The Latest Intellectual Property News

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Welcome to The Latest Intellectual Property News, a newsletter for updating you with recent information about Intellectual Property.

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ANDA INFRINGEMENT NOT DETERMINED BY ANOMOLOUS PRODUCT BATCH

By Sean A. Passino, Ph.D., Esq./Partner (spassino@ipfirm.com)

Infringement under §271(e)(2) is not determined by anomalous species in a product batch but is determined by what is likely to be sold by the ANDA applicant. *Ferring B.V. v. Watson Laboratories, Inc.-Florida*, slip op. 2014-1416 (Fed. Cir. Aug. 22, 2014). After losing in the district court, Watson appealed from the holding that it infringed under 35 U.S.C. § 271 asserted claims of Ferring's U.S. Patents 7,947,739 (the "'739 patent"), 8,022,106 (the "'106 patent"), and 8,273,795 (the "'795 patent") by filing an ANDA directed to a generic tranexamic acid product.

Ferring owns the '739, '106, and '795 patents, which are directed to modified release formulations of trans-4-(aminomethyl)cyclohexanecarboxylic acid, also known as tranexamic acid, the active ingredient in the drug marketed as a treatment for heavy menstrual bleeding under the brand name Lysteda®. A representative claim recites a *tranexamic acid tablet* formulation having a specified *dissolution release rate in water*.

Watson's abbreviated new drug application ("ANDA") specification contains no specification on how its generic tablet dissolves in water. Biobatch data of its coated generic tablets, which contain an uncoated core, show that most tested samples fall outside the recited *dissolution release rate in water* but a few fall within.

Ferring sued Watson alleging that both Watson's uncoated core (a component of the tablet) and coated tablet product infringe the asserted patents. A district court agreed.

A panel in the United States Court of Appeals for the Federal Circuit reversed. It noted that under §271, the act of filing an ANDA, by itself, does not necessarily establish infringement. "The filing only constituted a technical act of infringement for jurisdictional purposes." According to the panel, the ultimate infringement inquiry compares the asserted patent claims and the product that is likely to be sold following ANDA approval using traditional patent law principles.

The panel noted that, in some cases, the ANDA specification directly resolves the infringement question, because it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or not. In other cases, the ANDA

specification itself does not resolve the infringement question, and the district court references relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the United States Food and Drug Administration ("FDA").

Here, the ANDA specification does not resolve the infringement question, as there is no specification for the dissolution of the finished, coated product in water. Moreover, the panel found it was an error to focus on the uncoated cores of the generic tablet, as the uncoated cores are not the final product to be sold, because Watson sought approval to commercialize a tablet containing the cores, and Watson cannot sell the cores alone.

The evidence regarding Watson's generic tablets showed that about 4 in 180 tablets had the recited *dissolution release rate in water*. Rather than side with the district court's findings of fact, the panel cited evidence from Watson's expert, who testified that these tablets were anomalous in the sense that the tablets had incomplete coating integrity. As a result, the panel reversed the holding of infringement.

COULD HAVE INFRINGED IS NOT THE ANDA INFRINGEMENT STANDARD

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Silence in an ANDA specification is not proof of infringement, let alone a license to infringe. *Ferring B.V. v. Apotex Inc.*, slip op. 2014-1377 (Fed. Cir. Aug. 22, 2014). As noted in the previous case's discussion, Ferring owns the '739, '106, and '795 patents, which are directed to tranexamic acid for treating heavy menstrual bleeding. Recall, a representative claim recites a *tranexamic acid tablet* formulation having a specified *dissolution release rate*.

Apotex's original 2010 ANDA for its generic tranexamic acid tablet was silent regarding the *dissolution release rate.* The district court found that Apotex was infringing the asserted patents, because Apotex *could* violate the patents-in-suit based on Apotex's 2010 ANDA. Apotex agreed to amend its ANDA to limit the *dissolution release rate in water* of its generic. After the FDA accepted the amendment, the district court concluded that the 2014 ANDA did not infringe the asserted patents. At a hearing, Apotex agreed to stipulate and to inform the FDA that both the district court and Ferring would be notified if Apotex attempted to change its *dissolution release rate*. Apotex sent the letter to the FDA indicating that the *dissolution release rate* "will not be removed from its ANDA without first informing the Court, counsel for Ferring and the FDA." The district court dismissed the suit as moot.

The panel in the Federal Circuit found that the district court erred for finding that Apotex infringed merely because it could have infringed the asserted patents due to the 2010 ANDA's silence on the *dissolution release rate*. Silence does not amount to proof that an ANDA specification defines an element of a claim. As Ferring's expert admitted that no batch data showed that Apotex's generic product infringed, the evidence shows that Apotex is *not* likely to sell an infringing product, even under the 2010 ANDA.

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