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### PATENTS

By spreading the litigation costs and risks, venture capital and private equity investors may provide generic drug makers with new incentives to challenge the patents of brand-name drug companies under the Hatch-Waxman Act.

### **Leveling the Playing Field—The Role of Venture Capital in Hatch–Waxman Act Patent Litigation**



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## I. Introduction—The Absence of a Level Playing Field

**A**s many in-house counsel for generic manufacturers will tell you in candid, off-the-record moments, the costs of funding Hatch-Waxman patent cases seem increasingly prohibitive to senior management, especially because at least half the time, the innovator patentee will either prevail or force the generic litigant into an economically unattractive settlement. Even in cases where the generic manufacturer negotiates a favorable settlement or wins the case outright on summary judgment or trial, the return on the investment in legal and expert fees will often not be realized for many years.

In the present economic environment, senior managers are under enormous near-term pressure to obtain prompt returns on their investments, and are unhappy when they are told that they will have to make seemingly speculative investments for five years or more before they find out if they have struck gold. There are only a small number of generic manufacturers whose management has the intestinal fortitude to invest millions (and sometimes tens of millions) of dollars into a litigation battle with no guarantee of receiving any return on the investment for five years or more, and with the distinct possibility that the entire investment will be flushed down the drain should the innovator pharmaceutical giant prevail.

Meanwhile, outside counsel for generic companies (at least when they speak candidly among themselves), frequently bemoan the lack of resources available to them when they battle giant pharmaceutical companies in Hatch-Waxman cases. The innovator typically has the upper hand at all stages of the litigation, since the innovator often spares no expense to hire the best expert witnesses, aggressively pursues discovery, and takes advantage of the most sophisticated technological resources and outside consultants available to prepare and try the case.

The generic litigant, on the other hand, has to cut corners in light of budgetary constraints, which involves hiring less expensive experts from less-prestigious academic institutions, limiting the scope of pre-trial discovery and fact investigations, and limiting use of expensive technological resources and outside trial consultants. Further complicating the situation is the fact that in many recent cases involving blockbuster products, eight or more generic companies attempt to enter the battle—each of whom employs its own counsel even though the fruits of the battle will have to be split eight ways—thereby reducing the payoff that any single generic litigant will garner if successful.

As a result of these trends, and the willingness of the Federal Trade Commission, the U.S. Department of Justice, and many courts to give the green light to most proposed Hatch-Waxman case settlements, an increasing percentage of Hatch-Waxman cases have been settled, and only a shrinking number of generic litigants are willing to take the cases all the way to trial and appeal. Whereas a decade ago the system of incentives provided by Hatch-Waxman seemed to produce a reasonably level playing field between generic manufacturers and giant “innovators,” the playing field today seems tilted in favor of the innovators.

The absence of a level playing field in the current economic environment masks a fundamental truth:

there is still an enormous potential long-term economic payoff for a generic manufacturer who has the resources and fortitude to battle the innovator all the way through trial and appeal. The tricky part is that even many of the most sophisticated and well-financed generic manufacturers perceive, whether correctly or not, that they can no longer afford to devote the resources necessary to fight these Hatch-Waxman battles.

Even if many generic companies no longer feel comfortable investing millions of dollars of their own funds to support Hatch-Waxman gambits, there should still be creative ways to level the playing field and adequately fund Hatch-Waxman litigations. This seems to present an attractive opportunity for venture capital investors, who may be willing to assist generic manufacturers by funding litigation costs in exchange for sharing in the upside benefits of success.

I discuss below the system of incentives created by the Hatch-Waxman Act and the opportunities that these incentives provide for venture capital investors.

## II. The Hatch-Waxman Act System of Incentives

The Drug Price Competition and Patent Term Restoration Act, informally known as the “Hatch-Waxman Act” (Pub. L. No. 98-417), is a 1984 federal law which established the modern system of generic drugs.<sup>1</sup> The Hatch-Waxman Act was a complicated compromise between the interests of “innovator” pharmaceutical manufacturers and their generic competitors. The act increased patent and exclusivity protection for innovators while making post-patent entry easier for their generic competitors.

Under Hatch-Waxman, innovator brand manufacturers are generally allowed to extend one patent for each new product. Extensions must be applied for within 60 days of Food and Drug Administration approval of the marketing of the drug and may be for up to half the time that the drug spent in clinical trials plus all of the time during which the FDA was reviewing the New Drug Application (“NDA”), subject to a maximum extension of five years and a maximum effective life of 14 years. The Congressional Budget Office has estimated that overall, the average time that an innovator has been able to market its drug under patent exclusivity has increased under Hatch-Waxman from approximately nine to 11.5 years.<sup>2</sup>

In exchange for this (and several other) extended exclusivity provisions for innovators, Hatch-Waxman facilitated the ability of generic manufacturers to expedite entry of competing generic products into the market. When an innovator manufacturer submits an NDA, the innovator provides the FDA with clinical trial data and other information that the FDA relies upon in determining whether to approve the product. The innovator also must provide the FDA a listing of patents that purportedly cover the product, which the FDA lists in a publication commonly known as the “Orange Book.”

The Hatch-Waxman Act allows a generic company to file an Abbreviated New Drug Approval (“ANDA”) which “piggybacks” on the clinical trial data that the in-

<sup>1</sup> The act’s two primary sponsors were Rep. Henry Waxman (D-Calif.) and Sen. Orrin Hatch (R-Utah). Some would say this is one of the great bi-partisan “odd couples” ever to grace the name of fundamentally important congressional legislation.

<sup>2</sup> See, Chapter 1, July 2002 Federal Trade Commission Study titled “Generic Entry Prior to Patent Expiration.”

novator company has already submitted to the FDA in support of the NDA. This dramatically assists the generic manufacturer in expediting the approval process for its generic version of the drug, because the generic manufacturer is only required to demonstrate that its product is bioequivalent to the innovator's brand product—i.e., that the generic product has the same active ingredient, dosage form, strength, and purity. This greatly reduces the time and expense associated with bringing a generic product to market.

Most importantly, the Hatch-Waxman Act provides incentives to generic companies who are willing to challenge patent rights listed by the innovator in the Orange Book and purportedly covering the innovator's products. An ANDA must contain a certification regarding each patent listed in the Orange Book covering a product (referenced by an NDA).

One of four certifications must be made:

- (1) Paragraph I certification—certifying that patent information has not been filed in connection with an NDA. The FDA may immediately approve an ANDA making this certification.
- (2) Paragraph II certification—certifying that a patent covering an NDA has expired. The FDA may immediately approve an ANDA containing this certification.
- (3) Paragraph III certification—certifying that ANDA approval is sought only after a listed patent expires. The FDA may approve the ANDA only after such patent expiration.
- (4) Paragraph IV certification—certifying that a listed patent is either invalid or will not be infringed by the generic drug for which the ANDA (applicant) seeks approval.

“Paragraph IV certifications” result in a balance of statutory incentives that fuel Hatch-Waxman Act patent litigations, including (a) a 180-day exclusivity right for the first generic entrant, and (b) a 30-month automatic stay for the NDA filer. The 180-day exclusivity right provides a powerful incentive for generic manufacturers to submit Paragraph IV certifications and thereby assume the obligation to challenge patents listed in the Orange Book in federal patent litigation. The first generic company to enter the market will capture a significant amount of market share and will profit enormously during this period of exclusivity.

Likewise, the 30-month automatic stay provides a powerful incentive for NDA filers to institute patent litigation against generic manufacturers since they are assured that pending ANDA applications will not be approved for 30 months, thereby avoiding the loss of market share and profits associated with generic competition. These two incentives operate in the context of the Hatch-Waxman Act as described below.

As part of the Paragraph IV certification process, an ANDA filer must provide the patent holder and the NDA filer (usually but not always the same company) a detailed statement of the factual and legal bases, known as an FLB, for the assertion that one or more Orange Book patents are invalid, non-infringed, or unenforceable. Once the ANDA filer has provided the FLB, a patent holder can obtain a 30-month “automatic stay” in approval by the FDA of the ANDA filer's proposed generic product by filing suit within 45 days.

If suit is not filed within 45 days, the FDA can approve the ANDA as soon as other regulatory requirements are fulfilled.

If the patent holder files suit within 45 days, FDA approval of the ANDA product is stayed until the earliest of (1) the date the patent expires, (2) a federal district court determination of noninfringement, patent invalidity, or patent unenforceability, or (e) 30 months after a patent holder is notified of the Paragraph IV certification (including the FLB).

Most Hatch-Waxman cases take longer than 30 months to litigate. When the 30-month automatic stay expires, the NDA filer can further extend its exclusivity and block generic competition by asking the court to preliminarily enjoin the generic company from entering the market and/or by seeking an agreement with the generic company to stay off the market during the course of the litigation.

After the 30-month automatic stay expires, the generic company may elect to engage in an “at risk” launch of its generic product (assuming the FDA approves and the innovator is unable to convince a district court to extend the stay by granting a preliminary injunction). A generic launch is described as “at risk” in such circumstances because if the generic company ultimately loses the litigation and the patent is found to be valid and infringed, the generic company can be liable to the innovator for substantial damages, including lost profits resulting from price erosion and loss of market share.

The first generic company (or companies) to file a Paragraph IV certification enjoys a 180-day exclusivity right. Two or more generic companies may share in this 180-day exclusivity right if they are both “first to file”—i.e., if they filed on the same day, at least one day before any other generic competitors file Paragraph IV certifications.

Once an ANDA filer (or more than one ANDA filer) receives this 180-day exclusivity right, the FDA is forbidden from approving any other ANDA for the same drug product until six months after (a) the ANDA filer (or filers) with the exclusivity right first markets its product, or (b) a district court declares the patent at issue invalid or not infringed, whichever is sooner. One important consequence of this rule is that if a first filer has not triggered its exclusivity period because it resolved its litigation with the NDA filer by agreeing not to enter the market for several years, the NDA filer could foreclose entry by later filers, even if they clearly did not infringe its patents, simply by not filing an infringement suit.

In 2003, Congress revised the Hatch-Waxman Act in its Medicare Prescription Drug, Improvement and Modernization Act. The purpose of the amendments was to address perceived abuses of the Hatch-Waxman Act by innovator and generic companies by (a) limiting patent holders to a single 30-month stay for each product, (b) establishing forfeiture events resulting in loss of 180-day marketing exclusivity for ANDA applicants, and (c) requiring parties to provide notice of settlement agreements to the antitrust enforcement agencies.

The centerpiece of the 2003 legislation was the single 30-month stay provision designed to avoid “evergreening” abuse of the system by innovators who would periodically add new patents to the Orange Book in order to become entitled to additional 30-month stays. Under the original Hatch-Waxman Act, an innovator firm could wait until a generic filed an ANDA and provided a Paragraph IV certification and then list additional patents in the Orange Book. If the generic then filed a sec-

ond Paragraph IV certification concerning the newly listed orange book patents, the innovator could sue a second time and receive another 30-month stay.<sup>3</sup>

The 2003 changes addressed this issue by limiting the stays to patents submitted to the FDA before submission of the ANDA.<sup>4</sup> This eliminated most but not all multiple 30-month stays.<sup>5</sup>

The 2003 modifications were also designed to eliminate abuse of the 180-day exclusivity period by “first-to-file” generics against later filing generic competitors. The 2003 legislation created various “use it or lose it” forfeiture events. A generic first-to-file loses its 180-day exclusivity by:

- (a) failing to market its drug within 75 days of FDA approval;
- (b) failing to market its drug within 75 days of a final judicial decision (generally by the Federal Circuit) or consent decree finding that the patent is invalid or not infringed;
- (c) withdrawing its ANDA;
- (d) failing to obtain tentative FDA approval within 30 months of filing of the ANDA;
- (e) witnessing the expiration of the patents entitling the applicant to exclusivity; and/or
- (f) entering into a settlement agreement with an innovator found to violate the antitrust laws.<sup>6</sup>

These changes reduced the possibility that a first-to-file generic could enter into settlement agreements with the innovator that result in a complete bottleneck for many years against generic competition. Before the 2003 amendments, an innovator who successfully negotiated a settlement agreement with a first ANDA filing generic wherein the first ANDA filing generic agreed to refrain from entering the market could indefinitely forestall generic entry by not suing subsequent ANDA filers. The 2003 amendments were designed to eliminate such bottlenecks to generic competition.<sup>7</sup>

<sup>3</sup> Federal Trade Commission, “Generic Drug Entry Prior to Patent Expiration: An FTC Study,” at 5, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (“Generic Drug Study”).

<sup>4</sup> 21 U.S.C. § 355(j)(5)(B)(iii)

<sup>5</sup> Multiple 30-month stays are still theoretically possible. For example, a generic could file Paragraph III and Paragraph IV certifications on different patents and then, before submission of the ANDA, change the Paragraph III designation to Paragraph IV. See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, “Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,” at 8-9 (October 2004), <http://www/fda.gov/cder/guidance/6174dft.pdf>. But for the most part, the 2003 amendments eliminated multiple 30-month stays in all but a very few cases.

<sup>6</sup> 21 U.S.C. § 355(j)(5)(D)(i).

<sup>7</sup> In 2007, the Federal Circuit also eliminated such bottlenecks, at least in part, by making it easier for generic ANDA filers to file declaratory judgment actions against brand companies for the purpose of “triggering” exclusivity belonging to first to file ANDA holders. *Teva Pharmaceuticals USA Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330,1344, 82 USPQ2d 1225 (Fed. Cir. 2007) (73 PTCJ 674, 4/6/07) (holding that the court had subject matter jurisdiction to entertain the declaratory judgment action even though the innovator declined to so, because there was a real and immediate case or controversy). The increased availability of declaratory judgment actions may be a more important development than the

Third, recognizing that settlement agreements between innovator and first ANDA filing generics may to some extent undermine the objective of the Hatch-Waxman Act to encourage increased competition from generic products, the 2003 amendments require innovator and generic companies to file agreements to settle Hatch-Waxman cases with the FTC and DOJ within 10 days of the agreement, allowing these antitrust regulatory agencies at least 30 days to object to the settlement.<sup>8</sup> As the Senate Judiciary Committee explained, the amendments were designed to “put an end to the exploitation” by which brand firms “abused the Hatch-Waxman law” by “agreeing with smaller rivals to delay or limit competition.”<sup>9</sup>

### III. Economic Realities of Hatch-Waxman Litigation

From an economic perspective, the 180-day exclusivity right seems to provide a powerful incentive for generic manufacturers to prepare and file Paragraph IV certifications and thereby trigger Hatch-Waxman patent litigation. The first generic company to enter the market will likely capture at least 50 percent of market share during this 180-day exclusivity period while keeping prices at levels that assure a high level of profitability. For a blockbuster drug with U.S. sales of a billion dollars or more, the payoff for a successful generic litigant can be substantial—literally hundreds of millions of dollars.

Given the enormous potential payday for the successful generic litigant, the investment in legal fees and litigation costs that such a litigant must make may, on the surface, seem minor. There is a general consensus that a typical Hatch-Waxman litigation requires an investment by the generic company of around \$3 million to \$20 million to cover legal fees and costs (depending on the complexity of the case, the length of time it takes to litigate the case, and the number of issues that are being litigated).

Moreover, it is generally understood that generic litigants receive favorable outcomes (in court or through settlement) in approximately 50 percent of Hatch-Waxman cases.

However, to some extent this oversimplifies the situation. This macroeconomic reasoning fails to account for changes in the economic and legal landscape which make the legal investment and level of risk required to participate in Hatch-Waxman litigation far more significant than one might think. While theoretically there is still an enormous potential payday for generic manufacturers who file Paragraph IV certifications, in actuality, several factors often cause the ultimate payoff to be lower than expected.

Ten years ago, there were many Hatch-Waxman cases involving a single first-to-file generic litigant. Today, however, there are often three or more generic litigants, in cases involving blockbuster drugs, who qualify as having first-to-file status.

This author was recently lead counsel for a generic company in a case involving 14 generic defendants.

2003 amendments in avoiding bottlenecks to generic competition.

<sup>8</sup> Medicare Prescription Drug, Improvement and Modernization Act of 2003, §§ 1112, 1113, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>9</sup> S. Rep. No. 106-167, at 4 (2002).

When there are three or more first-to-file generics in a case, the theoretical enormous payday must be divided among the first-to-file generics, reducing significantly the upside potential from the litigation.

Additionally, the pipeline of blockbuster drugs (drugs with annual U.S. sales of \$1 billion or more) seems to have diminished. In many drug classes, a single blockbuster drug has been replaced by a series of “me too” drugs, each of which promises slightly different or better medical outcomes than the original blockbuster.

For example, omeprazole (brand name Prilosec) was originally a block buster anti-ulcer drug in a class known as “proton pump inhibitors,” but soon there was a series of “me too” proton pump inhibitors, not one of which (with one possible exception) could be deemed a blockbuster—i.e., rabeprazole (brand name Aciphex), pantaprazole (brand name Protonix), lansoprazole (brand name Prevacid), esomeprazole (brand name Nexium)—primarily as a result of fabulous marketing, Nexium retains blockbuster status.

While sales of these “me too” drugs have been robust, each of them is effective in treating the same indications, and they have to some extent cannibalized the market for proton pump inhibitors. Since there is significant competition between patented “innovator” drugs in the “proton pump inhibitor” class, and since none of these drugs other than omeprazole was a true blockbuster, the potential upside for generics who file Paragraph IV certifications to challenge the “me too” drugs is diminished. Further, a generic form of omeprazole is already available in the over-the-counter market.

This pattern has repeated itself for numerous classes of drugs. Today, while there continues to be substantial innovation by pharmaceutical manufacturers, the new drugs approved by the FDA often serve “niche” markets or are “me too” drugs in classes for which there is already substantial generic and/or brand competition, and, thus, these new drugs have less potential to achieve blockbuster status.

The cost of conducting Hatch-Waxman litigation has risen substantially as well. There are several reasons for this.

First, local patent rules have been enacted in many jurisdictions which require the parties to exchange their substantive contentions at early stages of the litigation. Furthermore, in some district courts in which a high volume of Hatch-Waxman cases are heard, the courts now prohibit parties from modifying contentions that they submit at an early stage of the case without showing good cause for why they could not have submitted the modified contentions at the time that contentions were originally exchanged.<sup>10</sup> The requirement of early exchanges of contentions has dramatically front-loaded the costs of conducting Hatch-Waxman litigations. Before these changes to local practice, generic companies often did not invest much time and resources in preparing their Paragraph IV certifications and FLBs—as long

<sup>10</sup> See, e.g., Local New Jersey Civ. Rule 9.3—Local Patent Rules at <http://www.njd.uscourts.gov/rules/BarOrd9.3.pdf>. New Jersey is the principal place of business for a large number of innovator and generic pharmaceutical companies and the District of New Jersey has very high number of Hatch-Waxman patent cases compared with most other districts. The district judges in New Jersey enacted these local rules despite substantial objections by members of the local patent litigation community, particularly those who represent generic litigants.

as their initial position as articulated in their Paragraph IV certifications was not frivolous and would avoid sanctions if challenged, they would move forward with the case, and use the discovery process to illuminate and sharpen their defenses and counterclaims. In many districts, generic litigants can no longer safely proceed in this way. Substantially more resources must be expended early in the game so that the need to modify the initial contentions can be kept to a minimum.

Moreover, whereas originally most Hatch-Waxman cases focused on the issue of infringement, it has become increasingly necessary to litigate more complex and time-consuming issues of invalidity and inequitable conduct. For example, Teva Pharmaceuticals, one of the most active generic participants in Hatch-Waxman litigations, reports that in 1999 only 18 percent of its Paragraph IV litigations were focused primarily on invalidity issues and 82 percent of those cases were focused on issues of non-infringement.

By contrast, in 2005, those percentages “literally flipped,” with invalidity cases accounting for 86 percent of the total and noninfringement cases accounting for 14 percent. Invalidity cases clearly are more difficult and expensive to win than are noninfringement cases.<sup>11</sup>

Further, in cases in which it is necessary to challenge the validity of the patent and/or assert that the patent was procured by inequitable conduct, electronic discovery from the innovator may be crucial to success. But the cost of electronic discovery is substantial.

The need to deal with potentially millions of e-mail messages and other electronic documents greatly complicates these cases and increases the time required to litigate them.

Additionally, court dockets are increasingly crowded, and district court judges and magistrate judges have less time to devote to supervising Hatch-Waxman cases. Because so much is at stake, counsel for litigants in Hatch-Waxman cases are often very aggressive and combative.

Judges have frequently criticized the patent litigation bar for its aggressive and, at times, uncivilized approach to litigation, including most significantly its lack of cooperation in discovery and pre-trial preparation activities. The lack of active supervision by district or magistrate judges results in increased cost and delay.

Even more significantly, in many districts, judges discourage filing of summary judgment motions in patent cases. For example, the District of Delaware forbids the filing of summary judgment motions in patent cases without advance approval of the district court.

This author has been told on numerous occasions by district court judges that they ordinarily view summary judgment motions to be a waste of time in patent cases. While there may be many cases in which summary judgment motions can expedite early resolution of the case on a cost-effective basis, in actual practice an increasing percentage of patent cases cannot be resolved on summary judgment and must proceed to trial.

Perhaps most significantly of all, there is an increasing disparity of resources available to generic companies and innovators for use in litigating Hatch-Waxman

<sup>11</sup> See testimony of Theodore C. Whitehouse on behalf of Teva Pharmaceuticals USA Inc. Concerning H.R. 1706 before the Subcommittee on Commerce, Trade and Consumer Protection of the Committee on Energy and Commerce of the U.S. House of Representatives (March 31, 2009).

cases. Over time, innovators have developed rosters of high-priced expert witnesses.

Innovators also usually deploy large and sophisticated teams of lawyers, resulting in a David and Goliath situation in which the lawyers for the generic litigants are at a distinct disadvantage. This increasing disparity in available resources has placed generic litigants at a significant disadvantage in Hatch Waxman cases, and in many instances has inhibited generic companies from entering into the fray.

In light of these new economic realities, settlements of Hatch-Waxman cases have become far more common than a decade ago. While settlements involving “reverse payments” to generic filers as rewards for staying off the market remain relatively rare,<sup>12</sup> increasingly sophisticated settlements have been crafted by innovator and generic litigants that preserve much of the value of market exclusivity for the innovator while still allowing the generic to benefit from the 180-day first-to-file market exclusivity. As such settlements have become increasingly common, and as the costs and risks associated with conducting Hatch-Waxman litigation have increased, fewer and fewer generics have been willing to devote sufficient resources to “go the distance”—i.e., take Hatch-Waxman cases through trial and appeal.

Unfortunately, the trends discussed above—more settlements, fewer blockbuster products, an increasing disparity of resources, and higher litigation costs—seem to be having a chilling effect on Hatch-Waxman litigants that is dramatically inhibiting the primary Hatch-Waxman objective of earlier access by the consuming public to generic competitors of branded pharmaceutical products.

Yet despite all of this, from an economic perspective, there remains an enormous economic upside for a generic litigant who “goes the distance” and prevails in a Hatch-Waxman case.<sup>13</sup> Something needs to be done to achieve a more level playing field between innovators and generic manufacturers so that more generic manufacturers will undertake the risks and burdens associated with litigating Hatch-Waxman cases through trial and appeal.

#### **IV. Risk Sharing Alternatives—The Role of Venture Capital in Supporting Hatch-Waxman Act Generic Litigants**

The trends described above, together with deteriorating economic conditions, have made some senior ex-

ecutives and in-house counsel for generic pharmaceutical companies reluctant to invest significant portions of their budgets in Hatch-Waxman cases. While some of the big players such as Teva Pharmaceuticals have continued to aggressively pursue these cases, there has been a noticeable decline in the willingness of mid-sized and smaller generic companies to invest in these cases—even where the upside potential remains solid. In many cases, generic companies will “dip their toe in the water” by filing Paragraph IV certifications, but then drop out of the litigation at an early stage if the economic upside will require substantial investment and/or will be divided among several other first-to-file litigants.

Hatch-Waxman cases often take more than three years or longer to litigate or settle, and the investment required for any individual case may seem very high, from a short term perspective, particularly because there is no guaranty of any return on the investment.

Meanwhile, law firms that handle these cases for generic companies find themselves under increasing pressure from their clients to reduce litigation costs—even in solid cases in which the upside potential remains strong. From the perspective of in-house counsel, the legal fees required for Hatch-Waxman cases can be “budget busters”—and quite often the bills from outside counsel turn out to be much higher than originally contemplated.

Even generic companies that make a solid commitment to pursue Hatch-Waxman cases often ask their outside counsel to cut back on resources devoted to the case, leading outside counsel to litigate fewer issues, seek less discovery, and retain less expensive expert witnesses. While generic companies acknowledge the long-term potential payoff, the increasing pressure for short-term profitability has profoundly reduced the financial resources that many generic companies are willing to invest in these cases.

Nevertheless, the basic economics underlying Hatch-Waxman cases remain unchanged. There remains an enormous upside for a first-to-file generic company which prevails in a Hatch-Waxman case. This is true even for products that do not achieve blockbuster status, and even in cases that take three years or more to litigate.

From a long-term perspective, investment in Hatch-Waxman cases should pay off big time—even if a generic company is unsuccessful in a single case, the chances are very high that the generic company will prevail in, or favorably settle, around 50 percent of these cases. From a purely economic perspective, investors who fund Hatch-Waxman cases are likely to reap a substantial long-term return on their investments.

The problem is that during the three or more years that it takes to litigate a typical Hatch-Waxman case, management of a generic company is likely to become increasingly nervous about the amount of funds invested into the case. The theoretical payoff at the end may be wonderful, but the short term drain on a company’s cash resources may seem painful, particularly because funds are expended without a guarantee of success.

Thus, there is a need to creatively restructure the manner in which generic companies fund their participation in Hatch-Waxman cases.

This seems to be a classic scenario where investment of venture capital might be welcome by generic compa-

<sup>12</sup> “Reverse payment” settlements attract a high level of antitrust scrutiny from regulators. Congress is presently considering legislation that would ban or substantially limit the circumstances in which reverse payment settlements would be permitted.

<sup>13</sup> Even in the case of a product that does not achieve blockbuster status (i.e., sales of \$1 billion per year or more), there still is an enormous potential upside for a Hatch-Waxman litigant. For example, a product that achieves \$300 million in U.S. sales per year will result in sales during the 180-day exclusivity period for the first generic entrant of at least \$75 million (based on the conservative assumption that the generic drug captures only 50 percent of the market; in practice the generic entrant usually captures more). An investment of \$10-15 million in legal fees in a situation like this can pay off in a big way, generating profits of \$50 million or more for the first generic entrant.

nies and, in view of the 50 percent track record of success for generic litigants, extraordinarily attractive to investors. A venture capital firm could develop a fund which would be devoted to investing in Hatch-Waxman cases.

A venture capital fund could invest in a single case or work with a single generic company, but a more likely scenario would be that a venture capital fund would invest in a portfolio of several Hatch-Waxman cases, litigated by several generic companies. The venture capital fund would hire its own legal experts to evaluate the strengths and weakness of proposed Hatch-Waxman cases, chose a portfolio of cases, and then fund part or all of the costs of litigating the case.

While the generic company would have to sacrifice a significant portion of the upside return on litigating a Hatch-Waxman case, the short-term costs and risks associated with participating in the case would be significantly reduced. Further, from the perspective of the generic company, venture capital funding would likely level the playing field between the innovator and the generic litigants, increasing the likelihood of success.

Venture capital participation would be particularly useful and productive in cases in which several generic companies file Paragraph IV certifications and thus, would likely have to divide the upside potential from 180-day exclusivity. Where several generic companies file Paragraph IV certifications, one might think that it would make sense for them to cooperate together in litigating the case, including designating lead counsel and sharing attorneys fees, expert fees, and other expenses, and if successful, sharing the upside from a generic launch.

Unfortunately, however, this author's experience in such cases is that individual generic companies have been very reluctant to participate in such arrangements, mostly because they fear losing control of the litigation to one of their competitors. This results in wasteful duplication in expenses.

However, investment by a venture capital fund in such a litigation would change the dynamics in the negotiations among the generic competitors and would increase the chances that the generic competitors would cooperate with each other in controlling litigation costs and sharing the upside economic benefits. Indeed, control or influence over such litigation by venture capital investors (or outside counsel selected by them) might be the perfect solution to the dilemma faced by generic companies when they find that three or more competitors timely filed Paragraph IV certifications on the same product.

Of course, there would be difficult issues to be negotiated between venture capital investors and the generic company. In some cases, management of the venture capital fund might assume control of the litigation, selecting outside counsel, guiding case strategy with their outside counsel, and making decisions on whether to

and on what terms to settle the case. In other instances, venture capital investors might play a far more passive role, allowing the generic company to control all major decisions in the litigation, including selection of counsel and settlement strategy. There would be no one-size-fits-all solution to these issues, but the advantages of a partnership between venture capital investors and generic Hatch-Waxman litigants is clear.

Most importantly, however, investment by venture capital funds in Hatch-Waxman cases would level the playing field, assuring that generic litigants have adequate resources to battle the giant innovator. The venture capital investment would diminish the short-term drain on a generic company's litigation budget.

This, in turn, would reduce the pressure on outside litigation counsel to cut corners in litigating the case. In the final analysis, the level playing field created by the participation of venture capital investors would restore the balance between innovator and generic litigants that Congress initially envisioned when it enacted the Hatch-Waxman Act. In turn, this would achieve the congressional objective of expediting the availability to consumers of low cost generic drugs while at the same time maintaining adequate incentives for innovator firms to develop and market new pharmaceutical products.

## CONCLUSION

The Hatch-Waxman Act continues to provide powerful economic incentives for generic companies to challenge patents of innovators. Battle and budget weary generic companies who have become less likely to take advantage of these economic incentives in the current economic climate may be receptive to finding alternative ways to fund Hatch-Waxman litigations.

Meanwhile, the substantial upside benefits may be quite attractive to venture capital and private equity investors. By spreading the litigation costs and risks among venture capital and private equity investors, in partnership with generic companies, there may be new and compelling opportunities to take advantage of the enormous potential upside benefits in Hatch-Waxman litigation.

At the same time, participation by venture capital and private equity investors would level the playing field between innovator and generic litigants. It seems inevitable that over the next year, more generic companies and venture capital investors will take advantage of this opportunity.

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*Ross's suggestion that generic litigants might rely on venture capital to fund their Hatch-Waxman litigation reflects the theories explored in an earlier article by BNA author, Ralph Lindeman, titled, "Third-Party Investors Seen as New Source of Funding for Major Commercial Lawsuits" (79 PTCJ 566, 3/12/10).*