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The Impact of a Brand Generic Launch on the Recovery of Patent Damages

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In the continuing battle between brand name drug companies and generic competitors, certain brand companies have begun launching, either directly or by license, "authorized" or "brand" generic drug products when a generic drug is to be introduced on the market by a competitor. The launch of a brand generic has both positive and negative potential consequences for the brand company. On the one hand, the launch of the brand generic significantly reduces the profitability of the launch by the first generic competitor, who otherwise is often entitled to a six-month window of exclusivity before other generics can enter the market. In addition, the launch of its own generic allows the brand company to increase sales, albeit potentially at the expense of significant profits on its branded product.

On the other hand, if the brand company also has patent claims against the generics, its launch of a brand generic might generate additional costs because any damages it might be entitled to recover could be substantially less than it might have recovered had it refrained from launching the brand generic in the first place. Because the brand generic would be a noninfringing alternative to the generic product, lost profits damages could be wholly or partially unavailable and the brand company would have to rely on a lower measure of damages than lost profits. For example, the alternative reasonable royalties measure of damages could provide for a substantially lower award than a lost profits measure would provide. In addition, the profits on a brand generic sale would ordinarily be substantially lower than on the sale of a branded product. Accordingly, the launch of a brand generic might suggest that the brand company lacks confidence in either the merits of its patent claims or its ability to collect the full measure of damages from generic companies. Alternatively, it could suggest that the brand company is at least partially motivated by other factors, such as reducing the incentives of generic companies to challenge brand company patents.

The Hatch-Waxman Framework

Before marketing a new drug in the United States, the federal Food, Drug and Cosmetics Act (FDCA) requires a drug company to submit a new drug application (NDA) to the Food and Drug Administration (FDA), demonstrating that the drug is safe and efficacious for its proposed use.[1] Once approved by FDA, new drugs are generally referred to as "brand name" drugs because they are marketed under a trademark for the drug product rather than the chemical name for the active ingredient in the drug product. Along with the technical studies and other data submitted to FDA, brand companies are also required to provide FDA with the patent number and expiration date of any patent claiming the drug product or method of using such drug product.[2] Upon approving the drug, FDA lists this patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly referred to as the "Orange Book."

In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA, aiming to increase the number of generic drugs on the market by providing a streamlined process for manufacturers to obtain approval for generic drugs. In particular, manufacturers of generic drugs are allowed to file an abbreviated new drug application (ANDA), relying on the safety and efficacy data of the brand name drug and simply demonstrating that the proposed generic product is bioequivalent to the approved drug.[3] By, among other things, relieving generic manufacturers from having to undertake the significant cost of producing their own safety and efficacy data, the Hatch-Waxman Amendments helped to foster the incredible growth in the generic drug industry over the last 20 years.

A generic drug company seeking FDA approval for a generic version of a brand name drug must file, in addition to technical data, a certification with respect to any patent claiming the generic product or a method of using such product. These certifications include: (1) that the brand company has not filed patent information; (2) that the patent has expired; (3) that the patent will expire on a particular date (and until such time the generic company is not seeking to market its generic product); or (4) that the patent is invalid or would not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted.[4] This final certification is commonly

referred to as a "Paragraph IV certification." With respect to a method-of-use patent, the generic company alternatively might file a statement that such patent does not claim a use for which it is seeking approval.[5]

To encourage patent challenges, Congress provided that the first ANDA applicant to file an ANDA with a Paragraph IV certification (First Filer) is entitled to a 180-day period in which it is the only ANDA applicant allowed to market a generic version of the brand name product.[6] Regarding products for which Paragraph IV certifications were filed prior to December 8, 2003, the 180-day exclusivity period begins to run on the earlier of: (1) the date of the first commercial marketing by the First Filer; or (2) the date of a decision by a court finding that the patent that is the subject of the Paragraph IV certification is invalid or not infringed.[7] Under significant changes made to the Hatch-Waxman Amendments by the 2003 Medicare Modernization Act,[8] the 180-day exclusivity period relating to products for which the first Paragraph IV certification was filed after December 8, 2003, is triggered only by the first commercial marketing by the First Filer.[9] The exclusivity period is, however, now subject to numerous forfeiture events, including the failure to commence marketing within 75 days of a favorable court decision.[10]

Brand Generics

The 180-day exclusivity period awarded to the First Filer is extremely valuable to manufacturers of generic drugs. The courts have repeatedly recognized the importance of the incentive structure set forth in the generic exclusivity provisions of the FDCA.[11] In fact, most of the profits from a generic drug are generated in the first six months of sales, corresponding to the exclusivity period.[12] Thus, the First Filer is rewarded with a first-mover advantage in the form of market share and contracts that can benefit it for many years. As summarized in a recent *Wall Street Journal* article:

> When two generics hit the market at the same time, companies have to jostle for market share, which often causes prices to fall. The first generic to market typically only discounts 20% to 30% off the branded price, but another entrant could push that to 40% to 50% off.[13]

Shortly after the expiration of the exclusivity window, half a dozen or more generic competitors might enter the market, causing prices on the generic drug to fall by 80 percent or more.

A brand company might launch an unbranded, or generic, version of its brand product either by licensing a third party or by selling the product itself, typically through a subsidiary. In either case, the authorized generic product is usually launched when market entry by the first generic competitor is imminent or has occurred. Critically, the authorized generic is marketed and sold during the 180-day exclusivity period, and, as a result, the First Filer might see its profit during the exclusivity period cut in half. GlaxoSmithKline, Johnson & Johnson, Pfizer, Bristol-Myers Squibb, and Procter & Gamble are among the companies that have launched brand generics.[14]

The reasons behind the launch of a brand generic have been hotly debated. Some brand companies have claimed that the practice allows them to maintain sales that would otherwise inevitably decline in the face of generic entry. These companies have further claimed that launching during the exclusivity period enables them to obtain a form of first-mover advantage against subsequent generic entrants, which translates into increased profits for years to come. Nevertheless, generic companies dispute these claims, pointing out that brand companies often lose substantially *more* profits from lost sales of branded products than they make from the sale of brand generic profits, particularly where the generic company lacks the capacity or wherewithal to supply the entire generic demand. They claim that brand companies launch brand generics solely to reduce the value of the exclusivity period to First Filers, which has the consequence of making it less worthwhile for generic companies to challenge Orange Book patents. Commentators appear to be in agreement with the generics' assessment; variously referring to the brand companies' practice of launching an authorized generic as nothing more than a "patent protection method"[15] or "a new tactic to ding generics."[16]

Not surprisingly, the sale of brand generics during the exclusivity period has been subject to a variety of legal challenges, including FDA petitions and court challenges.[17] For example, both generic companies and public interest groups have challenged the marketing of brand generics under antitrust and unfair competition laws. These parties have alleged that brand companies monopolize or attempt to monopolize the relevant market in violation of Section 2 of the Sherman Act and state unfair competition laws by substantially reducing the incentive to challenge patents. In addition, some parties have alleged that the launch of a brand generic violates various state competition laws by deceiving the public into believing that they are purchasing a drug that is not identical to the brand drug and by price discriminating between people who purchase the brand labeled drug and people who purchase the nearly identical, unlabeled-brand generic drug.[18]

In addition to these court challenges, both Mylan Pharmaceuticals Inc. and Teva Pharmaceuticals USA, Inc., two of the largest generic companies, have submitted citizen petitions to FDA asking that it prohibit the marketing and distribution of brand generics until after the expiration of the 180-day exclusivity period.[19] These generics have argued, among other things, that the practice

violates the incentive structure created by the Hatch-Waxman Amendments to encourage prompt generic drug entry. So far, these arguments have been unsuccessful FDA denied both Mylan's and Teva's petitions, responding that, unless any related manufacturing changes pose safety or efficacy concerns, the FDCA does not "prohibit an ANDA or NDA holder's use of alternative marketing practices for its own approved new drug."[20] FDA also noted a separate approval was not required as a general matter for third-party distribution of an approved drug. Teva and Mylan have filed separate suits to challenge FDA's denial of theft citizen petitions.[21]

Regardless of the legal merits of these challenges, many generic companies have argued that the practice of launching brand generics undermines the Hatch-Waxman Amendments and that congressional action is required. However, having recently passed the Medicare Modernization Act, it is doubtful that Congress will take up again soon the Hatch-Waxman Amendments.[22] Thus, the practice of launching authorized generics during the 180-day exclusivity period likely will remain a key brand company strategy for some time to come.[23]

Patent Damages

As discussed above, a brand company's decision to launch a brand generic is complex and the reasons for doing so are a matter of debate. This decision becomes even more complex, however, when the brand company has commenced patent litigation or has potential claims against the First Filer and other generic companies.[24] In this situation, the launch of a brand generic could significantly reduce any damages award by limiting lost profits damages wholly or in part, thereby forcing the brand company to rely, at least in part, on reasonable royalty damages. The brand company might also be forced to accept a lost profits award that is based on the lower profitability of a brand generic sale. Thus, although there are many relevant considerations, the launch of a brand generic could suggest that the brand company is not confident that it will either prevail in its patent infringement litigation or it will be able to recover the full amount of lost profits damages from the generic company.

A brief review of the pertinent areas of patent damages law helps explain the point. On a finding of infringement, the patent owner is entitled to recover "any foreseeable lost profits the patent owner can prove"[25] or, alternatively, a reasonable royalty.[26] As the Federal Circuit recently explained in *Ericsson, Inc. v. Harris Corp*:

> To recover lost profits, a patent owner must prove a causal relation between the infringement and its loss of profits. More specifically, the patentee must show a reasonable probability that "but for" the infringing activity, the patentee would have made the infringer's sales. To show "but for" causation, the patentee must reconstruct the market to determine what profits the patentee would have made had the market developed absent the infringing product. Such market reconstruction must be supported by sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture.[27]

The Federal Circuit has approved the *Panduit*[28] test as one permissible means[29] of inferring a reasonable probability of causation.[30] Under this test, the patentee is required to prove "(1) a demand for the patented product, (2) the marketing and manufacturing capability to exploit demand, (3) an absence of acceptable noninfringing substitutes, and (4) the amount of profit the patentee would have made."[31]

As a supplement to the *Panduit* test, the Federal Circuit has approved the so-called two-supplier test.[32] Under the two-supplier test, a patentee must show "1) the relevant market contains only two suppliers, 2) its own manufacturing and marketing capability to make the sales that were diverted to the infringer, and 3) the amount of profit it would have made from these diverted sales."[33] Although certain Federal Circuit decisions refer to the two-supplier test as being distinct from the *Panduit* test, in effect it merely collapses the first two *Panduit* factors into one factor.

Of importance is that the presence of acceptable noninfringing substitutes may preclude lost profits damages altogether or at least limit their availability.[34] Indeed, the Federal Circuit regularly precludes lost profit damages on a finding of acceptable substitutes.[35]

In certain circumstances where there are more than two suppliers on the market, however, the Federal Circuit has approved using a market share approach to meet the second *Panduit* factor, allowing the patent owner to collect lost profits based on a percentage of the infringing sales, even when there are acceptable substitutes. In the *State Industries* case, the Federal Circuit explained that "[i]n the two-supplier market, it is reasonable to assume, provided the patent owner has the manufacturing and marketing capabilities, that it would have made the infringer's sales. In these instances, the *Panduit* test is usually straightforward and dispositive."[36] However, if there are multiple competitors, and the patentee shows an established market share and, at the same time, meets the three other *Panduit* factors, an award of lost profits based on market share may be proper.[37] Under this approach, a patentee recovers lost profits on the percentage of infringing sales equal to its market share.[38]

Courts have cautioned, however, that the market share approach should be used only where the patentee has presented "sound economic proof of the nature of the

market."[39] In particular, the market share approach "assumes that the patent owner and the infringer compete in the same market."[40] Thus, it is not appropriate to apply the market share approach when the patentee's product and the infringing product do not directly compete, such as when their prices are so dramatically different that consumers do not view the two products as substitutes.[41]

For the portion of the infringer's sales for which the patentee is unable to demonstrate "but for" causation in order to collect lost profit damages, the patentee is entitled to receive a reasonable royalty. [42] "The royalty may be based upon an established royalty, if there is one, or if not, upon the supposed result of hypothetical negotiations between the plaintiff and defendant."[43] The hypothetical negotiation takes place at a time before the infringement began and "necessarily involves some approximation of the market as it would have hypothetically developed absent infringement."[44] The hypothetical negotiation is sometimes conceptualized as "arm's length negotiations between a willing licensor and a willing licensee."[45]

To determine the amount of a reasonable royalty, the court should look to the comprehensive list of relevant evidentiary facts set out in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*[46] The so-called Georgia-Pacific factors include, among others:

- royalties paid by the licensee for comparable patents;
- the licensor's licensing and marketing policy;
- commercial relationship between the licensor and licensee;
- the duration of the patent and the term of the license;
- the profitability of the patented product;
- advantages over alternative devices; and
- the amount that a licensor and a licensee would have agreed upon if both had been reasonably and voluntarily trying to reach an agreement.[47]

The Federal Circuit has eschewed an undisciplined weighing of these factors in favor of a more rational analysis incorporating these factors, which should leave the hypothetical licensee with a reasonable profit based on the value that the patented invention contributes to the product being sold.[48]

Except in highly unusual situations that are not likely to be found in brand/generic pharmaceutical cases, lost profit damages will typically far exceed the amount that might be recovered under a reasonable royalty approach.

How Launching a Brand Generic Could Significantly Reduce Patent Damages

If a generic company chooses to go to market before the patent infringement issues are resolved, the brand company may potentially be entitled to enormous patent damages in the form of lost profits. By the time generic entry occurs, profit margins on brand sales typically range from 80 percent to 90 percent. Moreover, annual sales for major drug products can range in the billions of dollars. As a result of generic substitution requirements and the vast difference in price for the generic versus the brand drug, the first generic entrant is typically able to gain a substantial market share in the first six months of sales.[49] The ability to quickly capture a large percentage of the market, coupled with what is typically lucrative brand sales prior to the generic's entry, means that a generic could be liable for significant damages if the generic's launch comes before any patent disputes are finally resolved. Because of this risk, the Federal Trade Commission found in its 2002 study that most potential first generic entrants typically wait until at least a district court decision of invalidity or noninfringement regarding the listed patent before entering the market.[50]

As discussed more fully below, however, if the brand company launches a brand generic when the generic market forms, its ability to collect the maximum amount of lost profit damages from the infringer may be significantly reduced. Specifically, the measure of damages the brand company will be entitled to collect will turn on whether the brand company launches its brand generic through (1) a license to a third party or (2) through direct sales or sales by an affiliated company. In either case, the brand company will likely argue that it should still be entitled to the full measure of lost profits on the brand product.

Licensing

In the case of a third-party license, the brand company has introduced an acceptable noninfringing substitute into the marketplace. The brand company will not be able to dispute that the brand generic, which is identical to the brand product and bioequivalent to the generic product, is an acceptable substitute. Rather than exploiting its patent through its own sales of patented products, the brand company has made a choice to exploit its patent through licensing. As such, unlike the case where the substitute is sold by an unlicensed company, the courts would likely limit the brand company to damages based on reasonable royalties.[51]

If the brand company grants the third party an exclusive license to market the authorized generic, the exclusive licensee may join as a plaintiff in any suit and recover its lost profits against an unlicensed generic entrant.[52] Because the brand generic will be selling at a much lower price than the brand product and because the exclusive licensee will be paying some sort of royalty to the brand company (and/or purchasing its supply from the brand company), any profits lost by the licensee will be significantly lower than the profits lost by the brand company. Accordingly, even if the exclusive licensee recovers lost profits against any generic entrant, the corresponding damages will be considerably lower than

they would if the brand company had not granted a license in the first place.

The brand company might nonetheless attempt to recover some measure of its own lost profits based on the market share theory—that is, it would argue that a portion of the generic company's sales came at the expense of brand product sales. The courts, however, are not likely to be very receptive to this argument. The vast majority of generic sales likely come at the expense of sales made by the brand generic company. As discussed above, the Federal Circuit has been reluctant to apply the market share approach in circumstances where the patentee's product and the infringing product are not directly substitutable, such as when they are offered at different price ranges to different segments of the market. Although the generic product is bioequivalent to the brand product, it is sold at a much lower price and marketed in a much different manner. Patients who forego the generic product are highly likely to choose the similarly priced and marketed brand generic rather than the brand product. In the antitrust context, one court recently determined that generic drugs form a separate market from brand drug products in light of the differences in price and distribution chains, along with consumer substitution decisions.[53]

In addition, the residual market share of the brand product is typically very low, often in the 10 percent range. At such low levels, the Federal Circuit could rule out the award of lost profits damages altogether.

The reasonable royalty per unit of sates is likely to be substantially less than the amount of profits made on each brand sale. The amount paid by the authorized generic licensee to the brand plaintiff will provide an effective ceiling on the amount recoverable by the brand company. In addition, the generic defendant will have a number of arguments, based on the *Georgia-Pacific* factors, that the reasonable royalty should be substantially lower. For example, the defendant will argue that the reasonable royalty should exclude payments that are effectively being made by the authorized generic for anything other than the patent license, such as product supply or marketing support.

Direct or Affiliate Sales

If the brand company sells the brand generic itself or through an affiliate, it would be able to argue that it is losing brand generic sales to the generic company and should be entitled to lost profits on those sales. Lost profits on affiliate sales, however, would likely not be recoverable in the (unlikely) event that the affiliate is operating under a nonexclusive rather than an exclusive license.[54]

In the case of an exclusive license, the profits lost on sales of brand generics would typically be substantially less than the profits lost on sales of the brand product. As discussed above, in order to compete in the generic market, the brand generic may sell at a price that is 50 percent or less of the brand price.[55] Obviously, this significantly reduced price will result in a drastically reduced lost profits calculation.

The Brand Argument

A counterargument to the foregoing analysis is that but for the generic launch, the brand company would not have launched a brand generic and there would have been no acceptable, noninfringing substitute. The brand company would further argue that the relevant measure of damages is the amount of "profits the patentee would have made *had the market developed absent the infringing product*."[56] Absent the generic launch, the argument would go, the brand company would not have launched the brand generic and, under the circumstances, would just be mitigating its damages.

This issue will be debated in the courts. The generics will likely argue that a brand company's decision to launch a brand generic is a substantial intervening event that is under its control. Having adopted the business strategy of launching a brand generic, the generics will assert that the brand company cannot have it both ways and recover full damages. In other words, the allegedly infringing sales would no longer be the proximate cause of the loss of brand company sales. Moreover, it is unclear whether the brand generic launch would, in fact, minimize short-term profit loss. The recovery of full damages would appear to be inappropriate if there is an issue as to whether the brand generic launch is motivated by a desire to reduce the incentive of generic companies to challenge patents.

Conclusion

Many reasons have been advanced for the launch of brand generics. Some brand companies have claimed that brand generics prevent the otherwise inevitable erosion of sales in the face of generic entry, and give them long-term first-mover advantages over later-entering generic companies. Some generic companies have claimed that the launch of a brand generic actually reduces overall brand company profits, at least in the short run; and for this reason is no more than an attempt by the brand companies to reduce the value of the generic's exclusivity period, which may have the effect of deterring patent challenges.

When the brand company has potential patent claims against generic entrants, the launch of a brand generic may further reduce overall profits by limiting the damages awards that are available to the brand company. In such circumstances, the launch of a brand generic could suggest that the brand company is not confident about its ability to prevail on its patent claims or its ability to recover the full damages award from the generics. On the other hand, the erosion of brand profits that will result from the marketing of a brand generic certainly supports the argument of some

generic companies that the launch of a brand generic has more to do with decreasing the incentives of generic companies to challenge brand company patents than it has to do with maximizing profits on the product-at-issue.

Endnotes

1. 21 U.S.C. § 355(a), (b).

2. 21 U.S.C. § 355(b)(1).

3. 21 U.S.C. § 355(a), (j).

4. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)(A).

5. 21 U.S.C. § 355(j)(2)(A)(viii).

6. 21 U.S.C. § 355(J)(5)(B)(iv).

7. *Id*. (effective prior to December 8, 2003).

8. 2003 Medicare Prescription Drug, Improvement and Modernization Act, Pub L. 108-173, 117 Stat. 2066 (2003).

9. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

10. 21 U.S.C. § 355(j)(5)(D).

11. *See, e.g*., Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1298 (11th Cir. 2003); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 n.11 (D.C. Cir. 1998).

12. *Unconventional Medicine; Pharmaceuticals*, ECONOMIST, July 31, 2004.

13. L. Abboud, *Diminutive Alpharma Takes a Risky Slap at Drug Titan Pfizer*, WALL ST. J., Oct. 11, 2004 (hereinafter, Abboud, *Diminutive*). In addition, in its 1998 study of the pharmaceutical industry, the Congressional Budget Office found that the average price of generic drugs continues to drop as additional generic products enter the market. *See* CBO Study: How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry at 33 (July 1998), *available at* www.cbo.gov/ftpdoc.cfm?index=655&type=1.

14. L. Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004 (hereinafter, Abboud, *New Tactic*); *FDA Upholds Authorized Generics, Lawsuits Likely to Follow,* GENERIC LINE, July 28, 2004; N. Balakrishnan, *Why Pharma is Good Prescription*, BUS. LINE, Aug. 1, 2004.

15. Simon King, *Barr's FY2004 Sales Leap 45% Year-on-Year*, WORLD MARKETS ANALYSIS, Aug. 6, 2004.

16. Abboud, *New Tactic*, *supra* note 14.

17. In addition, those taking the generics' side in the authorized generics battle have argued that the Centers for Medicare & Medicaid Services (CMS) should use the authorized generic price when determining the "best price" for a branded product in calculating reimbursements. *GPhA Seeks Change on Medicaid 'Best Price' for 'Authorized' Generics,* PINK SHEET (Oct. 4, 2004); *'Authorized' Generics will be Subject to 'Best Price' Calculations—CMS*, PINK SHEET (Apr. 11, 2005) (indicating that CMS is leaning towards adopting the generics' position). If CMS were to formally adopt this policy, brand companies may think twice about launching an authorized generic in the face of losing millions of dollars in Medicaid reimbursements from the sale of the branded products.

18. Two actions have been filed in California state court challenging the authorized generic practice, Mylan Pharmaceuticals, Inc. v. The Proctor & Gamble Co., Dkt. No. CGC-04-429860, and Congress of California Seniors v. Glaxosmithkline P.L.C., Dkt. No. CGC-04-429456. In addition, Mylan has filed a similar suit against both the brand company and the FDA, which is pending in the United States District Court for the Northern District of West Virginia. Mylan Pharmaceuticals, Inc. v. FDA, Dkt. No. 04CV242 (stayed pending a resolution of Teva Pharms., Indus., Ltd. v. Crawford, Dkt. No. 05-5044 (D.C. Cir)).

19. *Mylan Pharmaceuticals Inc.,* "Prohibit the marketing and distribution of Authorized Generics until the expiration of the first generic applicant's exclusivity period," docket # 2004P-0075; *Teva Pharmaceuticals USA, Inc*., "Prevent Pfizer Inc. from marketing a generic version of Accupril until after the expiration of Teva's 180-day exclusivity period," docket # 2004P-0261.

20. Letter to Stuart A. Williams, Chief Legal Officer, Mylan Pharmaceuticals Inc. and James N. Czaban, White & McAuliffe LLP, Re Docket Nos. 2004P-0075/CPI & 2004P-026l/CP1, at 6, *available at* www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0261-pdn000l.pdf.

21. On December 23, 2004, summary judgment was entered by the court against Teva, finding that the plain language of the statute supported FDA's position. Teva Pharms., Indus., Ltd. v. FDA, 355 F. Supp. 2d 111 (D.D.C.), *appeal pending*, Teva Pharms., Indus., Ltd. v. Crawford, Dkt. No. 05-5044 (D.C. Cir.) (oral argument held May 9, 2005). *See also* Mylan Pharmaceuticals, Inc. v. FDA, Dkt. No. 04CV242 (N.D.W.V.) (stayed pending a resolution of *Teva Pharms*., Dkt. No. 05-5044 (D.C. Cir.)).

22. On May 9, 2005, three Senators did send a letter to FTC requesting that it study the short-term and long-term competitive impact of brand generics. *Three Senators Ask FTC to Study 'Authorized' Generic Drugs*, INSIDE CMS (May 19, 2005).

23. *Report Indicates Authorized Generics are Here to Stay*, FDANEWS DRUG DAILY BULL., Mar. 16, 2005 ("At this point, it doesn't look like a legislative solution is likely and the Federal Trade Commission doesn't seem to perceive a problem either. We believe [under these circumstances] that the number of authorized generic agreements will continue to grow and that the practice will become the norm.") (citing a Prudential Equity Group research report) (brackets in original).

24. Although patent infringement claims have often been resolved through the Hatch-Waxman litigation procedure prior to the first generic product entering the market, brand companies are likely to increasingly delay filing patent infringement suits against pending ANDA holders as a result of the elimination of multiple 30-month stays under the 2003 Medicare Modernization Act. As a result, generic companies will more often find themselves launching a product while under the cloud of uncertain legal risk.

25. Grain Processing Corp. v. American Maize-Products Co., 185 F.3d 1341, 1349 (Fed. Cir. 1999) (citation and quotation marks omitted).

26. 35 U.S.C. § 284.

27. 352 F.3d 1369, 1377 (Fed. Cir. 2003) (citations omitted).

28. *Id*. at 1140 (citing Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978)).

29. State Industries Inc. v. Mor-Flo Industries, Inc., 883 F.2d 1573, 1577 (Fed. Cir. 1989).

30. Kaufman Co. v. Lantech, Inc., 926 F.2d 1136, 1141-42 (Fed. C 1991) ("[W]hen the patentee establishes the reasonableness of the inference, the patentee has sustained the burden of proving his entitlement to lost profits for all infringing sales. The onus is then placed on the infringer to show that it is unreasonable to infer that some or all of the infringing sales probably caused the patentee to suffer the loss of profits.")

31. *Id*. at 1140-1141.

32. Micro Chem. v. Lextron, Inc., 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Kaufman*, 926 F.2d at 1141 ("When the patentee and the infringer are the only suppliers present in the market, it is reasonable to infer that the infringement probably caused the loss of profits.")

33. *Micro Chem.*, 318 F.3d at 1124 (citing Lam, Inc. v. Johns-Manville Corp., 718 F.2d 1056 (Fed. Cir. 1983)).

34. Grain Processing Corp. v. American Maize-Products Co., 185 F.3d 1341, 1353 (Fed. Cir. 1999). *See also* R. HARMON, PATENTS AND THE FEDERAL CIRCUIT, 6th ed., § 15.1(b), at 821 (2003).

35. *See, e.g., Grain Processing*, 185 F.3d at 1343 (affirming the district court's ruling denying any lost profits damages for patent infringement because a noninfringing substitute was available, instead awarding a reasonable royalty); Comair Rotron, Inc. v. Nippon Densan Corp., 49 F.3d 1535, 1538 (Fed. Cir. 1995) (because there were noninfringing substitute fans in the market place, the damages awarded for the infringement would be based on a reasonable royalty, not on lost profits); Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 926 F.2d 1161, 1167 (Fed. Cir. 1991); Datascope Corp. v. SMEC, Inc., 879 F.2d 820, 827 (Fed. Cir. 1989); Gyromat Corp. v. Champion Spark Plug Co., 735 F.2d 549, 551 (Fed. Cir.1984).

36. *State Industries*, 883 F.2d at 1578 (citation omitted).

37. *Id*. at 1578-80; BIC Leisure Prods. v. Windsurfing Int'l, 1 F.3d 1214, 1219 (Fed. Cir. 1993) ("[A] patent owner may satisfy the second Panduit element by substituting proof of its market share for proof of the absence of acceptable substitutes. This market share approach allows a patentee to recover lost profits, despite the presence of acceptable, noninfringing substitutes, because it nevertheless can prove with reasonable probability sales it would have made 'but for' the infringement.") (*citing State Industries*, 883 F.2d at 1578).

38. Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc., 246 F.3d 1336, 1356 (Fed. Cir. 2001); *State Industries*, 883 F.2d at 1578.

39. *Crystal Semiconductor*, 246 F.3d at 1355 (quoting *Grain Processing*, 185 F.3d at 1350).

40. *BIC Leisure*, 1 F.3d at 1219.

41. *Id*. at l218-l 9 (market share approach inapplicable where the products sold by the patentee and the infringer sold at significantly different prices through different channels); Bose Corp. v. JBL, Inc., 112 F. Supp. 2d 138, 161-63 (D. Mass. 2000) (declining to apply market share approach where products did not sufficiently compete at the same price levels).

42. *Crystal Semiconductor*, 246 F.3d at 1354.

43. Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1554 (Fed. Cir.1995).

44. Riles v. Shell Exploration & Prod. Co., 298 F.3d 1302, 1311 (Fed. Cir. 2002).

45. Institut Pasteur v. Cambridge Biotech Corp. (*In re* Cambridge Biotech Corp.), 186 F.3d 1356, 1377 (Fed. Cir. 1999) (internal citation and quotation marks omitted).

46. 318 F. Supp. 1116 (S.D.N.Y. 1970); *see also* Dow Chem. Co. v. Mee Indus., 341 F.3d 1370, 1382 (Fed. Cir. 2003) ("[T]he district court should consider the so-called Georgia-Pacific factors in detail, and award such reasonable royalties as the record evidence will support.").

47. *Georgia-Pacific*, 318 F. Supp. at 1120.

48. *See, e.g*., Hughes Tool Co. v. Dresser Industries, Inc., 816 F.2d 1549, 1558 (Fed. Cir. 1987) ("[A] reasonable royalty must be fixed so as to leave the infringer a reasonable profit."); *see also* 7 CHISUM ON PATENTS § 20.03[3][b][iv] ("The theory is that a willing licensor and willing licensee in a hypothetical negotiation would have set a royalty that would divide between them the predicted economic benefits to be realized by the licensor's adoption of the product or process."). However, the court will consider the expectations of the parties at the time when determining the royalty. Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1081 (Fed. Cir. 1983). If the hypothetical licensee's expectation is not realized, the reasonable royalty is still determined by that expectation, even if the royalty is greater than realized net profits. *State Industries*, 883 F.2d at 1580.

49. Collagenex Pharms., Inc v. Thompson, 2003 U.S. Dist. LEXIS 12523, at *32-33, Dkt. No. 03-1405 (RMC) (D.D.C. 2003) (discussing generic drug market penetration rates).

50. FTC Study: Generic Drug Entry Prior to Patent Expiration at viii (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

51. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1222-23 (Fed. Cir. 1995) (patentee who granted a non-exclusive license to an infringer in order to settle a separate lawsuit was precluded from recovering lost profits for every sale made by another infringer in a later lawsuit after the date of the license); Novo Indus. L.P. v. Micro Molds Corp., 239 F. Supp. 2d 1282, 1286-87 (S.D. Fla. 2002) (same), *rev'd on other grounds*, 350 F.3d 1348 (Fed. Cir. 2003).

52. *Rite-Hite*, 56 F.3d at 1552; Invacare Corp. v. Ortho-Kinetics, Inc., 1998 U.S. App. LEXIS 15202, at *7, Dkt. No. 98-1074 (Fed. Cir. July 6, 1998) (unpublished); *see also* 8 CHISUM ON PATENTS § 21.03[2][c] ("reservation of the patent owner of the right to personally make, use or sell the claimed invention does not preclude exclusivity [and the resulting standing to bring suit]").

53. Geneva Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496-99 (2d Cir. 2004).

54. Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310-11 (Fed. Cir. 2004).

55. Abboud, *Diminutive, supra*, note 13.

56. *Grain Processing*, 185 F.3d at 1350 (emphasis added).

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