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Federal Circuit Patent Bulletin: *AstraZeneca AB v. Apotex Corp.*

April 7, 2015

"[T]he period during which damages are to be measured under section 284 may [not] include the post-expiration pediatric exclusivity period."

On April 7, 2015, in *AstraZeneca AB v. Apotex Corp.*, the U.S. Court of Appeals for the Federal Circuit (O'Malley, Clevenger, Bryson*) affirmed-in-part, reversed-in-part, and remanded the district court's damages award in a case involving U.S. Patents No. 4,786,505 and No. 4,853,230, which related to pharmaceutical formulations containing omeprazole marketed by Astra as Prilosec®. The Federal Circuit stated:

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." 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." 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. . . .

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." . . . 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. . . .

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. . . . 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. . . . 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. . . .

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 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. . . .

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. 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. That six-month extension is known as the pediatric exclusivity period. . . .

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. 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 right for sales made during the pediatric exclusivity period. . . .

The only issue here is whether the period during which damages are to be measured under section 284 may include the postexpiration pediatric exclusivity period. We hold that it may not. [T]he 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." The pediatric exclusivity period is not an extension of the term of the patent. 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." . . . 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. 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.