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Damages for Infringement of a Pharmaceutical Patent: A Novel Analysis

By Jeffrey T. Thomas and Anne Y. Brody

During the patent reform debate that led to the America Invents Act (AIA), the pharmaceutical industry's expressed concern about the legislative proposal of mandatory damages apportionment led Congress to leave damages reform to the courts. But since the enactment of the AIA up until recently, the courts had not had the chance to develop guidance on pharmaceutical patent damages. This year, the Federal Circuit in *AstraZeneca v. Apotex*[1] finally had a chance to address the issue of mandatory damages apportionment in a pharmaceutical context. The *AstraZeneca* Court wielded a sharper patent reform scalpel by denying application of the entire market value rule—which it has so rigorously applied to patent infringement damages analyses in IT and other ''high tech'' cases—to an infringing drug product. The Court instead presented a novel damages analysis by considering whether the claimed drug product, made up of old elements, constituted a completely new and commercially viable product.

Mandatory Damages Apportionment Proposed During Patent Reform

As part of the legislative efforts to enact the AIA, both the House and the Senate proposed changes to the calculation of reasonable royalty for patent infringement under 35 U.S.C. § 284. In essence, these proposed changes effectively required the courts to apportion damages based on one of the following manners: (1) the entire market value rule of determining whether the patent's specific contribution is the predominate basis for market demand; (2) established royalty based on marketplace licensing; or (3) valuation of the economic value attributable to the patent's specific contribution over prior art.[2] Large technology companies supported these proposals as an effort to limit the amount of damages and the number of lawsuits, especially from the patent assertion entities. But the pharmaceutical and other industries strongly opposed, arguing that mandatory apportionment would devalue their patents and leave them more vulnerable to infringement. Ultimately, the AIA was enacted without any changes to Section 284, leaving damages reform to the courts.

In the recent years, the Federal Circuit and the lower courts have been rigorously applying the entire market value rule and apportioning damages in the high technology cases.[3] Meanwhile, more and more generic com-

[1] AstraZeneca AB v. Apotex Corp., 782 F.3d 1324 (Fed. Cir. 2015).

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[2] See e.g., Patent Reform Act of 2009, S. 515, 111th Cong. § 4(a) (2009); Patent Reform Act of 2009, H.R. 1260, 111th Cong. § 5(a) (2009).

[3] See e.g., Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292 (Fed. Cir. 2011); LaserDynamics, Inc. v. Quanta Com-

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panies launched their generic products at risk, and many of these cases settled before the courts were able to decide on damages. The entire pharmaceutical industry waited anxiously to see how the courts would calculate damages in a drug product case. The Federal Circuit's opinion in *AstraZeneca v. Apotex* directly addressed this issue.

The Federal Circuit Held that Apportionment of Damages Was not Necessary for a Drug Product

AstraZeneca's asserted patents were directed to pharmaceutical dosage forms containing the active ingredient omeprazole, and the patent claims described three key elements of the dosage form: a drug core comprising omeprazole, a subcoating as the middle layer, and an enteric coating as the outer layer. Accused infringer Apotex argued that because the active ingredient patents had expired, the damages should be calculated by applying the entire market value rule and thus apportioning the relative contribution of value between the active ingredient and the subcoating in the dosage form patents. But the Federal Circuit disagreed and held that AstraZeneca's patent claims covered the entire dosage form and not just a part of the dosage form. As such, the Court expressly declined to apply the entire market value rule and thus flatly rejected any notion of a mandatory damages apportionment.[4]

A Novel Analysis on Whether the Drug Product Constitutes a Completely New Product

In declining to apply the entire market value rule, the Court adopted a novel damages analysis by considering whether the combination of old elements created a completely new and marketable product.[5] Importantly, the Court found that this was not a case in which ''the value of all conventional elements *must be subtracted* from the value of the patented invention.''[6] The Court further reasoned that ''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.''[7]

Using this novel analysis, the Court agreed with the district court that the combination of the key elements in AstraZeneca's formulation created a new, commercially viable product.[8] The active ingredient omeprazole was notoriously difficult to formulate because it has issues with storage stability and is particularly susceptible to degradation by gastric acid in the stomach. AstraZeneca's scientists spent years of research to come up with a subcoating that conferred increased stability and acid resistance. Also, AstraZeneca's prior formulations that did not have this subcoating were not commercially viable. Thus, the district court found that the subcoating was so important to the viability of the entire dosage form and was thus substantially responsible for the value of the drug product. The Federal Circuit agreed with the district court's finding and concluded that AstraZeneca's drug formulation was ''previously unknown in the art and was novel in its own right,'' and that there was ''no reason to exclude the value of the active ingredient when calculating damages in this case.''[9]

This opinion eased the branded companies' concern with mandatory damages apportionment. Instead of analyzing and apportioning the patents' specific contributions over prior art, the Court adopted a more flexible analysis similar to its analysis on the validity of the patents.[10] Because AstraZeneca's dosage form constituted a completely new and commercially viable product, the Court assigned the entire value to the dosage form.

In light of *AstraZeneca*, the determination of pharmaceutical patent damages in future cases would include an analysis of whether the drug product can be considered as a completely new and viable product. As the *AstraZeneca* Court noted, this analysis would involve the conventional *Georgia-Pacific* factors nine, ten, and thirteen,[11] which refer to ''utility and advantages of the patent property over any old modes and devices that had been used,'' ''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,'' and the ''portion of the realizable profit that should be credited to the invention.''[12] Moreover, this analysis would look at additional factors such as (1) whether an old element can be rendered more valuable when used in the patented combination;[13] and (2) whether the patented combination can be novel its own right.[14] These new factors would require a more detailed examination of the state of prior art, the problems to be solved, and the inventors' time and efforts in developing the patented inventions.

As a corollary, once a court finds the patents to be valid, the court's validity opinion can be a good predictor of its damages determination. In other words, if the court finds a drug product to be novel and non-obvious, the court is likely to use a similar analysis in determining damages. As such, the parties may be able to better assess the relative strengths of their positions on damages after the court's validity findings. Overall, whether this new manner of determining damages would deter generic at-risk launches or settlements in the future cases remains to be seen.

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puter, Inc., 694 F.3d 51 (Fed. Cir. 2012); VirnetX, Inc. v. Cisco Sys., Inc., 767 F.3d 1308 (Fed. Cir. 2014).

[4] AstraZeneca, 782 F.3d at 1338.

[5] Id. at 1338-39.

[6] Id. (emphasis added).

[7] Id., citing to Westinghouse Elec. & Mfg. Co. v. Wagner Elec. & Mfg. Co., 225 U.S. 604, 614 (1912).

[8] Id. at 1339-40.

[9] Id.

[10] In re Omeprazole Patent Litigation, 536 F.3d 1361, 1372-75 & 1379-81 (Fed. Cir. 2008).

[11] In Georgia–Pacific Corp. v. U.S. Plywood Corp., 318 F.Supp. 1116 (S.D.N.Y.1970), the district court laid out a set of fifteen factors in determining reasonable royalty damages. Since then, courts frequently use some or all of the so-called Georgia–Pacific factors to analyze reasonable royalty damages.

[12] AstraZeneca, 782 F.3d at 1338.

[13] Id.

[14] Id. at 1340.

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Lingering Questions on Damages Based on the Infringement of the Active Ingredient Patents

Compared to the high-tech cases, the law on pharmaceutical patent damages is still not as extensively developed. The *AstraZeneca* opinion leaves open a number of questions, particularly on the calculations of damages based on infringement of a patent covering an active ingredient. For example, if an accused drug product contains an infringing active ingredient but is in a non-infringing dosage form, can the accused infringer now argue that the dosage form is a completely new and commercially viable product? Notably, the *AstraZeneca* district court found that while the subcoating did not create the market demand for omeprazole, the subcoating did substantially create the value of the drug product.[15] In that case, would a court then need to apportion damages and, if so, in what way? It may be a while before the Federal Circuit has a chance to address some of the lingering questions. But at the very least, the Court now has made clear that apportionment of damages is not mandatory and the trial courts can come up with novel analyses in determining damages.

[15] AstraZeneca AB v. Apotex Corp., 985 F. Supp.2d 452, 490 (S.D.N.Y. 2013).