

4-14-2015

## Federal Circuit Addresses Damages in the Hatch-Waxman Context

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### Recommended Citation

D'Amore, Matthew, "Federal Circuit Addresses Damages in the Hatch-Waxman Context," Morrison Foerster Client Alert, April 14, 2015

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April 14, 2015

# Federal Circuit Addresses Damages in the Hatch-Waxman Context

By **Matt D'Amore**

On April 7, 2015, the United States Court of Appeals for the Federal Circuit issued its decision in *Astrazeneca AB v. Apotex Corp.*, No. 2014-1221, affirming an award of a reasonable royalty of 50% in a case arising from the Hatch-Waxman Act. While largely affirming a damages award of over \$70 million, the Federal Circuit reversed the district court's award of damages during the period of pediatric exclusivity that AstraZeneca's product held after patent expiration.

The case provides important guidance regarding damages in the Hatch-Waxman context, and in particular whether damages are available in the period of pediatric exclusivity awarded to pharmaceutical patent holders who conduct qualifying pediatric studies.

Of note, the Federal Circuit specifically considered the use of the "entire market value" rule in this case, and held that the entire market value rule was inapplicable because the infringed patents "cover the infringing product as a whole," but also that the district court still must consider the relative value of the invention compared to "conventional" features in the claim.

### BACKGROUND

Omeprazole is the active ingredient in AstraZeneca's Prilosec® product. AstraZeneca's product was covered by several patents, including patents related to the active ingredient (which expired in 2001) and patents related to the pharmaceutical formulation (which expired April 20, 2007).

Beginning in 1997, Apotex and several other generic manufacturers filed "Paragraph IV Certifications" as to the formulation patents, certifying to the FDA their belief that those patents were invalid or not infringed, and AstraZeneca in turn sued. The "Paragraph IV Certifications" permitted the FDA to approve the generic products before AstraZeneca's patents expired, even though litigation was ongoing. Apotex and some other generic companies thus launched their products "at risk" before infringement and validity were determined by the court.

Unlike some of the other generics, Apotex's product was found to infringe the formulation patents on May 31, 2007, and it was enjoined from further sales shortly thereafter. In 2008, the Federal Circuit affirmed the infringement ruling against Apotex, *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008), and the case returned to the district court to set AstraZeneca's damages.

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## AFFIRMING THE 50% REASONABLE ROYALTY

### The Relevance of the Market

The district court found a 50% royalty on Apotex's gross margin to be appropriate in view of the *Georgia-Pacific* factors commonly employed to assess a reasonable royalty. Among other facts, the district court found that the market for omeprazole in 2003-2007 had several features that supported a high royalty rate. First, while there were other generic entrants during that period, only one had been found not to infringe; the cases against the others were, like Apotex's, still pending. Accordingly, the district court found that the generic prices (and profits) stayed high because the "at risk" entrants hedged against a possible later finding of infringement. With this pricing, Apotex reported a profit margin of more than twice its average. The district court thus found that a license to Apotex would have a high value, because Apotex would have a greater ability to price its product below its competitors and take market share. Second, the district court found that Apotex would have had difficulty switching to a non-infringing product, given patent coverage on other formulations and likely regulatory delays. Third, the district court considered other licenses, settlements, and offers for settlement, and found that they supported its royalty award. Apotex challenged these factual findings, but the Federal Circuit found no error.

### The Relevance of the Entire Market Value Rule

Separate from its challenges to the district court's factual findings about the market, Apotex contended that the district court erred by considering the value of its product as a whole, rather than just the patented improvements. In Apotex's view, because the active ingredient of the formulation was known in the prior art, under the entire market value line of cases the district court should have based its damages calculation on the value of the patented improvements – specifically, a subcoating that improved the stability of the drug – excluding the value of the omeprazole active ingredient.

The Federal Circuit rejected this argument. The court acknowledged that its precedent "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 for customer demand or substantially creates the value of the component parts." Slip op. at 20-21 (quoting *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2001)). But the Federal Circuit nonetheless held that:

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.**

*Id.* at 22 (emphasis added).

However, the court also held that the relative contribution of the invention remains important:

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.

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*Id.* And the Court further noted that “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.” *Id.* at 22-23. The Federal Circuit observed that this approach was already reflected in the *Georgia-Pacific* factors, which include consideration of the benefits of the invention, and the portion of profit attributable to that invention.

In this case, the district court observed that the formulation claimed by the patents is what made the sale of the active ingredient commercially viable. The Federal Circuit saw no error in that factual finding, and thus no reason to exclude the value of the active ingredient from the damages calculation.

## NO AWARD OF DAMAGES DURING PEDIATRIC EXCLUSIVITY

While AstraZeneca’s formulation patents expired on April 20, 2007, the company enjoyed pediatric exclusivity with respect to those patents until October 20, 2007. The district court’s injunction against Apotex issued on May 31, 2007, and required the FDA to revoke its approval of Apotex’s product on June 28, 2007, in view of AstraZeneca’s exclusivity. (The FDA subsequently reapproved Apotex’s product after the exclusivity period expired.)

The Federal Circuit held that AstraZeneca could not recover a royalty for Apotex’s sales during this period. It held that damages may only be awarded in a patent case for patent infringement, and there can be no infringement after a patent expires. While the court noted that a generic might be willing to agree to pay for a license during the pediatric exclusivity period as part of the bargain for a license, infringement damages were unavailable on the facts here, because the patents had expired and the Hatch-Waxman Act provides no other damages remedy for sales during this period.

Notably, while the court observed that a generic might agree to a license that includes royalties during this post-expiration period, it did not reach the question of whether such agreements would be permissible under *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), which held (outside of the Hatch-Waxman context) that agreements to pay royalties after a patent had expired were unenforceable. That precedent is presently under review in *Kimble v. Marvel Enterprises, Inc.*, now pending before the [Supreme Court](#).

## CONCLUSION

The Federal Circuit’s holding demonstrates that in assessing damages, whether the claim is directed to the entire pharmaceutical product or just one component is important. But even where the claim covers the whole product, the relative contribution of the new features of the invention compared to those known in the art also must be considered. Here, the district court found that the commercial value of the product depended on the patented improvements, not just the active ingredient, which along with other facts justified a high royalty rate in this case. That will not be so in all pharmaceutical cases, especially where formulation patents may cover later versions of previously commercialized products with the same active ingredient.

Additionally, the Federal Circuit’s holding regarding the unavailability of damages during the pediatric exclusivity period provides important guidance for brands and generics. However, it will need to be evaluated again in view of *Kimble v. Marvel Enterprises, Inc.*, on the issue of whether agreements to pay royalties after patent expiration – such as during the pediatric exclusivity period – are permissible.

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