed off to overseas partners. Not long ago, offshoring tended to encompass basic call centers, contract manufacturing and IT maintenance, but companies have since added everything from accounting to product development and engineering to the list—activities that involve vital processes, ideas and innovation. McKinsey, in fact, estimates that in the packaged software and IT services arenas, for example, companies will be offshoring 18 percent and 13 percent of their high-wage employment demand, respectively, by 2008.

According to a report in India's *Economic Times*, “the acronym BPO (business process outsourcing) is passé.”

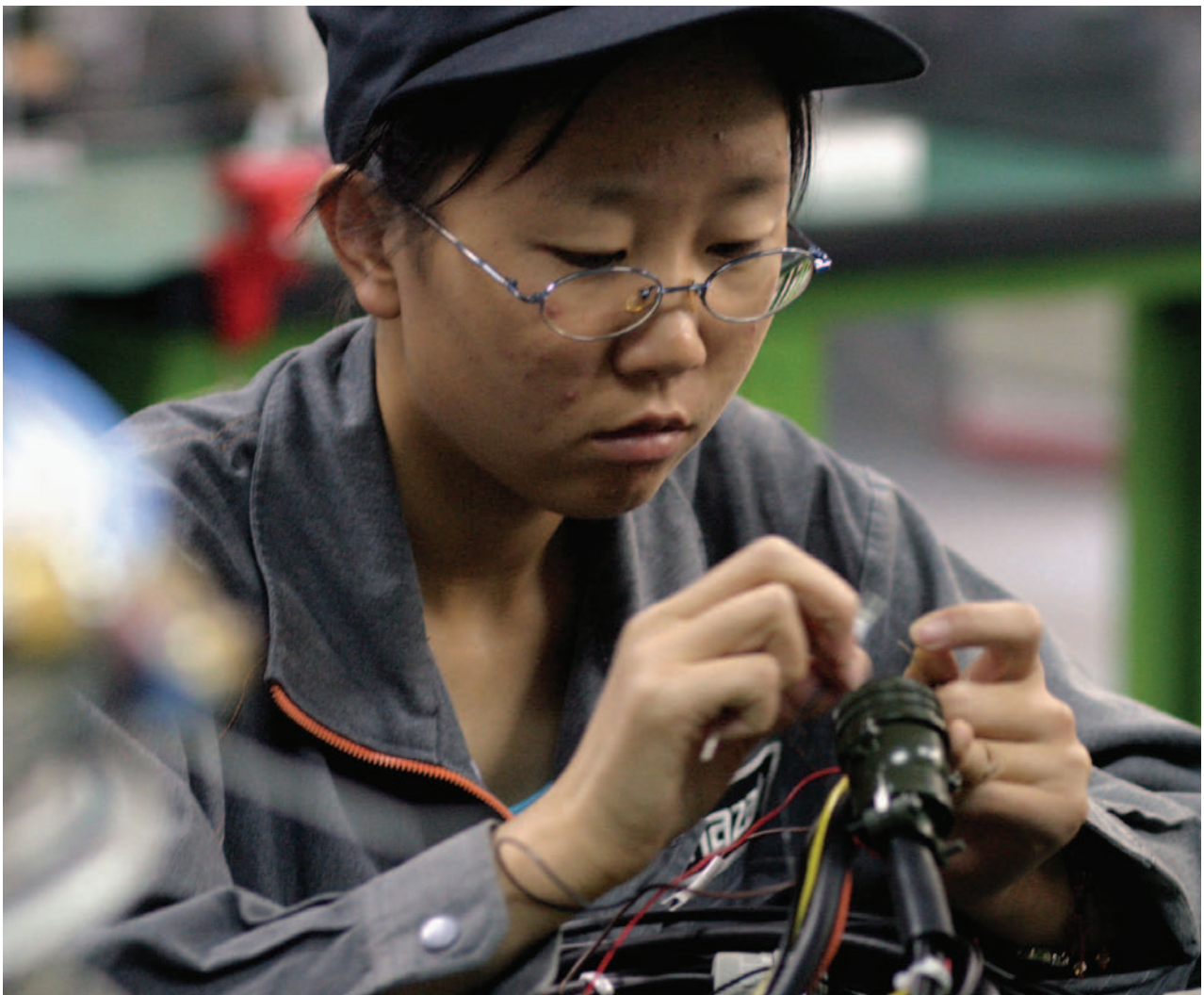
The newspaper goes on to explain that the offshore outsourcing business is now moving on to what it calls “KPO”—or knowledge process outsourcing—which, according to *Economic Times*, includes such services as “legal and medical research, R&D, pharma, biotechnology-related research and process outsourcing, data mining, equity research, market research, content and journalistic outsourcing, data cleansing, data validation, data analysis, formation of libraries,

indexing, cataloging, and the creation and updating of databases and directories.”

Those types of processes naturally require the increased sharing of IP with offshore partners. In virtually any close outsourcing or partnership arrangement—whether onshore or offshore—there is some level of risk that one company will exploit the other’s IP, says Contreras. But that risk is amplified when working across borders because the strength and scope of IP laws can vary

from country to country. “You have to be aware of the different levels of protection that different countries give to IP,” he says. “For example, in India, there is patent protection, but trade secret protection is very weak.”

Even if laws are in place, local officials may not have the ability—or motivation—to enforce those laws. “In different parts of the world, there are very different concepts and deeply held views about what is intellectual property and



KATHARINA HESSE/GETTY IMAGES

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what kind of IP somebody should be able to protect,” says J. Beckwith Burr, a partner at Wilmer Cutler Pickering Hale and Dorr. China, for example, is often noted for a cultural tendency to view IP as something to be shared, rather than protected. And while that country and others have taken steps to strengthen IP protection, the reality of daily life sometimes lags behind the legal mandates.

“Through international treaties, IP protection has been harmonized somewhat,” says Burr. “But I think that it’s still fair to say that in a number of regions in the world, the sort of fundamental thinking about IP is pretty different than it is in the US or Europe. They just start from a different place.”

While companies working with offshore providers have not been overwhelmed with IP theft and infringement, the threat is real. According to a report in the *San Francisco Chronicle* last year, a US company received messages from some employees in its Indian operation “who

threatened to reveal confidential materials unless they received a cash payoff.”

For its part, Wilmer Cutler Pickering Hale and Dorr has helped companies that use contract manufacturers in Asia deal with the infringement of technologies ranging from electronic devices to chemical formulas to children’s toys. “Those companies have found that there is a very real risk that your contract manufacturer can be off on the side manufacturing the same thing they are manufacturing for you and selling it elsewhere—either to your competitors or for internal use in the local market, or perhaps using it themselves to compete with you. And it’s often very hard to police these things,” Contreras says.

## Putting the Right Framework in Place

All of this is not to say that companies are inevitably in deep trouble if they offshore processes—they simply need to understand and weigh the risks and do what

they can to be prepared. Indeed, preparation is key, because enforcement after infringement or theft has occurred may not be a realistic option. “In some places, the legal remedies after the fact aren’t there. And once the IP cat’s out of the bag, it’s very difficult to get it back in,” says Contreras.

Being prepared means having a thorough contract in place—one that takes into account the changes that are likely to occur over the life of an agreement that may span five or 10 years. Both parties should clearly understand just what IP is being shared, and companies should make sure the vendor is licensed to use any relevant technology. It’s also important to spell out, up front, who owns and uses any jointly developed improvements and innovations that emerge through the relationship.

An agreement should also require the vendor to have comprehensive policies and processes that keep sensitive information secure, electronically and physically.

## Labor Issues: Who’s in Charge Here?

The cost savings and elimination of staffing responsibilities associated with the offshore outsourcing of certain business processes are attractive to many companies. When companies decide to outsource offshore, they also intend to transfer all employment-related liability associated with those business processes to the offshore vendor. However, that may not always be what happens.

“If a company exerts sufficient control over the means and manner of performance of the offshore vendor’s employees or co-determines their essential terms and conditions of employment, then the company can be deemed a ‘joint employer’ of the offshore vendor’s employees,” explains Jonathan Rosenfeld, chair of Wilmer Cutler Pickering Hale and Dorr’s Labor and Employment Department. This means the company may be responsible for complying with local employment laws and vulnerable to employment claims from the offshore vendor’s employees. Rosenfeld suggest that companies thinking of

offshore outsourcing should be aware of the local labor laws, which may impose greater obligations than do US labor laws.

To avoid joint employer problems, Rosenfeld suggests that companies draft their offshore outsourcing vendor agreements so that they clearly spell out the respective responsibilities and limitations of both the company and the offshore outsourcing vendor when it comes to managing the offshore vendor’s employees and determining their terms and conditions of employment. Companies should also make sure that their managers are fully aware of the implications of the joint employer doctrine. “Managers should not take employment-related actions such as ‘firing’ or even recommend any such action for the offshore vendor’s employees,” says Rosenfeld. Moreover, if the business process in question is one that the company considers critical enough to require it to need control over the employees performing the function, Rosenfeld adds, “it may make sense for the company to keep that process in-house.”

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## In virtually any close outsourcing arrangement—whether it’s onshore or offshore—there is some level of risk that one company will exploit the other company’s IP.

“You want to know that the mechanisms are in place on-site to ensure that the access isn’t misused by an employee of the service provider,” says Wilmer Cutler Pickering Hale and Dorr’s Burr. She adds that companies should be prepared to check up on those mechanisms from time to time. “The US corporation that is hiring the offshore company should retain rights to inspect the vendor’s facilities,” she says. “It’s important not only to retain those rights, but to also actually do those inspections.”

Companies in some industries need to keep another set of legal issues in sight when turning to an overseas partner. “When regulated companies begin to go offshore, there’s an additional overlay of risk and concern,” says Contreras. “For example, pharmaceutical companies work under very strict FDA-imposed requirements for manufacturing, and they need to be sure their foreign outsourcer is complying with those. In some cases, that might even require the foreign outsourcer to open up its facility to inspection by US regulatory authorities.”

Similarly, companies need to be cautious when dealing with IP that involves US government-funded technologies. With such technologies, says Contreras, “there is a requirement that US manufacturing be used—that licensees manufacture in the US for sale to the US market.” Many patents held by universities, which often rely on government funding, fall into this category. “If a pharmaceutical company licenses patents from, say, Johns Hopkins, there will most likely be requirements that it must have US manufacturing for at least a substantial portion of the product.”

### Looking Beyond Legal Protections

In practice, legal safeguards are vital, but they can only do so much, given the varying levels of IP protection available in different countries. But companies can augment their legal efforts with the right processes and methods.

For example, Contreras says that companies using offshore product developers or contract manufacturing might split up activities among different vendors. “Let’s say you have an electronics product,” he explains. “You could have the monitor for that product manufactured by one vendor, the memory circuit designed by another, and so on, so that different people in different countries are working on separate components, and nobody has the full picture.”

Companies should also consider what the offshore operation is doing to increase awareness of IP protection and security in the workforce, especially when an operation is in a region where such protection is a relatively new and still-developing concept. “People simply may not be in the habit of locking things or turning things off,” says Burr. “Or, companies that have call centers will tell you that in some countries, people are much more likely to be victims of social engineering, where someone calls up, pretends to be somebody he isn’t, and talks them into giving out information that they shouldn’t give out. That has to do with cultural values about assisting people and avoiding confrontation, which vary from culture to culture.”

Training can go a long way toward building awareness of IP security, Burr continues. “When trained to understand

and be sensitive to these differences—and to appreciate the importance of IP—people can move beyond those cultural factors,” she says. “Anecdotally, my clients have found that if they provide the right training—if they are pretty hands-on in the initial stages of the relationship—then their social engineering problems, for example, are not any different than they would be in a domestic facility. In fact, one client that had real problems at first found that once they did the training, the incidence of successful social engineering was much lower than it was in their US call centers.”

To a large extent, IP safety in this environment comes down to picking the right partner and doing the kind of due diligence that looks at everything from references to hiring practices and employee retention rates. “It may sound trite, but you want to go with the most stable, reputable company you can,” says Contreras. “That might mean larger companies that have experience in handling contracts for major corporations, and that are more likely to have the resources and internal controls in place to protect IP. And it might mean looking for a vendor with an established US presence, which will make it easier to pursue legal remedies if there is a problem.

“Really, that’s probably the most important thing of all—knowing your potential partner,” Contreras continues. “Doing things like filing patents in those other countries may not be that effective. What will help is ensuring that the right processes are in place, making sure that you’re working with a good partner and really doing your homework before you jump in.”



# New Boundaries in Cyberspace

By Jeffrey A. Heilman

## From Betamax to Grokster: Downloading Rights Shift

The highly charged battle over music and movie downloading has its own soundtrack, composed of a chorus of consumers, organizations, musicians and corporations sounding out across the US and Europe. On the consumer side are the more than 6,000 individuals in the US, Canada and Europe who have been sued for downloading copyrighted material from the Internet. A multitude of groups have chimed in on such concerns as free speech and the tension between supporting creativity through copyright protection and promoting technological innovation by limiting infringement liability. Entertainment companies on both sides of the Atlantic have aggressively prosecuted the “thievery” through US courts.

Until recently, says Mark Haftke, Europe has lightly followed the US in chasing providers of file-sharing services, as in the notorious shutdown of Napster. Haftke, who heads up Wilmer Cutler Pickering Hale and Dorr’s Intellectual Property and Information Technology Department in the UK, says that differing laws, lack of statutory damages and the likelihood of failure have contributed to a general trend in Europe of pursuing end-users rather than service providers. As of this June, however, the nature of the fight in the US stands to change with the Supreme Court’s ruling in favor of MGM and 27 other entertainment concerns in their action against the makers of file-sharing software products Grokster,

Morpheus and KaZaA. While the implications for Europe are uncertain, says Haftke, he foresees providers and users changing their ways. “This decision increases the possibility of similar actions, with more bite than before,” he says. “And the song remains the same for end-users, whom the British record industry has said it will still vigorously pursue. Looking ahead, it is safe to say that the pressure is now on for industry-wide authorized, paid services. Once the relationship between profits from online and analogue sales becomes more balanced, the tide will turn unstopably toward online distribution.”

## Battling Cybersquatters on Their Own Turf

Spies, hijackers, extortionists. The cast reads like a classic espionage novel, but these arch-villains are the scourge of domain name holders world-

wide, tarnishing images, diverting clients and interfering with business through domain-name abuse.

Cybersquatters register an existing trademark as a domain name, with the intent of selling it to the trademark owner for profit. Typosquatters register domain names close in spelling to a known trademark or name, to take advantage of typing errors by web users.

“Internationally, cyberlaw has generally followed the US lead,” says Wilmer Cutler Pickering Hale and Dorr’s Tom Olson, “which recognizes cyber-trespasses as trademark infringements.” While the ubiquitous nature of cyberspace presents unprecedented challenges for domain-name dispute resolution, Olson says that international online arbitration is a viable alternative to expensive, time-consuming and uncertain court battles.

“As the private body overseeing the domain name system,” explains Olson, vice chair of the firm’s Intellectual Property Litigation Department, “ICANN, the Internet Corporation for Assigned Names and Numbers, enforces a Uniform Domain Name Dispute Resolution Policy.” Because they’ve registered a domain name, he notes, “accused infringers are obligated to arbitrate.”

The appeal of online arbitration, says Olson, is that the entire procedure is Internet-based. “One to three arbitrators consider the case. Within weeks, they return a decision canceling the name, ordering the name transferred to the complainant or denying the complaint. Practical and streamlined, online arbitration is fast becoming a success story.”

