BY DENISE MYSHKO

Striking a Balance for INNOVATION

Recently proposed regulations **strive to restore the balance between protecting the intellectual assets** related to innovation by pharmaceutical manufacturers and the **opportunity to bring lower-cost generic products to market** by nonbrand manufacturers.

For hundreds of years, patents protecting intellectual property have been recognized as incentives for innovation. The U.S. constitution contains a line that underscores this understanding, that "Congress shall have the power to … promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

In the pharmaceutical industry, patent protection of intellectual property and assets is a particularly important way for brand-name drug manufacturers to recoup the tremendous investment made in research and development — not just for those drugs that make it to


CHARLES GUTTMAN

There is a great deal of economic pressure for brand-name manufacturers to try to extend their monopolies longer. They are using the system and looking for loopholes (in Hatch-Waxman) that were not contemplated at the time the act was ratified.

market but for those drug candidates that failed during development.

For years the pharmaceutical industry's practices for protecting its intellectual property have been scrutinized by public citizen groups and challenged by generic manufacturers.

Industry critics are turning up the heat, accusing brand-name drug manufacturers of engaging in anticompetitive practices, acting in collusion, and skirting around loopholes in

Anticompetitive or Sound Business Strategy?

WITH SO MUCH AT STAKE, IT'S EASY TO UNDERSTAND WHY SO MANY PATENT DISPUTES END UP IN COURT. Brand-name blockbuster products, valued at more than $36 billion in U.S.sales, are expected to lose market exclusivity in the next four years, according to analysts at Frost & Sullivan. Lovenox, Prevacid, Pravachol, Zocor, and Zoloft are among the major blockbusters that are scheduled to lose their market exclusivity within the next three years.

But some say pharmaceutical companies have gone too far to protect their intellectual property and the revenue streams stemming from their brand-name products.

The Federal Trade Commission has taken antitrust law enforcement actions against certain brand-name and generic drug companies whose allegedly anticompetitive agreements took advantage of one or more of the other of the Amendments under Hatch-Waxman related to 180-day exclusivity and the 30-month stay provisions. The FTC is taking an active role in ensuring that consumers benefit from competition in the pharmaceutical industry.

SOME SAY PHARMACEUTICAL COMPANIES HAVE GONE TOO FAR TO PRO TECT THEIR INTELLECTU AL PROPER TY.

Recently, several major pharmaceutical companies have reached agreements with the FTC and other federal authorities in regard to antitrust issues.

IN MARCH 2003, Bristol-Myers Squibb announced that it had reached an agreement with the FTC on the terms of a proposed consent decree that would resolve antitrust proceedings relating to BuSpar, Taxol, and Platinol. In addition, the company reached a similar agreement on the terms of injunctive relief with the states involved in antitrust litigation relating to BuSpar and is in the process of negotiating similar terms with respect to Taxol.

The proposed agreements outline the terms that will govern the company's activities in, among other things, obtaining patents from the U.S. Patent & Trademark Office, listing patents in the Orange Book, and litigating and resolving patent infringement claims relating to its patent rights. In general, the terms require that Bristol-Myers Squibb comply with existing laws and abide by certain additional restrictions that track current enforcement policies of the FTC in these areas.

IN APRIL 2003, GlaxoSmithKline and Pharmaceutical Resources Inc., and its subsidiary Par Pharmaceutical Inc., reached a settlement with Pentech Pharmaceuticals Inc. in their patent litigation over Pentech's proposed generic capsule version of GSK's antidepressant Paxil (paroxetine hydrochloride). The settlement allows Par to distribute in Puerto Rico substitutable generic paroxetine hydrochloride immediate-release tablets supplied and licensed from GSK for a royalty paid to GSK.

Par is entitled to distribute the same product in the U.S. market once another fully substitutable generic version of Paxil becomes available.

GSK lost another key court case — involving Paxil — in March 2003 to TorPharm, a wholly owned division of Canadian generic company Apotex. The judge for the U.S. District Court for the Northern District of Illinois (Chicago) ruled that GSK's patent in the United States covering the hemihydrate form of Paxil is valid but not infringed by Apotex's product. Paxil had sales of $2.2 billion in 2002. The patent expires in 2006.

Apotex won tentative FDA approval for the generic paroxetine hydrochloride in May 2001. Since Apotex filed its ANDA application with the FDA, GSK has filed nine additional patents leading to four additional patent infringement suits against Apotex.

Final FDA approval of Apotex's product is still blocked by two 30-month stays — the last of which is to expire in September 2003.

IN DECEMBER 2002, Pfizer lost a key patent dispute. Dr. Reddy's Laboratories Ltd., a generic manufacturer in India, won a court case in New Jersey, allowing the company to market a generic version of Pfizer's cardiovascular product Norvasc. Pfizer's lawsuit alleged that the patent extension given to amlodipine besylate also covered the maleate salt version of Norvasc. Pfizer raised these objections after Dr. Reddy's claimed its product did not violate Pfizer's patent.

This isn't Pfizer's only battle with Dr. Reddy's. In February 2003, Dr. Reddy's filed a suit against Pfizer challenging four of Pfizer's five key patents related to the antidepressant Zoloft. Dr. Reddy's is seeking marketing approval from the FDA to sell a generic version.

Leading Blockbusters Going Off Patent

December 2004
Lovenox
COMPANY: **Aventis**
CLASS: **Anticoagulant**
2002 SALES: **$1 billion**

July 2005
Prevacid
COMPANY: **TAP**
CLASS: **Anti-ulcer**
2002 SALES: **$3.2 billion**

October 2005
Pravachol
COMPANY: **BMS**
CLASS: **Anticholesterol**
2002 SALES: **$1.2 billion**

December 2005
Zocor
COMPANY: **Merck**
CLASS: **Anticholesterol**
2002 SALES: **$4.8 billion**

December 2005
Zoloft
COMPANY: **Pfizer**
CLASS: **Antidepression**
2002 SALES: **$1.6 billion**

December 2006
Paxil
COMPANY: **GSK**
CLASS: **Antidepression**
2002 SALES: **$2.0 billion**

Source: Frost & Sullivan, February 2003. For more information, visit frost.com.

current regulations to keep generic products from reaching the market.

Industry advocates say pharmaceutical companies are employing strategies common in other industries to protect intellectual property (IP) and maintain shareholder value.

Regulatory changes, however, are on the horizon, which if enacted, could limit the industry's protection of its branded products.

In October 2002, President George W. Bush announced a proposed FDA regulation that addresses certain features of the Hatch-Waxman Act and its amendments.

The law and its amendments established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. The amendments compensate brand-name companies, in certain circumstances, for a lengthy drug-approval process, which can shorten the effective life of patent protection for drug products. The amendments also streamline the procedures for bringing generic drug products to the market.

The Hatch-Watchman Act was designed to address generic approvals. It was not designed to address patent litigation between innovator and generic drug companies. Among the regulation's requirements, innovator companies are required to list their patents in the Orange Book. The FDA can only rule on whether patent information is submitted according to the law for listing. It is the Federal Trade Commission (FTC) that addresses anticompetitive agreements and antitrust issues.

The FTC stated in a July 2002 report that two of the provisions of the Hatch-Waxman Act governing generic drug approval prior to patent expiration — the 180-day exclusivity and the 30-month stay provisions — are susceptible to strategies that, in some cases, may have prevented the availability of more generic drugs. The commission states these provisions continue to have the potential for abuse.

"For more than a year, the Federal Trade Commission has investigated delays and abuses in the process of bringing generic drugs to the market," President Bush said in an Oct. 21, 2002, press conference. "I have reviewed the FTC findings and I am taking immediate action to ensure that lower cost, effective generic drugs become available to Americans without any improper delays."

According to the Oct. 31, 2002, issue of CDER's News Along the Pike, the proposed rule change would modify the FDA's interpretation of the Hatch-Waxman Act. The law allows for an automatic 30-month delay in the approval of a generic drug when the generic manufacturer challenges a patent held by the innovator and is sued within 45 days of the innovator being notified. This delay gives the innovator drug company a chance to protect its patent rights in court.

In some instances, generic drug approvals have been delayed for multiple 30-month periods. The new approach, as outlined in the Federal Register notice, would eliminate the possibility of a brand-name pharmaceutical company receiving multiple 30-month delays related to newly obtained patents. Under this proposal, brand-name pharmaceutical companies would still be able to protect their patent rights through traditional patent infringement lawsuits.

The proposed rule also would clarify the requirements for listing drug patents in the Orange Book. In particular, the regulation would make clear that drug manufacturers could not submit to the FDA patents on product aspects such as packaging, metabolites, and intermediates that are unlikely to represent significant innovations.

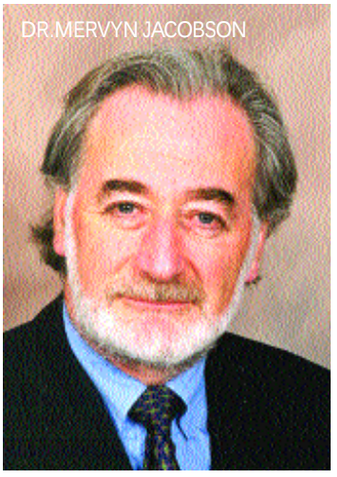
This is aimed at discouraging brand-name manufacturers from submitting patents that are not permitted to be listed under the statute and regulations. This detailed patent declaration will be subject to criminal penalties for misrepresentation.

The proposals are consistent with recent recommendations made by the FTC in its July 2002 study, Generic Drug Entry Prior to Patent Expiration. The FTC recommended that there be only one 30-month approval delay per generic drug application. The FTC's study found an increase in the listing of patents, which had been issued by the Patent and Trademark Office after the brand-name drug product had been approved and also after a generic application had been filed.

Before the FDA's proposed rule, Congress attempted to make legisla-


SCOTT REQUADT

If innovators fail to be proactive about identifying and patenting all of the commercially relevant forms of their compounds, they risk having others beat them to the punch on product life-extension opportunities.


DR. MERVYN JACOBSON

tive changes to the existing rules for generic drug approval under the Hatch-Waxman Act. The Senate approved a bill last July that would have changed parts of the law relating to 30-month and 180-day exclusivity for the first generic applicant. The House was unable to pass similar legislation. These legislative efforts, however, have now been pre-empted by the proposed FDA rule.

In the Federal Register notice — 67 Fed. Reg. 65447 — FDA officials were quoted as saying the proposed rule has multiple objectives: "We are clarifying the types of patents that must and must not be listed, and revising the declaration that NDA applicants must provide regarding their patents. In addition, through this proposal, we are adopting a different interpretation of the act that will limit the number of 30-month stays to one per ANDA or 505(b)(2) application. This clarification, revision, and reinterpretation will help ensure that NDA applicants list appropriate patents in the Orange Book while preventing the NDA holders from thwarting generic entry through the use of multiple 30-month stays. Through these actions, we are preserving the balance struck in the Hatch-Waxman Amendments between encouraging innovation and encouraging the availability of generic drugs."

According to the Federal Register notice, to the extent that this proposed rule would eliminate multiple 30-month stays per ANDA after the first, the estimated impact on innovator companies would be an annual revenue decrease of about $3.16 billion. The cost impact on innovators is driven by the fact that a delay in generic entry extends the time the innovator collects peak sales and shortens the time the innovator collects 30% of peak sales. Absent discounting, the impact on innovators would be the length of the delay times 70% of the peak innovator drug revenue.

FDA officials estimated the increase in sales to generic drug companies using the same model used to estimate losses in sales to innovators. Assuming typical drug peak sales to be $2.72 billion (including 2.0 frequency factor) and a typical delay of 23 months, the estimated increase in one-year revenue to generic firms is about $1.12 billion.

The model assumes that after generic entry, the market eventually will stabilize where the price of a generic drug will be 33.5% of the equivalent innovator drug. The gain to consumers would be the difference between the generic and innovator price. This price gap is equal to 66.5% of the innovator price. Under the FDA's assumptions, the estimated consumer impact of the proposed rule is a one-year gain of about $2.04 billion. This gain would be from the elimination of multiple 30-month stays per ANDA that delay the availability of less expensive drugs.

After increasing this one-year estimate to account for the annual expected increases in baseline pharmaceutical expenditures, the total expected benefit to consumers for the period 2002 to 2011 is about $34.82 billion. The annualized benefit to consumers, using a 7% discount rate, would be about $3.29 billion.

Generic Entry

The Hatch-Waxman Act allowed a generic company to submit an ANDA that references safety and effectiveness research already submitted to the FDA by the brand-name drug manufacturer. Before Hatch-Waxman, formally called The Drug Price Competition and Patent Term Restoration Act, the generic company had to conduct this research.

Current law requires generic manufacturers to prove that their versions of branded drugs are chemically and biologically equivalent, meaning that the compound acts in the body in the same way as the branded product.

Under Hatch-Waxman, generic companies can begin testing their products before the patent of the branded product expires. The first generic company to file an application with the FDA is granted 180 days of market exclusivity during which time no other generic product can come to market.

In the course of its study, which represented some of the largest drug products as measured by annual sales, the FTC subpoenaed documents from both brand-name and generic drug manufacturers and examined instances since 1992 in which generic applicants filed an application with the FDA seeking to enter the market with a generic version of a drug product before expiration of the brand-name drug product's patents. According to the FTC, an increasing number of generic applicants have sought entry before patent expiration. During the 1980s, only 2% of generic applications sought entry this way. From 1980 to 2000, about 20% of the generic applications sought entry before patent expiration.

Generic companies must certify with the FDA that their submission does not infringe on innovator-held patents as listed in the Orange Book. At this time, the innovator company can challenge the generic manufacturer's claims, which triggers the 30-month stay.

This is the provision of Hatch-Waxman that has generated the most criticism and debate.

Families USA and Public Citizen claim that brand-name pharmaceutical companies have manipulated this provision and are employing "tricks" to extend their patents. Families USA claims that brand-name manufacturers are "warehousing" patents and then listing them in the Orange Book when older patents are about to expire.

We were quite aware early on that if we were successful, the legal process of forcing someone to respect the patents could be a very expensive and drawn out procedure. A small company may be in the right, but a large company willfully can drag out the process and incur expenses to exhaust a smaller company before the case ever gets before a judge.


PETER GERKEN

Patent infringement is an expensive liability and a catastrophic risk. Companies don't want to be slammed with big litigation that is going to be painful to cash flow or impact their valuations as public companies.


KATHI KEDROWSKI

Advancing line extensions and new formulations — that are within patent law — is a sound business strategy to maintain market share.

"Since the FDA does not make legal judgments regarding patents, a company could file a frivolous lawsuit and still obtain the 30-month stay," says John Lucas, Ph.D., J.D., VP and chief patent counsel of TransForm Pharmaceuticals. "There have been a number of cases, due to the timing of patents granted, in which brand-name companies have been able to extend their market exclusivity by years by using sequential 30-month stays. This has led to complaints by the generic industry and public-interest groups that generic drugs are being unfairly kept off the market. Indeed, the courts have found cases of abuse in the 30-month stay provision."

The Hatch-Waxman Act was not originally intended to allow for multiple 30-month stays, says Charles Guttman, a partner in the intellectual property department at Proskauer Rose LLP. "Brand-name manufacturers are using the system and looking for certain loopholes, which were not contemplated at the time Hatch-Waxman was approved, as a way to extend their monopolies longer then anticipated."

Mr. Guttman says the Hatch-Waxman Act was meant to be a compromise between brand-name and generic pharmaceutical companies.

"The compromise was that the brand-name drug manufacturers would get longer patent exclusivity to make up for the time lost to FDA approval," he explains. "The generic drug manufacturers received two benefits. First was the ability to file ANDAs rather than full-blown drug applications, which are very expensive. The second benefit is that they have the ability to do some limited manufacturing and experimental work needed to file the ANDA while the innovator patents are still in force and it is not considered infringement."

Jeff Trewhitt, a spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA), says the 30-month stay provision of Hatch-Waxman does not represent a loophole in the law.

"The Hatch-Waxman Act says a generic drug company can challenge the validity of a patent before the expiration of the patent," he says. "As part of this fine balancing act, the drug company can assert that it has a perfectly legitimate patent and can file a suit to prove its claim in court. When that lawsuit is filed there can be a stay of the generic drug going to market for up to 30 months. But the patent doesn't get extended. If the patent expires while the court case is still ongoing, the court case ends immediately, and the next day, theoretically, a generic drug can be on the market.

"And as for this notion that brand-name drug companies are 'gaming' the Hatch-Waxman Act to keep generic drugs off the market, nothing could be further from the truth," Mr. Trewhitt says.

Since the Hatch-Waxman law was passed, about 8,500 generic drugs have been approved by the FDA. The portion of generics on the market has increased from 19% in 1984 to about 51% today. According to the FTC, generic drugs now comprise more than 47% of the prescriptions filled for pharmaceutical products, up from 19% in 1984.

"The generic industry has done quite well under Hatch-Waxman," Mr. Trewhitt says.

Improving on the Original

According to the National Institute for Health Care Management Foundation (NIHCM) in an August 2000 report, laws protecting IP encourage companies to derive new products from compounds or drugs already patented. According to some at the NIHCM, these laws have had an unintended impact — the number of new molecular entities being submitted and approved has decreased.

In the 1990s, almost half of the drugs approved by the FDA were new formulations or new combinations of compounds already approved, according to the NIHCM report. The report found that pharmaceutical companies that make incremental improvements to a blockbuster product are extending patent life as a relatively safe way to maximize profits.

According to PhRMA, in 2002, 17 new molecular entities (NMEs) and 9 new biologics were approved; in 2001 24 NMEs were approved. The FDA received 23 applications for innovative drugs last year, down from 30 the year before.

Others say the reduced number of NME applications has nothing to do with extensions of patent life for established products, but rather pharmaceutical companies are focusing on fledgling technologies that have yet to pay dividends.

"One of the reasons for fewer NMEs is that companies are making the transition from old, traditional chemistry to new cutting-edge techniques of biotechnology," Mr. Trewhitt says. "A number of companies are on a steep learning curve. Some companies are doing more fundamental research than they've done in years and a number of companies are spending more time and money to make the transition to biotechnology."

From a business perspective, the pharmaceutical industry is not doing anything unusual, says Kathi Kedrowski, partner in the global investigations and dispute advisory practice and leader of the intellectual asset solutions team practice at Ernst & Young.


ALBERT JACOBS JR.

"Intellectual property and especially patents are key assets for every company," she says. "In the past about 80% of a company's market cap correlated to the value of book assets. Today, this correlation is just the opposite; 20% of the market cap is book assets and 80% is related to brands, technologies, patents, and other intellectual property. Before a company only protected the tangibles. Now it has to protect and exploit the intangibles."

The biggest challenge that biotech companies face with intellectual property is how to define what it is they think they've discovered. Often in the early stages, a biotechnology company may believe it has something but it isn't quite sure what that is.

Before a generic maker can gain market approval, it must certify noninfringement of patents listed in the Orange Book. An infringement suit by the innovator against the generic company triggers an automatic 30-month stay of approval.

Ms. Kedrowski says advancing line extensions and new formulations — that are within patent law — is a sound business strategy to maintain market share and protect assets.

Ms. Kedrowski points out that designing products around existing patents is a common and legitimate practice within many industries.

"In other industries, companies try to find ways to design around another company's patent; one company might buy another company's products, take those products apart, and figure out how do the same thing better without infringing on the patent," she says. "All that pharmaceutical companies are doing is conducting that same process internally with their own patents."

Companies, however, often file patents that over-reach, says Albert Jacobs Jr., chair of national intellectual property department and cochair of the national biotechnology group at Greenberg Traurig LLP.

"A company can twist the construction of a patented mechanism technology or compound and sue another company if its product or technology is too similar and deemed competitive," he says.

Mr. Jacobs says this is a common practice among pharmaceutical and biotechnology companies, and even universities.

"The strategy is to block the launch of a competing product," he says. "Frequently, the originator company can make enough of a case before a district court judge, who may not know anything about molecular biology, chemistry, or bioassays, to have the ruling in its favor. An expert testifies that two technologies are very similar, and the judge grants an injunction to block the second company from launching its product. The originator's patent may fall a year or two later, but in the interim the winning company can make some money by keeping the other company's product off the market."

Creating Value from IP

"Patents are intended to be an obstacle to competitive access in the short term," says Dr. Mervyn Jacobson, executive chairman and cofounder of Genetic Technologies. "A company's inventions may be very significant, but the ownership of that innovation is for a brief moment in time and then it reverts to public ownership forever. The concept of patent protection is very sound and very effective in encouraging invention by awarding a company what is effectively a monopoly for a brief moment in history. Companies can't get value from their innovations unless they are able to exploit and commercialize their products."

Industry experts believe that to maximize their intellectual assets, companies need to think outside the box.

According to Patrick H. Sullivan, senior president at Intellectual Capital Management Group Inc. (ICMG), pharmaceutical companies too often leave intellectual property and assets on the shelf.

"We're finding that companies have more ideas than they can focus on in their business," Mr. Sullivan says. "In the past, companies would discard noncore intellectual assets. Today, there are mechanisms that allow companies to profit from their innovations, even if these are not in their areas of specialty."

Ms. Kedrowski says companies should have a proactive strategy for managing their intellectual property.

"Companies need to look at their inventions and decide, from a business and legal perspective, whether the product or technology should be patented and then what to do to exploit that patent," she says. "There are tons of great inventions sitting on the shelves of companies because they weren't core to the business."

For those products that aren't core to the business, companies have to decide how to gain additional value from their IP. This can be done by out-licensing or even forming a joint venture or strategic alliance, Mr. Sullivan says.

"Innovator companies have to make absolutely sure that they understand their product's pharmaceutical options earlier and better than any other company," says Scott Requadt, director of business development at TransForm Pharmaceuticals Inc. "It's tempting, for instance, for an innovator to stop looking for alternative formulations or solid forms of a drug candidate once it has identified one approach that seems suitable for development. There may, however, be other formulations or solid forms of the compound that would enable even better performance, that might make new delivery systems possible, or that might enable a competitor to market a bioequivalent drug as soon as the original chemical entity goes off-patent, even while other important patents on the drug remain in place. In today's hypercompetitive environment and with shrinking pharma product pipelines, this is a new opportunity to create value."

Beyond patents on IP, intellectual assets can be found throughout an organization — on an employee's e-mail system, desk, and shelves, says Barak Pridor, CEO of ClearForest Corp.

This "unstructured content" includes articles, research, memos, e-mails, reports, anything that company personnel read during the course of a day. This information can be sorted and be used for business intelligence, Mr. Pridor says.

"Managing data information to enforce patents and determine the patent strategy of competitors can help protect against patent infringement lawsuits," Mr. Pridor says.

Insuring Intellectual Property

Pharmaceutical patents are the most often challenged, says Richard Reed, VP at Chubb & Son, and global intellectual property and e-commerce practice leader at Chubb Commercial Insurance. And yet the market for patent infringement and enforcement insurance for this sector is in its infancy.

"One of the challenges for an insurer is to determine the appropriate trigger of coverage and what the policy responds to," he says. "Another challenge is to come up with an appropriate grant of coverage. Today, insurance companies take a very conservative look at the income streams that flow from each individual product and each individual patent. An insurer will look at the streams that are predictable, stable, and have a much smaller risk of being overturned from a validity standpoint."

IP insurance is not cheap nor is it a widely available option.

"Insurance, however, is a moderate cost in comparison with the cost of IP litigation," says Peter Gerken, VP and practice leader of the intellectual property practice of insurance broker Marsh Inc. "Litigation is expensive and experts are expensive. Companies do not want to be slammed with the cost of litigation that will be painful to their cash flow or hurt their valuation as a public company."

While there are two basic approaches, including infringement and enforcement, there are other insurance solutions as well. Those solu-

tions include: capping uninsured IP litigation; insuring loss of profits arising out of patent invalidity; and facilitating deals by wrapping insurance around representation, warranty, indemnification, and title risk. In addition, key types of services such as risk assessment can assist companies in managing IP risk.

"The enforcement insurance typically is suitable for small- to mid-size companies because this is a better use of cash than to fund litigation from cash resources," Mr. Gerken says.

Among the leading insurance companies that offer infringement liability are American International Group (with a policy limit of $10 million), Swiss Re (with a limit of $30 million to $50 million), and XL Capital (with a limit of $5 million). XL Capital also offers enforcement insurance.

One company that has been aggressive in defending its patents is the Australian-based biotech company Genetic Technologies Ltd. Genetic Technologies recently filed lawsuits against three U.S. companies for infringing its patents. Genetic Technologies also is in negotiations with many other companies worldwide to get value from its inventions by entering into licensing arrangements for its technology.

The company has a series of patents that address the use of information within noncoding DNA for sequence analysis for diagnostics and for noncoding sequence mapping for identification of genes of interest.

"We were quite aware early on that if we were successful, the legal process of forcing someone to respect these patents could be a very expensive and drawn-out procedure," Dr. Jacobson says. "We're a small company in terms of market capitalization and cash reserves compared with multinational companies that may have billions of dollars in sales and tens of thousands of employees and armies of people who can defend them against claims by small companies such as Genetic Technologies." ✥

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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