United States Court of Appeals for the Federal Circuit

ASTRAZENECA AB, aka ASTRA ZENICA AB, AKTIEBOLAGET HASSLE, KBI-E INC., KBI INC., ASTRAZENECA LP,
Plaintiffs-Appellees

v.

APOTEX CORP., APOTEX INC., TORPHARM INC.,
Defendants-Appellants

2014-1221

Appeal from the United States District Court for the Southern District of New York in No. 1:01-cv-09351-DLC, Senior Judge Denise Cote.

Decided: April 7, 2015

CONSTANTINE L. TRELA, JR., Sidley Austin, LLP, Chicago, IL, argued for plaintiffs-appellees. Also represented by JOHN W. TREECE, DAVID C. GIARDINA; JOSHUA EUGENE ANDERSON, Los Angeles, CA; PAUL ZEGGER, Washington, DC.

JAMES F. HURST, Winston & Strawn LLP, Chicago, IL, argued for defendants-appellants. Also represented by

STEFFEN NATHANAEL JOHNSON, EIMERIC REIG-PLESSIS, CHRISTOPHER ERNEST MILLS, Washington, DC.

Before O'MALLEY, CLEVENGER, and BRYSON, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Apotex Corp., Apotex Inc., and TorPharm Inc., (collectively, "Apotex") appeal from a final judgment entered against them by the United States District Court for the Southern District of New York. We previously affirmed the district court's decision in an earlier phase of the same litigation holding that Apotex had infringed certain patents held by AstraZeneca AB and related parties (collectively, "Astra"). *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008). In the portion of the proceeding now under review, the district court awarded damages to Astra on a reasonable royalty theory of recovery. We affirm in part, reverse in part, and remand.

I

A

The patents at issue in this case are U.S. Patent No. 4,786,505 ("the '505 patent") and U.S. Patent No. 4,853,230 ("the '230 patent"). The two patents relate to pharmaceutical formulations containing omeprazole, the active ingredient in Astra's highly successful prescription drug, Prilosec.

Omeprazole is a "proton pump inhibitor" ("PPI"). It inhibits gastric acid secretion and for that reason is effective in treating acid-related gastrointestinal disorders. However, the omeprazole molecule can be unstable in certain environments. In particular, it is susceptible to degradation in acidic and neutral media. Its stability is also affected by moisture and organic solvents.

To protect the omeprazole in a pharmaceutical dosage from gastric acid in the stomach, formulators have tried covering the omeprazole with an enteric coating. Enteric coatings, however, contain acidic compounds, which can cause the omeprazole in the drug core to decompose while the dosage is in storage, resulting in discoloration and decreasing omeprazole content in the dosage over time. To enhance the storage stability of a pharmaceutical dosage, alkaline reacting compounds ("ARCs") must be added to the drug core. The addition of ARCs, however, can compromise a conventional enteric coating. Ordinarily, an enteric coating allows for some diffusion of water from gastric juices into the drug core. But when water enters the drug core, it dissolves parts of the core and produces an alkaline solution near the enteric coating. The alkaline solution in turn can cause the enteric coating to dissolve.

The inventors of the '505 and '230 patents solved that problem by adding a water-soluble, inert subcoating that separates the drug core, and thus the alkaline material, from the enteric coating. The resulting formulation, consisting of an active ingredient core with ARCs, a water-soluble subcoating, and an enteric coating, provides a dosage form of omeprazole that has both good storage stability and sufficient gastric acid resistance to prevent the active ingredient from degrading in the stomach. Once the dosage reaches the small intestine, where the drug can be effectively absorbed, the solubility of the subcoating allows for rapid release of the omeprazole in the drug core.

Astra held patents on both the active ingredient, omeprazole, and the formulation for delivering it. The active ingredient patents expired in 2001, but several patents covering the formulation, including the patents at issue in this case, did not expire until April 20, 2007.

Starting in 1997, anticipating the expiration of the active ingredient patents, eight generic drug manufacturers, including Apotex, filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"), seeking permission to manufacture and sell omeprazole. Those applications were accompanied by what are known as "Paragraph IV certifications," in which the generic drug manufacturers asserted that their formulations did not infringe the '505 and '230 patents and that the patents were invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Astra subsequently sued all eight generic drug companies in the same district court. The lawsuits were divided into two groups, each involving four defendants.

In the "first wave" litigation, the district court found that the '505 and '230 patents were not invalid and that three of the first wave defendants—all except Kremers Urban Development Co. and Schwarz Pharma, Inc. (collectively, "KUDCo")—infringed the patents. We affirmed the district court's decision in *In re Omeprazole Patent Litig.*, 84 F. App'x 76 (Fed. Cir. 2003) ("*Omeprazole I*"), and *In re Omeprazole Patent Litig.*, 483 F.3d 1364 (Fed. Cir. 2007) ("*Omeprazole II*").

On May 31, 2007, during the "second wave" litigation, the district court issued an opinion holding that the generic version of omeprazole manufactured by Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc., (collectively, "Mylan") did not infringe the patents. The district court also held that the generic version of omeprazole manufactured by Lek Pharmaceutical and Chemical Company D.D. and Lek USA, Inc., (collectively, "Lek") did not infringe Astra's patents. The court, however, entered judgment of infringement against Apotex. We affirmed the judgment in favor of Mylan in *In re Omeprazole Patent Litig.*, 281 F. App'x 974 (Fed. Cir. 2008) ("*Omeprazole III*"). We affirmed the judgment of infringement

against Apotex in *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008) ("*Omeprazole IV*").

Apotex started selling its generic omeprazole product in November 2003, during the pendency of the second wave litigation. It continued selling its generic product until 2007, when the district court held that Apotex's formulation infringed Astra's patents. After we affirmed the district court's judgment of liability against Apotex, the district court held a bench trial to determine Astra's damages.

B

Upon a finding of infringement, the 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." 35 U.S.C. § 284. The two "alternative categories of infringement compensation" under section 284 are "the patentee's lost profits and the reasonable royalty he would have received through arms-length bargaining." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009).

The parties in this case agreed that damages were to be assessed based on a reasonable royalty theory. The district court sought to determine the reasonable royalty by analyzing the royalty that would have been reached through a hypothetical negotiation between the parties in November 2003, when Apotex began to infringe. Following the bench trial, the court held that Astra was entitled to 50 percent of Apotex's gross margin from its sales of omeprazole between 2003 and 2007.

In the course of its analysis, the court made detailed findings of fact. In summary, the court's findings were as follows:

Three generic companies launched their generic omeprazole products after the district court's first wave

opinion in 2002 and before Apotex launched its generic product. KUDCo, whose formulation had been found to be non-infringing, was first on the market, but it did not have the manufacturing capacity to supply the full needs of the market immediately, and it kept the price of its omeprazole product high. Lek and Mylan were second wave defendants, and at that time the district court had not yet ruled on Astra's infringement claims against them. Nonetheless, they made the decision to launch their products in August 2003, knowing that they were at risk of later being held to infringe. In light of the risk that they might be held to be infringing Astra's patents, Mylan and Lek did not cut their prices aggressively.

The district court found that after those generic manufacturers entered the market, the price of generic omeprazole declined, but not significantly. However, the court found that the sales of Prilosec, Astra's prescription PPI drug, declined precipitously, both before 2002, when Prilosec was being replaced by Astra's newer prescription PPI drug, Nexium, and after 2002, when the generic manufacturers entered the market. Nonetheless, Astra continued to reap substantial revenues from Prilosec, which had net sales of $865 million in 2003, and $361 million in 2004.

After surveying the relevant data, the district court concluded that the price of generic omeprazole remained "relatively and uncharacteristically high" as of November 2003, due to the fact that only KUDCo was operating "freely and without the threat of litigation hanging over it." The district court therefore concluded that if Apotex had obtained a license from Astra in November 2003, it would have had "a golden opportunity to take significant market share away from both other generic manufacturers and perhaps even branded PPIs by launching at a lower price."

The district court found that Astra had anticipated the expiration of its patent on omeprazole, and that before the omeprazole patent expired, it had introduced Nexium, which it hoped would take the place of Prilosec over time. Nexium quickly developed into a highly successful drug. In 2003, Astra's net sales of Nexium totaled $2.5 billion.

Astra's strategy was to extend the period of market dominance for Prilosec through the strategic use of its patents and to attempt to transition Prilosec patients to Nexium, which was marketed as a superior drug that would offer relief to some patients who failed on Prilosec. Astra believed that patients who remained on Prilosec were more likely to transition to Nexium than patients who switched to generic omeprazole.

At that time, the district court found, Astra was intent on seeing that Nexium remained an approved drug with a favorable reimbursement formula from third-party payers ("TPPs"), such as health insurance providers, who paid a share of patients' prescription drug costs. Astra was already effectively reducing the price of Nexium by offering rebates to the TPPs to ensure that the TPPs would continue to approve prescriptions for Nexium. In fact, between December 2002 and November 2003, the cost of Nexium therapy to the TPPs was actually lower than the cost of omeprazole therapy, both because of the rebates the TPPs received from Astra and because the price of generic omeprazole remained relatively high. Importantly, the modest decline in the price of omeprazole after Mylan and Lek entered the market in August 2003 was not sufficient to cause the TPPs to take steps to promote the use of generic omeprazole over Prilosec or Nexium.

The district court found that Astra had "every reason to expect that the launch of a fourth generic, particularly for a licensed product, would swiftly accelerate the decline in omeprazole prices" and would lead to the destruction of

the remaining Prilosec market. In addition, the district court found, Astra would have been very concerned about the effect that the entry of a fourth generic product would have on the TPPs' willingness to continue to support Prilosec and Nexium.

In fact, after Apotex entered the market in November 2003, Astra had to increase its Nexium rebates to the TPPs to cope with pricing pressures from generic omeprazole. While prices declined even with Apotex's "at risk" entry into the market, the district court found that Astra would have been concerned that with a licensed product Apotex would have felt freer to cut prices in order to gain market share. That, in turn, would have caused an even more dramatic reduction in omeprazole prices, with the accompanying threat to Prilosec and, especially, Nexium.

Previously, in an agreement reached in 1997, Astra had licensed Procter & Gamble ("P&G") to market an over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003. Because the market for over-the-counter drugs is largely separate from the market for prescription drugs, Astra viewed the introduction of Prilosec OTC as a way to continue to sell Prilosec in the event the market for prescription omeprazole were to be completely "genericized."[1] In addition, Astra believed that the availability of Prilosec OTC could also help promote Nexium because, if a patient failed on Prilosec OTC, the patient would naturally proceed to Nexium, since it was the only PPI that had been shown to be superior to Prilosec.

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[1] A market is considered "genericized" when the TPPs impose a "maximum allowable cost," which is the maximum amount they will pay for a particular prescription drug. Typically, the maximum allowable cost is based on the generic price of the drug.

The introduction of Prilosec OTC caused a reduction in the market share of both Prilosec and the generic omeprazole products. Significantly, however, the court found that the introduction of Prilosec OTC did not have any effect on omeprazole pricing, "because the systems through which prescription and OTC drugs are paid for are largely separate."

Viewing the matter from Apotex's perspective, the district court found that, as Apotex prepared to enter the market in 2003, it expected to experience roughly $581 million in sales during its first five years on the market, and that in the first year it expected to earn profits of $27 million at a profit margin of 92.5 percent. Moreover, the court found that Apotex knew that sales of its generic omeprazole would help Apotex sell its other pharmaceutical products. Accordingly, the court found that because Apotex "expected to (and did) make substantial profits from its sale of omeprazole, it would have been willing to pay a large share of those profits for the right to use [Astra's formulation] patents in 2003."

Contrary to Apotex's argument at trial, the court found that as of November 2003, it was not likely that Apotex would be able to develop a non-infringing version of an omeprazole formulation within a reasonable period of time. Nor, the court found, would Apotex have been able to copy the formulations of others. As of November 2003, only KUDCo's patented formulation had been held not to infringe Astra's patents; the formulations used by Mylan and Lek had not yet been adjudged non-infringing. Moreover, the district court found that if Apotex had tried to copy either of those formulations, it would have incurred considerable time and expense in research and

development, because of the very different technical approaches taken by Mylan and Lek.[2]

With the background of those factual findings, the district court set about to determine what royalty rate Astra and Apotex would have agreed to if they had negotiated a license to Astra's patents in November 2003. In doing so, the court employed the so-called *Georgia-Pacific* factors, the set of 15 factors drawn from the frequently cited opinion in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970).

The court concluded that the parties would have settled on a royalty rate of 50 percent of Apotex's gross margin from the sales of its omeprazole product. The court based that conclusion principally on these considerations:

First, in November 2003 Apotex expected a gross margin on sales of its omeprazole product more than twice as large as the average gross margin on other generic products that it sold in the United States. The district court found that Apotex's estimates of its profits would have been even higher if it had had a license to Astra's patents, since the litigation would have ended and Apotex would not have had to act "with the caution in pricing its generic product that is customary for 'at risk' entrants into the generic market."

Second, Apotex's prospects of finding a non-infringing omeprazole formulation were not good. Delays in entering the market and obtaining governmental approval for a new formulation, moreover, would have put Apotex at risk of being shut out of the generic market altogether. That

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[2] In addition, by 2003 Lek had already obtained a patent relating to its formulation. Mylan obtained patent protection for its formulation the following year.

risk was enhanced, the district court noted, because of the practice among pharmacies of carrying only one generic version of a drug, a practice that could have severe consequences for late entrants into the market.

Third, Astra did not license generic manufacturers of prescription omeprazole, and it would have been especially reluctant to license Apotex in 2003, because Apotex's entry would have altered the dynamics of the PPI market, damaged Astra financially, and disrupted its long-term PPI strategy. In particular, the entry of a licensed generic manufacturer would have risked the "genericization" of the prescription omeprazole market, since the entry of low-priced generic drugs could have caused the TPPs to adopt a maximum allowable cost for prescription omeprazole or otherwise to restrict patients' use of branded drugs such as Prilosec and Nexium.

Fourth, the district court examined other licenses and settlements entered into by Astra relating to omeprazole and determined that those settlements, although not a "perfect benchmark" for the outcome of a hypothetical negotiation between Astra and Apotex in November 2003, nonetheless provided support for the 50 percent royalty rate selected by the court in this case.

Based on its conclusion as to the likely effects of the hypothetical negotiation, the court entered final judgment against Apotex in the amount of $76,021,994.50 plus prejudgment interest. This appeal followed.

II

The issue before us is whether the district court committed legal or factual error in concluding that, in a hypothetical negotiation, Astra and Apotex would have agreed upon a license to Astra's patents in exchange for a royalty rate of 50 percent of Apotex's profits from the sales of its infringing omeprazole product during the period of its infringement, 2003 to 2007. The amount of

damages awarded to a patentee, when fixed by the district court, is a factual finding reviewed for clear error, while the methodology underlying the court's damages computation is reviewed for abuse of discretion. *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1345 (Fed. Cir. 2003).

A

Apotex first contends that the district court's damages award overcompensated Astra because the court "lost sight of the essential purpose of the exercise: to compensate Astra for harm actually suffered." According to Apotex, the court's analysis (1) improperly discounted evidence that by November 2003 the market for omeprazole was "well on its way to full genericization"; (2) placed undue emphasis on Astra's ability to keep Apotex temporarily off the market by refusing to grant a license; and (3) gave "short shrift to contemporaneous licensing agreements that Astra entered with other companies" for royalty rates lower than 50 percent.

With respect to the first issue, Apotex argues that it was the fourth generic manufacturer to enter the omeprazole market, and therefore its entry caused little marginal injury to Astra. Because Astra suffered "negligible harm" from Apotex's infringement, according to Apotex, the damages award granted by the district court substantially overcompensated Astra for its loss.

Apotex's argument ignores many of the detailed findings made by the district court in support of the court's determination of the reasonable royalty in this case. For example, Apotex challenges the court's finding that in November 2003, Astra would have been concerned that Apotex's licensed entry would cause the price of generic omeprazole to plummet, thereby triggering a "genericization" of the omeprazole market. Apotex points

to the fact that, in reality, it did not aggressively cut prices. The district court, however, explained that a licensed generic drug manufacturer would be able to launch at a lower price while an "at-risk" entrant, with the threat of litigation hanging over it, would be forced to set an "uncharacteristically high" price on its generic product. Based on that distinction, the district court correctly concluded that Apotex's actual pricing history sheds little light on how Apotex would have priced its omeprazole if it had obtained a license from Astra.

Moreover, Apotex's focus on what it refers to as "the harm that Astra actually suffered" is more suited to a case involving lost profits. Apotex argues, for example, that "if Apotex's entry caused Prilosec sales to implode, that would be evidence of significant harm for which Astra would be entitled to a higher royalty."

That argument would be relevant in a lost profits case. The reasonable royalty theory of damages, however, seeks to compensate the patentee not for lost sales caused by the infringement, but for its lost opportunity to obtain a reasonable royalty that the infringer would have been willing to pay if it had been barred from infringing. *Lucent Techs.*, 580 F.3d at 1325. In determining what such a reasonable royalty would be, the district court was required to assess Astra's injury not according to the number of sales Astra may have lost to Apotex, but according to what Astra could have insisted on as compensation for licensing its patents to Apotex as of the beginning of Apotex's infringement, in November 2003.[3]

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[3] Apotex's intermingling of the lost profits and the reasonable royalty methods of calculating damages is illustrated by its reliance on this court's decision in *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341 (Fed. Cir. 1999). The statement in *Grain*

As the district court explained in detail, the benefits to Apotex, and the costs to Astra, of a license to the formulation patents would have been considerable. For its part, Apotex stood to (and did) garner immense profits from selling its generic omeprazole product. The district court found that even after a 50 percent royalty payment to Astra, Apotex would be left with a profit margin of 36 percent, which was "solidly in the range of 31 to 48% margins [Apotex] typically earned on its products at the time."

For Astra, on the other hand, a license would have entailed risks to both of its highly successful branded PPIs, Prilosec and Nexium. As the district court found, Astra would reasonably have expected that Apotex's entry into the market, armed with a license, "would swiftly accelerate the decline in omeprazole prices and lead to the destruction of the remaining Prilosec market" as well as a decrease in Nexium sales or a forced increase in Nexium rebates to the TPPs. Under those circumstances, the district court was justified in concluding that a reasonable royalty rate of 50 percent would not overcompensate Astra for Apotex's infringement.

Processing that a district court must reconstruct the market "as it would have developed absent the infringing product, to determine what the patentee would have made," is directed to a lost profits analysis, not to a reasonable royalty analysis, as the portion of the district court opinion quoted by the *Grain Processing* court makes clear. *See id.* at 1350 (citing *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 979 F. Supp. 1233, 1236 (N.D. Ind. 1997)). The reasonable royalty analysis does not look to what would have happened absent the infringing product, but to what the parties would have agreed upon as a reasonable royalty on the sales made by the infringer.

Apotex's second "overcompensation" argument is that a royalty rate that depends on the obstacles that would have "ke[pt] a competitor off the market, regardless of the actual harm the patentee suffers," is not reasonable. To the extent Apotex means to say that the costs the infringer would incur to produce a non-infringing product are not relevant to the reasonable royalty for a license to sell a product covered by the patent, we disagree.

When an infringer can easily design around a patent and replace its infringing goods with non-infringing goods, the hypothetical royalty rate for the product is typically low. *See Grain Processing*, 185 F.3d at 1347; *see also Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1312 (Fed. Cir. 2002) ("The economic relationship between the patented method and non-infringing alternative methods, of necessity, would limit the hypothetical negotiation."). There is little incentive in such a situation for the infringer to take a license rather than side-step the patent with a simple change in its technology. By the same reasoning, if avoiding the patent would be difficult, expensive, and time-consuming, the amount the infringer would be willing to pay for a license is likely to be greater.

The district court found that Apotex would have faced substantial technical and practical obstacles to marketing a non-infringing generic omeprazole formulation. Based on that finding, it was proper for the court to hold that the difficulties Apotex would have encountered upon attempting to enter the omeprazole market with a non-infringing product are relevant to the royalty rate a party in Apotex's position would have been willing to pay for a license to Astra's patents.

Apotex takes issue with the district court's consideration of the FDA regulatory delay as one factor affecting the result of the hypothetical negotiation. The district court found that Apotex would have faced considerable difficulties in marketing a non-infringing product of its

own, because Apotex's proposed changes to its existing infringing formulation either had been rejected for technical reasons or were unlikely to result in a non-infringing product. In the alternative, the court found that even if Apotex could have successfully created an alternative, non-infringing formulation that would have received FDA approval, the process of development and approval would have resulted in a delay of at least two years before Apotex would have been able to market its new, non-infringing product. That two-year period, according to the district court, would have included approximately a year for the completion of the FDA approval process.

Apotex argues that the district court overcompensated Astra by considering the regulatory delay, which applies to every drug application and bears no relation to the value of Astra's patents. Significantly, however, the district court's principal finding was that as of November 2003 Apotex would have had little chance of developing and marketing a non-infringing product of its own, and the evidence at trial supports that finding. The evidence shows that none of Apotex's proposed changes to its infringing formulation were feasible. Indeed, by the end of the trial, Apotex had "largely abandoned its argument that it could have altered the infringing formulation successfully." Simply put, in November 2003 Apotex's prospect of developing its own non-infringing alternative was bleak, with or without a period of FDA delay. The district court's consideration of the regulatory delay, as an alternative ground for its conclusion that Apotex would not have been able to market a non-infringing formulation within a reasonable period of time, therefore had no effect on the court's damages calculation.

Apotex's third claim regarding Astra's alleged overcompensation is that the district court's analysis of the evidence regarding settlement and licensing negotiations with omeprazole sellers other than Apotex was funda-

mentally flawed and that the court abused its discretion in the way it assessed that evidence. We do not agree. The district court analyzed the pertinent settlement and licensing negotiations in detail and with close attention to the similarities and differences between those negotiations and the hypothetical negotiation in this case. We are satisfied that the court fairly weighed those negotiations in reaching its ultimate determination as to the reasonable royalty rate for damages purposes.

With regard to the settlement and license negotiations, Apotex focuses principally on Astra's license to P&G for the rights to sell Prilosec OTC. Although the royalty formula in that case was complex, the district court found that the royalty rate turned out to be a blended rate of approximately 20 percent of P&G's net sales, or 23 percent for the first three years of the license, counting P&G's initial payment. Apotex argues that because that rate is significantly below the 50 percent rate assessed by the district court, the district court's royalty rate was plainly too high.

As the district court explained, and as Astra underscores in its brief, the P&G license for Prilosec OTC had an economic impact on Astra very different from the impact a license to a generic manufacturer such as Apotex would have had. For reasons explained in detail by the district court, the over-the-counter drug market is largely distinct from the prescription drug market. Astra did not expect Prilosec OTC to have a significant impact on the price and sales of its prescription drug, Prilosec. The risk to Prilosec from prescription generic omeprazole, by contrast, was much greater. Moreover, Astra expected sales of Prilosec OTC to be helpful to it by promoting Nexium as a more effective drug for patients who had not obtained satisfactory results with Prilosec. As the district court summarized the situation, the P&G licensing arrangement was especially favorable to Astra because

Astra "received a handsome royalty for a product that was an essential part of its long-term PPI strategy."

Besides criticizing the district court for giving insufficient weight to the P&G license, Apotex complains that the court gave too much weight to a settlement and offer of settlement between Astra and two other generic manufacturers, Andrx Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. The court found that the amount of Astra's settlement with Teva represented 54 percent of Teva's net profits on its omeprazole sales, and that the offer of settlement by Andrx was for 70 percent of Andrx's profits on the 40mg omeprazole dosage and 50 percent of its profits on the 20mg and 10 mg dosages. Astra did not accept Andrx's offer.

Apotex contends that the fact that the Teva and Andrx transactions occurred in the midst of litigation makes them irrelevant for purposes of determining a reasonable royalty rate in this case. That contention goes too far. While the fact that a settlement or settlement offer comes in the midst of litigation may affect the relevance of the settlement or offer, there is no per se rule barring reference to settlements simply because they arise from litigation. *See ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) (noting that "the most reliable license in this record arose out of litigation," while also recognizing that in other instances, "litigation itself can skew the results of the hypothetical negotiation"); *see also In re MSTG, Inc.*, 675 F.3d 1337, 1348 (Fed. Cir. 2012).

In this case, Teva's settlement and Andrx's offer both arose only after the district court had held the patents valid and had made a finding of infringement as to both defendants. The setting in which those events took place was therefore similar to the setting of a hypothetical negotiation in which infringement and patent validity are assumed. In that context, Andrx's willingness to take a

license for between 50 and 70 percent of its profits, and Teva's agreement to settle the infringement action against it for 54 percent of its net sales, constitute persuasive evidence that a royalty rate in the neighborhood of 50 percent of net sales for a similarly situated party would be reasonable. *See Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 862 F.2d 1564, 1570-72 (Fed. Cir. 1988); John M. Skenyon et al., *Patent Damages Law and Practice* § 1:15, at 25 (2013 ed.) ("[L]icenses negotiated to settle a case after a court has established validity and infringement of the patent are very probative of reasonable royalty. Such licenses duplicate the analytical process undertaken by the court in setting reasonable royalty damages in the 'willing licensor-willing licensee' fictional negotiation.").[4]

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[4] In its reply brief, Apotex argues that Andrx's situation at the time it made its offer was not comparable to Apotex's situation in 2003 because Andrx would have been the sole generic seller of 40 mg omeprazole for 180 days and because Andrx sought to have Astra drop its claims for willful infringement, past damages, and attorney fees. While those factors distinguish the Andrx offer from a pure license for future sales, the offer nonetheless served "as a marker of the value of licensing rights," as the district court held.

As for the Teva settlement, Apotex points to evidence that the amount paid by Teva was in settlement of claims against both Teva and Impax, and that the settlement actually constituted only 39 percent of the collective profits of those two entities. That number, while lower than the 54 percent royalty rate referenced by the district court, nonetheless demonstrates that generic manufacturers attached a high premium to the right to sell generic omeprazole. Moreover, generic entrance is often a race to the market, because most pharmacies keep only one

We therefore reject Apotex's challenges to the district court's evidentiary analysis and its conclusion from that analysis that the 50 percent royalty rate constituted fair compensation to Astra under the reasonable royalty theory of damages.

B

Apotex next contends that the district court improperly based its damages calculation on the value of the omeprazole product as a whole. According to Apotex, because the active ingredient patents had expired at the time of the infringement and the active ingredient had thus become a "conventional element," the district court should have calculated damages by apportioning the relative contribution of value between the active ingredient and the "inventive element" of the patents, i.e., the subcoating.

Apotex predicates its argument on this court's cases applying the "entire market value rule." The court has held that when small elements of multi-component products are accused of infringement, a patentee may "assess damages based on the entire market value of the accused product only where the patented feature creates the basis

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generic version of a drug on hand. In light of the fact that Teva/Impax were willing to pay at least a 39 percent rate on profits to become the fifth generic to enter the market, the district court's finding that Apotex would have paid a 50 percent rate to become the fourth generic entrant is reasonable.

In a footnote, Apotex points to Astra's licensing agreements relating to PPI products other than omeprazole. Because those agreements did not involve omeprazole and contained cross-licenses and other features, the district court properly found them irrelevant to the damages determination.

for customer demand or substantially creates the value of the component parts." *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011) (internal quotation marks omitted); *see also*. *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67 (Fed. Cir. 2012).

A threshold question arose below regarding the applicability of the entire market value rule in this case. As an initial matter, the district court noted that "there is little reason to import [the entire market value] rule for multi-component products like machines into the generic pharmaceutical context." While we do not hold that the entire market value rule is per se inapplicable in the pharmaceutical context, we concur with the district court that the rule is inapplicable to the present case.

The entire market value rule is derived from Supreme Court precedent requiring that the patentee "must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and unpatented features, and such evidence must be reliable and tangible, and not conjectural or speculative." *LaserDynamics*, 694 F.3d at 67 (quoting *Garretson v. Clark*, 111 U.S. 120, 121 (1884)). We recently reiterated that principle, holding that even when the accused infringing product is "the smallest salable unit," the patentee "must do more to estimate what portion of the value of that product is attributable to the patented technology" if the accused unit is "a multi-component product containing several non-infringing features with no relation to the patented feature." *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1327 (Fed. Cir. 2014). Thus, the entire market value rule applies when the accused product consists of both a patented feature and unpatented features; the rule is designed to account for the contribution of the patented feature to the entire product.

This case does not fit the pattern in which the entire market value rule applies. Astra's formulation patents claim three key elements—the drug core, the enteric coating, and the subcoating. The combination of those elements constitutes the complete omeprazole product that is the subject of the claims. Thus, Astra's patents cover the infringing product as a whole, not a single component of a multi-component product. There is no unpatented or non-infringing feature in the product.

While the entire market value rule does not apply to this case, the damages determination nonetheless requires a related inquiry. When a patent covers the infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1233 (Fed. Cir. 2014) ("[T]he patent holder should only be compensated for the approximate incremental benefit derived from his invention.") (citing *Garretson*, 111 U.S. at 121).

Several of the factors set forth in the *Georgia-Pacific* case bear directly on this issue. *Georgia-Pacific* factors nine and ten refer to "the utility and advantages of the patent property over any old modes or devices that had been used" and "the nature of the patented invention, its character in the commercial embodiment owned and produced by the licensor, and the benefits to those who used it," respectively. Factor thirteen, which refers to the "portion of the realizable profit that should be credited to the invention," embodies the same principle. Thus, the standard *Georgia-Pacific* reasonable royalty analysis takes account of the importance of the inventive contribution in determining the royalty rate that would have emerged from the hypothetical negotiation. However, while it is important to guard against compensation for

more than the added value attributable to an invention, it is improper to assume that a conventional element cannot be rendered more valuable by its use in combination with an invention.

In practice, "all inventions are for improvements; all involve the use of earlier knowledge; all stand upon accumulated stores of the past." *Cincinnati Car Co. v. N.Y. Rapid Transit Corp.*, 66 F.2d 592, 593 (2d Cir. 1933). Yet it has long been recognized that a patent that combines "old elements" may "give[] the entire value to the combination" if the combination itself constitutes a completely new and marketable article. *Westinghouse Elec. & Mfg. Co. v. Wagner Elec. & Mfg. Co.*, 225 U.S. 604, 614 (1912) (citing *Hurlbut v. Schillinger*, 130 U.S. 456, 472 (1889)); *see also Seymour v. Osborne*, 78 U.S. 516, 542 (1870) ("Improvements in machines protected by letters patent may also be mentioned, of a much more numerous class, where all the ingredients of the invention are old, and where the invention consists entirely in a new combination of the old ingredients, whereby a new and useful result is obtained, and many of them are of great utility and value, and are just as much entitled to protection as those of any other class.").

It is not the case that the value of all conventional elements must be subtracted from the value of the patented invention as a whole when assessing damages. For a patent that combines "old elements," removing the value of all of those elements would mean that nothing would remain. In such cases, the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone.[5]

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[5] We recently made the same point in *University of Pittsburgh v. Varian Medical Systems, Inc.*, 561 F. App'x 934, 947-50 (Fed. Cir. 2014). In addressing the proper

The district court addressed, and answered, that question. The court rejected Apotex's proposition that the patented formulation constituted only a minor, incremental improvement over the active ingredient. The court found instead that the formulation "substantially create[d] the value" of the entire omeprazole product. That was because, despite the effectiveness of omeprazole in reducing the production of gastric acid, it is notoriously difficult to formulate. Omeprazole is most effective when absorbed by the small intestine, but it is highly susceptible to degradation in the acidic environment of the stomach. In order to deliver the active ingredient to the part of the human body where it can take effect, scientists had to develop a formulation that would allow the drug to pass through the stomach and be absorbed by the small intestine, while ensuring adequate shelf life in a drug that is sensitive to heat, moisture, organic solvents, and light.

After years of effort, Astra's scientists determined that a water-soluble subcoat helped solve many of these problems and allowed them to formulate a commercially viable drug. The district court found that Astra's prior formulations, which lacked a subcoat, were not commercially viable.

The district court did not clearly err in concluding that the subcoating is so important to the viability of the commercial omeprazole product that it was substantially responsible for the value of the product. A commercially viable omeprazole drug requires both storage stability

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calculation of the royalty base in a reasonable royalty determination, we declined the defendant's invitation to remove the conventional elements from the overall value of the combination apparatus; we noted that guarding against compensation for more than the added value attributable to the invention "is precisely what the *Georgia-Pacific* factors purport to do." *Id.* at 950.

and gastric acid resistance. The former may be achieved with the addition of ARCs to the drug core, and the latter with the enteric coating. Without the subcoating, however, storage stability and acid resistance are irreconcilable, because the addition of ARCs would compromise the enteric coating. By inventing a structure in which a subcoating separates the drug core, and thus the ARCs, from the enteric coating, and finding the right subcoating material, Astra was able to achieve both storage stability and acid resistance. That combination of features made it possible for drug manufacturers to commercialize omeprazole.

Astra's formulation thus created a new, commercially viable omeprazole drug. That product was previously unknown in the art and was novel in its own right. Accordingly, the district court permissibly found no reason to exclude the value of the active ingredient when calculating damages in this case.[6]

C

Taking another tack in challenging the compensation awarded to Astra for Apotex's infringing sales, Apotex argues that the value of the patented formulation must be discounted in light of the non-infringing alternative formulations in existence at the time of the infringement.

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[6] In support of its apportionment argument, Apotex relies on a license that Astra granted to Takeda Chemical Industries, Ltd. that included the '230 patent, for Takeda to practice with a different PPI ingredient and formulation. The license enabled Takeda to develop and ultimately market its own formulation. The royalty rates paid by Takeda under that license do not bear on whether the damages for infringing the omeprazole formulation patents must be apportioned between the active ingredient and the formulation.

The district court examined those alleged non-infringing alternatives and concluded that none were available to Apotex as of the beginning of Apotex's infringement in November 2003. Apotex did not have a non-infringing alternative formulation at that time, and KUDCo was the only generic market entrant found to be non-infringing. KUDCo's formulation, however, was covered by its own patents, and the district court found that Apotex had failed to explain how it could copy that formulation without infringing KUDCo's patents. Finally, the district court found that the formulations used by two other generic manufacturers, Lek and Mylan, could not have been regarded as non-infringing alternatives in November 2003, as they launched at risk in 2003 and their formulations were not found to be non-infringing until 2007.

Apotex does not challenge the finding that it had no non-infringing formulation of its own, and we agree with the district court that the Lek and Mylan formulations, which were launched at risk amid on-going litigation with Astra and were not found to be non-infringing until 2007, would not have been considered as non-infringing alternatives in November 2003. *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1222 (Fed. Cir. 1995) (an accused alternative product offered by a third party could not be considered as a non-infringing alternative before the patentee and the third party voluntarily settled their litigation); *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 824 (Fed. Cir. 1989). The issue is therefore whether the KUDCo formulation was available to Apotex in November 2003.

In the district court, Apotex did not dispute that KUDCo's formulation was covered by KUDCo's own patents. Apotex argues that it was not shown that the KUDCo formulation was unavailable at the time of the infringement because Astra did not prove that using the KUDCo formulation would have infringed the KUDCo patents. We disagree.

The patents held by KUDCo were designed to protect its formulation. From that fact, the district court could reasonably infer that the KUDCo formulation was not available to Apotex as a non-infringing alternative. Apotex's conclusory assertion that it could have used KUDCo's formulation without infringing KUDCo's patents does not suffice to overcome that inference. *See Grain Processing*, 185 F.3d at 1353. Therefore, the district court did not clearly err by refusing to discount the value of Astra's patents based on the existence of alternatives to the infringing formulation that Apotex actually used.

III

Finally, Apotex objects to the district court's decision to award damages for sales of its generic omeprazole during the "pediatric exclusivity" period of the asserted patents. Under 21 U.S.C. § 355a, the FDA is authorized to make a written request to the holder of an approved New Drug Application ("NDA") for the holder to perform pediatric studies. *See Omeprazole IV*, 536 F.3d at 1368. If the NDA holder agrees to the request and performs the pediatric studies, and if the FDA considers the results of the studies acceptable, the statute extends the period during which the FDA is barred from approving ANDAs filed by competing drug manufacturers for six months beyond the patent's expiration date. 21 U.S.C. § 355a(b)-(c); *Omeprazole IV*, 536 F.3d at 1368. That six-month extension is known as the pediatric exclusivity period.

When a generic drug manufacturer files an ANDA with a Paragraph IV certification, the patent holder may then initiate a patent infringement suit against the ANDA applicant. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 35 U.S.C. § 271(e)(2)(A). If the district court determines that the patent is both valid and infringed, the court is required to order the effective date of the ANDA approval to be a date "not earlier than" the expiration date of the

patent. 35 U.S.C. § 271(e)(4)(A). If the FDA has not approved the ANDA at the time of the district court's decision, the FDA may not approve the ANDA (and the generic may not sell its drug) until after the patent expires. *Omeprazole IV*, 536 F.3d at 1367. If the FDA has already approved the ANDA, the district court's order alters the effective date of that approval. *Id.* at 1367-68.

Astra obtained the right to a six-month pediatric exclusivity before the district court's liability decision. Thus, although the asserted patents expired on April 20, 2007, the district court ordered that the effective date of Apotex's ANDA approval be set six months later, on October 20, 2007. *See Omeprazole IV*, 536 F.3d at 1376 (affirming the district court's order resetting Apotex's ANDA effective date). On June 28, 2007, pursuant to the district court's order, the FDA revoked its earlier approval of Apotex's ANDA, forcing Apotex to cease distribution of its generic drug until the FDA re-approved its ANDA on October 22, 2007. *See Apotex Inc. v. U.S. Food & Drug Admin.*, 508 F. Supp. 2d 78, 80 (D.D.C. 2007). Apotex made some sales between April 20, 2007, and June 28, 2007, i.e., during the pediatric exclusivity period and before the FDA's revocation order. The district court allowed Astra to recover a reasonable royalty on those sales, even though the sales had occurred after the expiration date of the patents.

The district court reasoned that the effect of the pediatric exclusivity period, like that of the patent term, is to bar the sale of a generic product until after the expiration of the exclusivity period. The court further noted that the FDA allows a party holding statutory exclusivity rights to waive those rights in favor of another drug manufacturer. *See Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 2 (D.D.C. 1997). The district court therefore concluded that if Apotex had obtained a license from Astra in 2003, the license would have included the right to sell omeprazole both during the original term of the asserted patents

and during Astra's pediatric exclusivity period. In exchange, Astra would have received both a royalty payment for sales made during the original patent term and a payment for its waiver of its pediatric exclusivity rights for sales made during the pediatric exclusivity period.

Apotex contends that the district court's award of damages for the period after the expiration of Astra's patents runs counter to the Supreme Court's decision in *Brulotte v. Thys Co.*, 379 U.S. 29 (1964). In that case, the Court held that a royalty agreement that projects beyond the expiration date of the patent is unlawful per se. *Id.* at 32.

We do not agree with Apotex that *Brulotte* controls the outcome in this case. In *Brulotte*, the Supreme Court barred a patentee from using a licensing agreement to extract royalties after the patent had expired because the Court deemed such a practice to be a wrongful leverage of the patent monopoly, "analogous to an effort to enlarge [that] monopoly" beyond its lawful duration. *Brulotte*, 379 U.S. at 32-33. The Court's analysis in *Brulotte*, however, does not apply to a situation such as this one, in which Congress, by creating the pediatric exclusivity period, explicitly authorized additional market exclusivity to be granted to the patent owner beyond the life of the patent. In *Brulotte*, anyone was free to use the patented technology after the patent expired. In this case, by contrast, absent a waiver from Astra the FDA was not free to authorize the sale of a generic drug using the patented technology until the end of the pediatric exclusivity period. Thus, Astra's demand for royalty payments for post-expiration sales does not rest on its patent monopoly; the demand is based on the fact of Astra's legal entitlement to a pediatric exclusivity period. The only issue here is whether the period during which damages are to be measured under section 284 may include the post-

expiration pediatric exclusivity period.[7] We hold that it may not.

For an act of infringement, as defined in 35 U.S.C. § 271(e)(2), the Patent Act provides three types of remedies. They are as follows:

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . [and]
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .

35 U.S.C. § 271(e)(4).

While the remedy under subparagraph (A) is unique to section 271(e)(2) infringement, subparagraphs (B) and (C) provide the "typical remedies" for patent infringement: injunctive relief and money damages. *Omeprazole IV*, 536 F.3d at 1367. When there has been "commercial manufacture, use, or sale of an approved drug," the patentee is

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[7] We do not decide whether the pediatric exclusivity period may be considered in determining the royalty *rate* that might be employed in a hypothetical negotiation. Neither party has raised that argument, and the district court made no finding regarding the relationship between the royalty rate and the pediatric exclusivity period.

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." 35 U.S.C. §§ 271(e)(4)(C), 284; *see Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (section 271(e)(2) created a "highly artificial act of infringement" to enable "judicial adjudication" upon which the ANDA and paper NDA schemes depend; monetary damages, however, are permitted only if there has been "commercial manufacture, use, or sale" of the patented invention).

The district court found that in November 2003, the parties would have agreed to a license that would extend beyond the expiration date of the patent, because the FDA allows Astra to monetize its exclusivity right by waiving it in favor of a generic drug manufacturer, much as a patentee may license the right to use its patent for a payment of royalty. Indeed, when Andrx, one of the "first wave" defendants, attempted to settle its dispute with Astra in 2005, it offered precisely such a royalty payment covering both the original patent term and the pediatric exclusivity period. Thus, the post-expiration royalty that the district court envisioned resulting from a hypothetical negotiation reflects what a generic drug manufacturer in Apotex's position would have agreed to in a real licensing negotiation. Nevertheless, on the facts of this case it was error for the court to award that amount as part of Astra's patent infringement damages under sections 271(e)(4)(C) and 284.

We have long held that "there can be no infringement once the patent expires," because "the rights flowing from a patent exist only for the term of the patent." *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994) (citing *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 386 (Fed. Cir. 1984); *Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo, Ltd.*, 754 F.2d 345, 347 (Fed. Cir. 1985)). The pediatric exclusivity period is not an extension of the term of the patent. *See* 21 U.S.C. 355a(o)(1) (distinguishing

patent exclusivity from non-patent exclusivity); *see also* FDA, *Guidance for Industry Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999) ("FDA Guidance"), at 13 ("Pediatric exclusivity . . . is not a patent term extension under 35 U.S.C. § 156."); *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004) (giving *Chevron* deference to the FDA's interpretation of the pediatric exclusivity statute). For that reason, it is clear that Apotex did not infringe Astra's patents during the exclusivity period, since those patents had expired; if Apotex had launched its generic product during the exclusivity period, Astra could not have sued Apotex for patent infringement based on those sales.

The royalty base for reasonable royalty damages cannot include activities that do not constitute patent infringement, as patent damages are limited to those "adequate to compensate for the infringement." 35 U.S.C. § 284; *see Hoover Grp., Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 304 (Fed. Cir. 1995) ("[A patentee] may of course obtain damages only for acts of infringement after the issuance of the [] patent."); *cf. Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1366 (Fed. Cir. 1998) (the district court abused its discretion in ordering the repatriation of the exported vials under section 283, because the injunction was directed at activities that did not constitute infringement).

For example, in *Gjerlov v. Schuyler Labs., Inc.*, 131 F.3d 1016 (Fed. Cir. 1997), the patent owner and the defendant had reached a settlement agreement under which the defendant agreed not to manufacture or sell certain products, including certain non-infringing products, in exchange for a release from patent infringement liability. Upon a request of the patent owner to enforce the settlement agreement, the district court awarded reasonable royalty damages under section 284 for the defendant's sales of a non-infringing product that were

prohibited under the contract. We reversed and vacated that portion of the district court's judgment because the reasonable royalty award included damages for the sale of non-infringing products. If the defendant had breached the contract by selling an infringing product, reasonable royalty damages under section 284 would have been the proper remedy. *Gjerlov*, 131 F.3d at 1022-23. We held, however, it was improper to award reasonable royalty damages for the defendant's sale of the prohibited non-infringing products, because acts that do not constitute patent infringement cannot provide a proper basis for recovery of damages under section 284. *Id.* at 1024.

That proposition follows from the familiar principle that the royalty due for patent infringement should be the "'value of what was taken'—the value of the use of the patented technology." *Aqua Shield,* 774 F.3d at 770 (quoting *Dowagiac Mfg. Co. v. Minn. Moline Power Co.*, 235 U.S. 641, 648 (1915) ("As the exclusive right conferred by the patent was property, and the infringement was a tortious taking of a part of that property, the normal measure of damages was the value of what was taken.")); *Ericsson*, 773 F.3d at 1226 ("As a substantive matter, it is the 'value of what was taken' that measures a 'reasonable royalty' under 35 U.S.C. § 284.").

In this case, what was taken by Apotex was the exclusive right conferred by Astra's patents up to the date that they expired. The damages determination should not include Apotex's sales during the post-expiration period of pediatric exclusivity, because Astra's rights during that period were not attributable to its patents and were not invaded by Apotex's infringement. Therefore, even though a party in Apotex's position would have agreed to a license covering both the patent term and the pediatric exclusivity period, determining damages adequate to compensate Astra for Apotex's infringement requires that we focus solely on those activities that constitute actual infringement, i.e., Apotex's pre-expiration sales. Apotex's

sales during the pediatric exclusivity period cannot support Astra's claim for reasonable royalties under section 284, because those sales did not infringe Astra's patents.[8]

Nor can the award of damages for post-expiration sales be justified on the ground that those damages can be treated as "'waiver' payments made in exchange for Astra's waiver of the pediatric exclusivity period," as the district court held. Astra did not assert a claim under the Federal Food, Drug, and Cosmetic Act; its sole claim for relief was predicated on 35 U.S.C. § 271(a), and the scope of recoverable damages under that section is defined by section 284. Even if it had asserted such a claim, the statute provides no such remedy. *See* 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.").

By prohibiting the FDA from approving an ANDA for six months after the expiration of the patent, section 355a in effect gives an NDA holder in Astra's situation six additional months free from competition from ANDA applicants. *See* 21 U.S.C. § 355a(b)-(c); FDA Guidance, at 13 ("Pediatric exclusivity . . . extends the period during which the approval of an abbreviated new drug application (ANDA) or 505(b)(2) application may not be made effective by FDA."). But the statute does not create a damages remedy against an ANDA applicant who was authorized by the FDA to make sales during that period, as Apotex was for the first two months following the expiration of Astra's patents.

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[8] Astra also argues that reasonable royalties are recoverable for Apotex's post-expiration sales under the so-called "accelerated market entry" theory. The cases cited by Astra, however, were all directed at lost profits analysis and are therefore inapposite.

The problem that arose in this case resulted from the timing of the district court's infringement ruling. If the liability determination had been made before the expiration date of the patents, the FDA would have revoked the approval of Apotex's ANDA in time so that Apotex would have been barred from selling its generic product during the entire pediatric exclusivity period. However, because the district court's ruling was issued after the expiration date of the patent, there was a two-month period during which Apotex was authorized to sell its generic products before the FDA withdrew its approval of Apotex's ANDA. Although the sales that Apotex was authorized to make during that two-month period may have benefited Apotex and injured Astra, section 284 is not designed to compensate for those post-expiration sales.

Given that section 284 fails to support Astra's claim for royalty payments on Apotex's post-expiration sales, we reverse the portion of the district court's damages award relating to the pediatric exclusivity period, and we remand for a recalculation of damages.

Costs to Astra.

AFFIRMED IN PART, REVERSED IN PART, and REMANDED