

PATENT ENFORCEMENT DURING THE GLOBAL ECONOMIC CRISIS

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Recent Developments

Intellectual property procurement and enforcement have gained even greater prominence during global economic downturn. Large and small companies alike are more aware of the value that can be derived from intellectual property. In the most recently-released figures, both international and U.S. patent filings grew to new heights, with many originating countries, including China, South Korea and Sweden, seeing double-digit growth rates. Emerging economies in Asia and the Middle East are beginning to showing more appreciation for intellectual property by increased enforcement.

But the trend of increased intellectual property procurement and enforcement has not been without opposition. In fact, some question whether the resulting innovation is worth the legal costs associated with protecting it. Others complain that the required legal processes to protect innovation are too slow and cannot keep pace with industry needs. Ultimately, the consumer pays for these added costs, and some have questioned whether the consumer is getting sufficient added value to justify them. These concerns have been present for decades, but have recently taken on more importance as consumers and companies struggle to remain competitive in today's tough economic environment.

One area where patent enforcement is often questioned is the pharmaceutical industry. Innovator pharmaceutical companies struggle to maintain exclusivity for their patented drugs while generic drug companies try to enter the market before patent protection has expired. In the U.S., virtually every major patented commercial drug product now gets challenged. An increase in pharmaceutical patent challenges has also been evident in Europe. The public and healthcare providers want innovation, but they also want low-cost options. In trying to achieve these competing goals, both government regulation and oversight in the U.S. has mounted. For example, the Drug Price Competition and Patent Term Restoration Act (a.k.a. the "Hatch-Waxman Act") has spawned a steady stream of patent challenges. The Act implicates policies of several government agencies, including the USPTO, the Food and Drug Administration (FDA), and even the Federal Trade Commission (FTC). Indeed, the FTC seems particularly intent on overseeing, or at least considering, every settlement of a patent dispute involving generic drug challenges to innovator patents. The Preserve Access to Affordable Generics Act, currently under consideration by the U.S. Senate, seeks additional oversight for such settlements.

Companies marketing drug products in the European Union are not immune to similar oversights. The European Commission recently conducted investigations of European drug companies, searching for evidence of possible anticompetitive delay of generic drug entries. The European Federation of Pharmaceutical Industries and Associations issued a response stating that the commission had failed to substantiate its initial allegation "that patenting strategies dampened innovation or delayed generic entry illegitimately." Ian Traynor, *Big Pharma*

'Delaying' Cheaper Drugs, Guardian.co.uk, 8 July 2009, available at <http://www.guardian.co.uk/global/2009/jul/08/business-pharmaceuticals-europeancommission>.

Unfortunately, such active regulatory oversight and intervention adds additional costs for everyone, including the consumer. It also may discourage innovation due to the increased costs. The regulatory frameworks emerging throughout the world may be placing a premium on lifecycle management and patent portfolio management while discouraging original technological innovation. Recent healthcare legislation in the United States, including the Preserve Access to Affordable Generics Act and the Patient Protection and Affordable Care Act will likely continue to drive increased regulatory pressure in 2010 and beyond. The latter of these two Acts was signed into law earlier this year, and, in addition to better-known healthcare reform subjects, includes provisions for generic drug companies to seek approval of more complex, biologic generic drugs, called "Biosimilars."

In the midst of the regulatory complications, pharmaceutical patent litigation increases each year. The reason is simple – the markets allow, and indeed require, unusual vigilance and challenge under the regulatory frameworks that have been created. As the financial stakes continue to rise, the number of enforcement activities also will rise.

In addition to increased regulatory oversight, the U.S. courts also have recently taken a more active role in shaping intellectual property issues. In *KSR v. Teleflex*, 550 U.S. 398 (2007), the U.S. Supreme Court scaled back from the traditional "teaching, suggestion or motivation" obviousness standard, making it less certain, and arguably more difficult, to obtain and defend a patent. More recently, the very nature of patentable subject matter, including whether certain methods should be protected at all, was considered in *Bilski v. Kappos*, No. 08-964 (U.S. June 28, 2010). The *Bilski* Court reversed the Federal Circuit's requirement that any such method be tied to a machine or apparatus or transform an article to be patentable, in favor of a more open-textured, albeit less certain, approach.

Despite this increasingly complex and dynamic international intellectual property landscape, tremendous business opportunities for intellectual property revenue continue to be lost each year. According to Harvard Business Review, each year U.S. companies fail to capitalize on over \$1 trillion-worth of patent assets. In these tough economic times, it is even more important for companies in all industries to continually monitor and improve their intellectual property management and enforcement strategies to capture that revenue and remain competitive. This is especially important in I.P.-intensive industries with heavy R&D, such as pharmaceuticals. The development of a good intellectual property enforcement strategy is no longer merely a way to take advantage of an exciting paradigm shift; it may be a matter of survival.

Methods of Patent Enforcement and Portfolio Valuation

The first step in establishing an effective patent enforcement strategy is a sensible valuation of the patent rights, taking into account the uncertainty of future value. This inquiry must extend beyond an assessment of potential damages for litigation claims. Valuation approaches differ depending on whether the patent covers a product with large annual revenue,

or a product with no current sales, a declining market and several competitive options. Licensing options or litigation options often depend on the value of patent rights. Sometimes the higher value properties are better candidates for litigation simply because it is less likely that high value patent owners will want to share the market if exclusivity is possible.

Predicting value and forecasting the potential of any intellectual property is never an exact science. However, in assigning value to any patent, the patentee should consider:

- the role of the patent in the patentee's core business;
- the costs and benefits of the patent to the patentee's competition and other third parties;
- the costs and benefits of maintaining exclusivity versus sharing the patented technology; and
- the stage of the market and patent lifecycle.

Only after the patent or patent portfolio has been evaluated can the owner rationally consider the enforcement options – primarily, licensing or litigation.

Licensing

Licensing usually represents a compromise of the ultimate value of a patent because it requires the patent owner to share its intellectual property with another company. Nonetheless, in the past 5 years, pharmaceutical companies have increased their licensing activities in light of decreased R&D productivity. Datamonitor estimates that the top 20 pharmaceutical companies will derive \$100 billion in licensing revenue in 2010 – roughly twice what it was in 2002. *Can Licensing Cure Big Pharma's Ills?* Pharmaceutical Field, available at <http://www.pharmafield.co.uk> Issue ID: 40, Article ID: 315.

Licensing options may be particularly useful for start-up organizations seeking to grow, both because of the relatively low immediate costs, and also because licensing often represents acceptance of the value of a patent by others in an industry. Licensing revenue provides a predictable stream of income, while litigation is expensive and unpredictable. Licensing in the pharmaceutical industry can include arrangements such as co-promotion agreements, co-marketing agreements, supply agreements and joint-development agreements. The exact structure of any cooperative licensing arrangement can widely vary depending on the creativity of the parties.

By some estimates, during the 1990s annual patent licensing revenue in the United States increased from approximately \$15 billion to over \$100 billion. According to Deloitte, worldwide patent licensing revenues totaled approximately \$500 billion in 2007. Deloitte, *Intellectual Asset Management*, July 29, 2009, available at <http://www.deloitte.com>. Licensing revenue in the pharmaceutical industry has also grown tremendously in recent years. According to Datamonitor, by 2004, the top 20 pharmaceutical companies were already yielding \$63 billion in annual licensing revenue, representing almost 20% of their total revenue. Datamonitor, *Licensing Strategies: Trends in the Top 20 Pharmaceutical Companies' Activity*, Oct. 2005.

In recent years, a trend of defensive patent portfolio development has also emerged, with more and more companies pursuing technologies ordinarily considered outside of their core business. Licensing is the natural option for such technologies because other companies with operations in those technological areas may be better situated to manufacture or market the licensed products or processes. Aside from realizing a new revenue stream from such a license, such arrangements can build long-term relationships with complementary businesses.

However, where the patented technology is within the patentee's core operations, sharing technology with competitors (even for a reasonable royalty) may be counter-productive. Disadvantages associated with licensing include: (i) loss of some control over the technology's implementation or (ii) lack of control of manufacturers, leading to inefficiencies and reduced profits or, even worse, harm to the reputation of the technology. To reduce those risks, a company may enter nonexclusive licenses, perform careful background investigations of potential licensees, and police the performance of its licensees.

Although generally more amicable, licensing negotiations still present many backfire risks normally associated with litigation, and may ultimately lead to litigation as well. As just one example, in 2006, Sun Microsystems Inc. unsuccessfully attempted to license software technology to Network Appliance Inc. Network Appliance responded with a patent infringement suit against Sun in late 2007 based on its own patent portfolio. As this example illustrates, the nature of the potential licensing partner must be carefully evaluated *prior* to entering into negotiations. Some companies may take being approached by a would-be licensor as an opportunity to launch a pre-emptive declaratory judgment action.

Some Examples of Licensing Success

Texas Instruments was an early success story in realizing the value of its patent portfolio with a licensing program. This computer hardware company earned hundreds of millions of dollars from a large, ageing patent portfolio in the 1990s. Owing to its uniquely assertive program, it was the first company to yield over \$1 billion from licensing revenue of a patent portfolio. More recently, IBM has generated over \$1 billion per year licensing and custom-developing patents. Steve LeVine, *IBM May Not Be the Patent King After All*, Businessweek, January 13, 2010.

Litigation

In contrast to licensing, patent infringement litigation often represents a more uncompromising approach to enforcement. By litigating, the patentee seeks to recover the entire value (or more) of its patented technology while maintaining exclusive control. The rewards associated with successful litigation are therefore potentially huge. However, in most cases, the costs and risks associated with patent litigation are greater than those associated with a well-crafted licensing program. Patent litigation is a serious undertaking and should be carefully conducted by specialized, experienced counsel. In the wrong hands or under the wrong circumstances, patent litigation can destroy those who initiate it, leaving the intended target unscathed.

There also may be important public relations and goodwill fallout from vigorous litigation. Even sophisticated corporations and their legal teams have suffered crippling, unexpected losses. Those unpredictable backfire risks include losing proprietary trade secrets in discovery, facing counterclaims from a defendant's competing patent portfolio and sanctions for alleged litigation misconduct.

In many respects, the benefits and risks of litigation are the mirror image of licensing. Whereas licensing is often the best option for a start-up business looking for acceptance of new technologies, with low up-front costs and a revenue stream, litigation is typically the best option for an established technology with a solid revenue stream and balance sheet where control is essential. Litigation seeks to exclude competitors that might tarnish the patented invention and take part of the established market. Litigation provides notice that patent rights will be enforced vigorously, reducing the risk of future infringement and increasing bargaining power in future licensing negotiations. Litigation also provides for greater certainty with respect to ending a competitor's infringing activity. Litigation against willful infringers in the U.S. may provide for treble damages, attorneys' fees (in exceptional cases) and interest.

Some Examples of Litigation Success

There are many examples of cases where patent litigation has driven significant business success. For example, Polaroid's effective litigation to enforce its instant camera patents resulted in an award of almost \$1 billion and is credited with shutting down competitor Kodak's instant camera operations. In *NTP Inc. v Research in Motion Ltd.*, No. 3:01CF767 (E.D.VA.) (settled March 3, 2006) the plaintiff obtained a \$612.5 million settlement following a complex litigation history. An initial damages judgment of \$23.1 million was raised to \$53.7 million after the plaintiff established willful infringement. A looming injunction threatened to halt the defendant's multibillion dollar BlackBerry handheld email device operations, leading to the stratospheric settlement. More recently, in June of 2009, Johnson & Johnson obtained a \$1.67 billion award against Abbott Laboratories in patent infringement litigation targeting Abbott's blockbuster anti-inflammatory drug, Humira®. This was the largest patent award in U.S. history.

Conclusion

Sound patent enforcement strategy is more important than ever as the global recession continues. Intellectual property has continued its rise in prominence during this economic downturn in the midst of stricter, more dynamic regulatory oversight and legal standards. The decision whether to litigate or license requires tempered consideration of all the relevant factors – some of which defy precise evaluation. Although licensing provides greater short-term certainty and litigation provides greater ultimate certainty, each option represents a compromise of risks and rewards not suitable to every circumstance. Eternal vigilance and flexibility are key to every successful patent enforcement strategy.

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