UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs, v. APOTEX CORP., APOTEX, INC. and TORPHARM, INC., Defendants.	01-CIV-9351 (DLC)
IN RE OMEPRAZOLE PATENT LITIGATION	M-21-81 (DLC) MDL Docket No. 1291

DEFENDANTS' PRETRIAL MEMORANDUM OF LAW

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I. INTRODUCTION

Pursuant to a stipulation between the parties, the damages available to Plaintiffs in this case are defined by the reasonable royalty that Apotex would have paid AstraZeneca ("Astra") for use of the technology embodied in U.S. Patent Nos. 4,786,505 and 4,853,230 (the '505 and '230 Patents, respectively). The parties further agree that determination of a reasonable royalty should be made by this Court. The Court's upcoming determination must address three areas of law.

One: the Court must determine the proper legal framework for determining an appropriate royalty amount. Below in Section II, Apotex shows that the proper analysis considers all of the *Georgia-Pacific* factors and focuses on the incremental commercial value of the patented technology. This focus recognizes that a potential licensor would not be able to extract, and a licensee would not be willing to pay, a royalty that is greater than the economic value of the technology compared to non-infringing alternatives. Put more simply, if a patented technology does not allow a licensee to derive additional profits when compared to alternatives, either from increased sales or lower costs, then a reasonable royalty will be low.

Here, the evidence shows that the patented technology did *not* result in increased sales or lower costs for Apotex. Indeed, the evidence shows that non-infringing alternative technologies, such as those seen in the KUDCo, Mylan, and Lek formulations, were very comparable to the claimed technology. Apotex's accidental use of the claimed coating system did not result in an economic benefit, which is determinative of a low royalty of not more than 7 percent.

Plaintiffs' expert, on the other hand, asserts that Apotex would pay over half of its profits to Astra for a patented technology that did not help Apotex make any sales compared to the alternatives. In Section III below, Apotex details the three foundational errors in Dr. Meyer's approach that lead to the unreasonably high royalty she asserts.

Two: the Court must determine the proper time period for allocation of the reasonable royalty. Here, the patents expired in April, 2003. Section IV below details the well-established rule that it is illegal to obtain a patent royalty after patent expiry. It also shows that pediatric exclusivity is *not* an extension of the patent term, but rather a rule relating only to FDA approvals. As such, it is improper to assess a royalty on Apotex's sales made after patent expiry during the pediatric exclusivity period.

Three: the Court must determine the proper parties who have standing to seek damages. Here, a number of the plaintiff entities are neither the patentee nor an exclusive licensee of the patents-in-suit. Section V below details how these parties do not have the requisite interest in the patents to seek damages in this action. Because patent damages are ultimately meant to compensate *patentees* for the infringement, a determination of which plaintiffs suffered a legally recognizable patent injury is appropriate.

II. APOTEX CORRECTLY APPLIES THE GEORGIA-PACIFIC FACTORS TO DETERMINE A ROYALTY OF NO MORE THAN 7 PERCENT.

A. The Proper Methodology for Determining a Reasonable Royalty

Patent damages are generally governed by 35 U.S.C. § 284, which provides that upon a showing of infringement, a patentee is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." *See Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). The parties have stipulated that a "reasonable royalty" is the appropriate measure of damages in this case. The burden of proving entitlement to damages falls on the patent holder. *Transclean v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002).

A common approach to determining the reasonable royalty rate is to consider the outcome of a hypothetical negotiation between a willing licensor and a willing licensee. *See*

Lucent Techs., 580 F.3d at 1324–25; *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1078 (Fed. Cir. 1983) (stating that a reasonable royalty "may be based . . . upon a hypothetical royalty resulting from arm's length negotiations between a willing licensor and a willing licensee.").

Reasonable royalty damages are not intended to punish the infringer or deter infringement. *See Lucent Techs.*, 580 F.3d at 1324 (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1223 (Fed. Cir. 1995)). Awarding an inflated royalty rate, beyond what a willing licensee would have paid for use of a patent, risks awarding patentees more than the economic value of their inventions and creates problems of overcompensation and market distortion. *See* FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 20–21 (2011) [hereinafter FTC REPORT], *available at* http://www.ftc.gov/os/2011/03/110307patentreport.pdf. Importantly, a reasonable royalty should not be inflated by unproven lost profits that the patentee may have suffered. *See Panduit Corp. v. Stalin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1157–58 (6th Cir. 1978); FTC REPORT at 20.

To prevent problems of overcompensation, a patentee's asserted royalty rate must be justified by "sound economic and factual predicates." *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002); *see also* FTC REPORT at 20. Courts often consider the factors set forth by this Court in *Georgia–Pacific Corp. v. United States Plywood Corp.* when determining the proper reasonable royalty rate:

1) the royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty;

2) the rates paid by the licensee for the use of other patents comparable to the patent in suit;

3) the nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold;

4) the licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly;

5) the commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter;

6) the effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales;

7) the duration of the patent and the term of the license;

8) the established profitability of the product made under the patent; its commercial success; and its current popularity;

9) the utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results;

10) the nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention;

11) the extent to which the infringer has made use of the invention; and any evidence probative of the value of that use;

12) the portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions;

13) the portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer;

14) the opinion testimony of qualified experts; and

15) the amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would

> have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

318 F. Supp. 1116, 1120 (S.D.N.Y.1970). As illustrated by several of the *Georgia-Pacific* factors, the commercial value of the patented technology and the royalty charged for the same or similar patents are important considerations in determining a reasonable royalty rate. *See, e.g.*, *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995); *Studiengesellschaft Kohle, M.b.H. v. Dart Indus., Inc.*, 862 F.2d 1564, 1568 (Fed. Cir. 1988); *see also Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317-18 (Fed. Cir. 2011) ("In particular, [*Georgia-Pacific*] factors 1 and 2 . . . remain valid and important factors in determining a reasonable royalty rate.").

1. The Commercial Value of the Patented Technology

The nature and value of the patented invention is a significant factor in determining the appropriate reasonable royalty rate. *See, e.g.*, *Rite-Hite*, 56 F.3d at 1554; *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1333 (Fed. Cir. 2009). The commercial contribution of the patented technology would be expected, as an economic matter, to dictate the maximum amount a willing licensee would pay to use it. The importance of this consideration is reflected in several of the *Georgia-Pacific* factors: Factor 9 (the utility and advantages of the patent property over the old modes or devices); Factor 10 (the nature of the patented invention; the character of the commercial embodiment; and the benefits to those who have used the invention); Factor 11 (the extent to which the infringer has made use of the invention; and any evidence probative of the value of that use); and Factor 13 (the portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements). *Georgia-Pacific*, 318 F. Supp. at 1120.

Where a patent only covers one aspect or element of a product, calculating a royalty on the entire product carries a "*considerable risk that the patentee will be improperly compensated for non-infringing components* of that product." *See LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67 (Fed. Cir. 2012) (emphasis added); *see also Riles,* 298 F.3d at 1312. Thus, "the trial court must carefully tie proof of damages to the claimed invention's footprint in the market place." *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010); *Lucent Techs.*, 580 F.3d at 1339. "Any evidence unrelated to the claimed invention does not support compensation for infringement but punishes beyond the reach of the statute." *ResQNet.com*, 594 F.3d at 869.

The Federal Circuit and other courts recognize a reasonable royalty rate should reflect the contribution of the patented technology to the value of the product. For example, in *Lucent Techs.*, the Federal Circuit vacated an award of damages that was based on the value of an entire computer but did not account for the proportional value of the patented feature, stating that a proper "reasonable royalty analysis should consider whether the patented feature is an essential part of the accused product or just a small nonessential feature of the product." *Lucent Techs.*, 580 F.3d at 1333; *see also Riles,* 298 F.3d at 1312 (rejecting damages model because "it does not associate [the] proposed royalty with the value of the patented method at all, but with the unrelated cost of the [entire commercial product.]"); *Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1446 (Fed. Cir. 1990) (reversing the damages award in part because the plaintiff's patent related "to only one aspect of" the infringing product and "did not contribute appreciably to [defendant's] sales price or profit").

In analyzing the commercial benefit of the patented technology, the improvement over available alternatives in the marketplace must also be considered. As the Federal Circuit has

observed, "only by comparing the patented invention to its next-best available alternative(s) . . . can the court discern the market value of the patent owner's exclusive right, and therefore his expected profit or reward, had the infringer's activities not prevented it from taking full economic advantage of this right." *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1351 (Fed. Cir. 1999).

The economic rationale for considering the value of the patent over available alternatives is explained in the FTC Report, published in 2011. In that report, the FTC explained:

> "A manufacturer will not pay more to use patented technology than the increased profits it anticipates from using the patented invention compared to the next best alternative. If royalties exceed this economic value of the invention, manufacturers can bargain for a lower rate or choose an alternative. Because alternative technologies play a crucial role in actual licensing negotiations, they must play a commensurate role in the hypothetical negotiation that determines reasonable royalty damages."

FTC REPORT at 20–21; *see also Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 607 (D. Del. 2007) (stating that parties "would consider available, or soon to be available, alternatives" in agreeing to a royalty); *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, No. C 03-01431 SBA, 2006 WL 1646113, at *2 (N.D. Cal. June 12, 2006) (stating that alternatives are "a key part" of a damages determination under *Georgia-Pacific*); *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, No. Civ.A. B-83-10, 1989 WL 418791, at *6 (E.D. Tex. June 30, 1989) (stating that a willing licensee "would be less inclined to agree to a high royalty because of the availability of such non-infringing alternatives . . . ."). The FTC stated that "the incremental value of the patented invention over the next-best alternative establishes the maximum amount that a willing licensee would pay in a hypothetical negotiation," and recommended that "Courts should not award reasonable royalty damages higher than this amount." FTC REPORT at 21.

The importance of considering the value of the patented technology is also reflected in the "entire market rule" which prevents a patentee from using the entire value of a product as a base for royalties unless the patentee can establish that it is the patented features that drive sales of the entire product. *See LaserDynamics,* 694 F.3d 51 at 67. The entire market rule serves as a "check to ensure that the royalty damages being sought under 35 U.S.C. § 284 are in fact "reasonable" in light of the technology at issue." *Id.*

If a royalty rate is disproportionate to the patented invention's relative contribution to a product, particularly in light of the alternatives in the market, then it is not "reasonable" under 35 U.S.C. § 284. *See, e.g.*, *Lucent Techs.*, 580 F.3d at 1333; *Tomita Techs. USA, LLC v. Nintendo Co., Ltd.*, No. 11 Civ. 4256, 2013 WL 4101251, at *8 (S.D.N.Y. Aug. 14, 2013) (overturning the jury's reasonable royalty award because, *inter alia*, the patented technology was secondary to the "core functionality" of defendant's product).

2. The Royalty Charged for the Same or Similar Technology

Evidence regarding actual royalties for use of the same or similar patent is a strong indicator of the proper reasonable royalty. This consideration is reflected in the *Georgia-Pacific* Factors: (1) the royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty; (2) the rates paid by the licensee for the use of other patents comparable to the patent in suit; (3) the nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold; and (12) "portion of the profit or of the selling price that may be customary . . . ." *Georgia-Pacific*, 318 F. Supp. at 1120.

Federal Circuit precedent underscores the importance of considering the royalty rate charged in previous license agreements for the same or similar patents. *See, e.g., Laserdynamics,*

694 F.3d. at 79 ("[a]ctual licenses to the patented technology are highly probative as to what constitutes a reasonable royalty for those patent rights because such actual licenses most clearly reflect the economic value of the patented technology in the marketplace.").

B. Apotex's Damages Analysis Properly Considers All of the Relevant Factors to Determine a Royalty of Not More than 7 Percent of Net Sales.

A proper analysis of the *Georgia-Pacific* factors applied to the facts of this case yields a royalty of at most seven percent of Apotex's net sales.

1. There Is No Proven Value To The Use Of The Patented Technology Versus Alternative Technologies

The patents-in-suit are very limited in scope. They claim a specific approach to formulating omeprazole that includes: (1) omeprazole and an alkaline reactive compound ("ARC") in the core, (2) a subcoating disposed on the core that is water-soluble or that rapidly disintegrates in water; and (3) an outer enteric coating.

Importantly, the patented technology is *not* the omeprazole compound itself. The omeprazole compound and certain omeprazole formulations were disclosed in the '431 substance patent which expired prior to 2003. By November 2003—the stipulated hypothetical negotiation date—omeprazole and the formulations disclosed in the '431 patent were in the public domain. As such, the value of omeprazole and omeprazole formulations disclosed in the '431 patent are not included in the hypothetical license being negotiated here.

Also, the patented technology is *not* the only formulation technique that can be used to produce a therapeutically safe and effective omeprazole drug product. By November 2003, at least *three other non-infringing formulations* of omeprazole were available in the market - the formulations used in the KUDCo, Mylan, and Lek products. The FDA found each of these three formulations to be AB-rated generic substitutes, meaning they each had the same clinical effect and safety profile as Astra's omeprazole product, Prilosec. These other formulations

demonstrate that the know-how to manufacture a safe and effective noninfringing alternative to Prilosec was publically known.[1] Moreover, KUDCo, Mylan, and Lek were able to secure 70 percent of the generic omeprazole market without using the patented technology.[2] This demonstrates that the patented technology did not provide an advantage in the market and was unnecessary for commercial success.

Similarly, the patented technology was not the basis for any incremental economic benefit to Apotex. The patented technology did not lower Apotex's manufacturing costs compared to non-infringing alternatives.[3] Further, there is no evidence that Apotex's use of the specific patented formulation helped it to garner sales. Apotex did not market the use of the patented formulation to customers, and there is no evidence that any customer bought Apotex's product because it used the patented formulation.

In fact, the evidence shows that neither Apotex nor its customers even knew that Apotex's product employed the patented technology. Apotex took affirmative steps to avoid infringement by omitting the claimed subcoating layer. While it was ultimately shown that a microscopically thin layer must have formed *in situ*, the formation of this layer was not intended or even known.[4] There is no showing that this accidental infringement had any functional benefit or assisted Apotex in making a single sale.

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[1] In addition, the precise details of KUDCo formulation, including the ingredients and how to manufacture the final product, were available to the public several months before November 2003. Apotex's Proposed Findings of Fact and Conclusions of Law ("FOF-COL") ¶ 15 & n.19, filed concurrently herewith.

[2] *Id.* ¶ 93 & n.86; Leitzinger Aff. ¶ 8; DTX 378.

[3] FOF-COL ¶ 5 & n.8; ¶ 295; ¶ 304 & nn.433, 433; ¶ 381 & n.570.

[4] Indeed, Apotex would have preferred, in retrospect, to have omitted the ingredients causing the formation of the sub-coating, as it would have resulted in a less complex product with a simpler manufacturing process and little or no increase in raw material costs. *Id.* ¶ 304 & n.433.

The absence of any real benefit, economical or technical, from the unintentional use of the patented technology is determinative of a reasonable royalty that represents a very small portion of the infringing sales revenue. Such a reasonable royalty is also consistent with the fundamental economic notion that a willing licensee would not agree to pay more in royalties than the amount of generated revenue and/or reduced costs from use of the licensed technology, particularly in the presence of several non-infringing alternatives. *See LaserDynamics,* 694 F.3d at 77; *see also Uniloc USA*, 632 F.3d at 1318 (rejecting the 25 percent rule of thumb for royalty rates in part because it ignored the relative significance of a patent in an infringing product).

2. Astra's Own Licensing History of the Patented Technology Suggests a Royalty Rate Less than 7 Percent.

Astra's own licensing history for the patents-in-suit is highly probative of the proper reasonable royalty because "such actual licenses most clearly reflect the economic value of the patented technology in the marketplace." *LaserDynamics*, 694 F.3d at 79. Astra previously licensed the patents-in-suit to other parties for much smaller royalties than they are claiming here. For example, Astra licensed the patents to Proctor & Gamble ("P&G") allowing P&G to develop and launch a highly-competitive over-the-counter ("OTC") version of Prilosec called Prilosec OTC. The base royalty rate for this license—which granted P&G significantly more substantive rights than Apotex is negotiating for here—was [redacted] percent.[5]

[5] DTX 114, License Agreement (Nov. 20, 1997) at -235. This agreement did envision the sharing of certain development costs between AstraZeneca and P&G. These development costs were addressed through a series of milestone payments made by P&G to AstraZeneca. *Id.* § 6.1, at 233–34; DTX 104, Attachment "A," Comparison of Offers from Proctor & Gamble and from JJMCP (Mar. 18, 1997), at -612, -621. This agreement also contained royalty rates higher than the base rate of [redacted] percent if P&G achieved certain sales levels. DTX 114, License Agreement § 6.1(b)(ii)(B), at 235–36. These higher royalty rates would not have been triggered [redacted]

Under that license, P&G received rights to practice not just the patents-in-suit, but also ten additional patents and three trademarks,[6] including the valuable '431 substance patent. Without rights to the substance patent, P&G could not have made any profits in an omeprazole market because it could not even make omeprazole product itself. Accordingly, one would expect the substance patents to have represented a much larger portion of the value being transferred under this agreement than the patents-in-suit.[7] In fact, an Astra deponent, Mark Uhle, admitted that substance patents are generally "more valuable" in the commercialization of a product than the types of patents that are at issue in this matter.[8]

The P&G license provided P&G with exclusive rights to commercialize the OTC product,[9] a product that would be expected to have a significant effect on Astra's Prilosec sales. This expectation was confirmed in the real world market. By November 2003, Astra lost nearly 41 percent of Prilosec sales to Prilosec OTC alone. FOF-COL ¶ 152; Schondelmeyer Aff. ¶ 86. P&G's product also negatively impacted Nexium sales by 3 to 4 percent. FOF-COL ¶ 156 & n.184; Schondelmeyer Aff. ¶ 89. Thus, P&G's OTC product was a much greater source of competition to Astra than Apotex's generic omeprazole product, which was the fourth generic product in the market. Yet even though Astra must have realized the effect that P&G's OTC

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[6] *See* DTX 114, License Agreement at -308, -309.

[7] One of the reasons Dr. Meyer rejects the use of this agreement for purposes of evaluating a reasonable royalty is based upon the "scope of intellectual property covered." Expert Rep. of C. Meyer ("Meyer Rep.") ¶ 98 (June 5, 2013). But the presence of other intellectual property does not preclude the use of this agreement as evidence regarding an upper bound on a reasonable royalty. Certainly, the inclusion of rights to additional intellectual property would not have driven down the royalty rate negotiated by AstraZeneca and P&G.

[8] Uhle Dep. Tr. 162:24–163:24 (Mar. 15, 2012); *see also* DTX 142, THE MERCK INDEX (13th ed. 2001), at -420.

[9] *See* DTX 114, License Agreement, at -231–33. The OTC would have "FDA exclusivity" for three years. *See* DTX 047, McKesson Prilosec Rx to OTC Switch, at -030.