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Process Limitations Are Not Relevant to the Validity of Pharmaceutical Product Claims

By Mark Remus, Andrew McElligott

February 05, 2016

Two recent cases from the Federal Circuit and Patent Trial and Appeal Board ("PTAB") emphasize the limited role of process limitations when analyzing the validity of pharmaceutical product claims. See *Purdue Pharma L.P. v. Epic Pharma, LLC*, No. 2014-1294 (Fed. Cir. Feb 1, 2016); *Fresenius Kabi USA LLC v. Cubist Pharmaceuticals LLC*, Case IPR2015-01566, Paper No. 20 (PTAB January 28, 2016). In both cases, the patents related to blockbuster drugs with sales over $1 billion per year and key limitations in product claims were disregarded in the validity analysis because they related to process steps, rather than the structure or function of the pharmaceutical product.

Purdue v. Epic
In Purdue, the Federal Circuit reviewed a district court judgment that claims covering the pharmaceutical OxyContin® were invalid. The claims-at-issue required the removal of an impurity that is "derived from" a particular byproduct of the manufacturing process. The Federal Circuit agreed with the district court that "derived from" is a process limitation that is irrelevant to the validity analysis. The Federal Circuit noted that "in determining the validity of a product-by-process claim, the focus is on the product and not the process of making it." Slip Op. at 16 (quoting *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012)). An old product does not become patentable solely because it was made by a new process. *Id*. However, process steps may be relevant if they impart "structural and functional differences" between the claimed product and the prior art. In this case, the Federal Circuit found that the process steps in the Purdue claims did not impart any such differences, because the structure of the impurity was the same regardless of the source from which it was derived. Id.

Fresenius v. Cubist
In *Fresenius*, the PTAB instituted *inter partes* review of several patent claims directed to the antibiotic Cubicin®. The claims covered a pharmaceutical composition that was "obtained by" a specific process in order to create a product with a lower level of impurities. The PTAB found that the process limitations did not limit the scope of the claims because the Patent Owner did not offer any evidence that the process steps add structural or functional features that distinguish the claimed product from the prior art. Fresenius, at 9-10. To the extent the Patent Owner relied on the product's higher purity as a structural or functional difference, the PTAB found that the Patent Owner did not provide persuasive evidence that the claimed purity levels were distinguishable from the prior art.

Practical Implications
Regardless of whether one is in a district court or in front of the PTAB, process steps do not limit the scope of pharmaceutical product claims unless those steps add structural or functional features that distinguish the claimed product from the prior art. Use of process limitations in a product claim should be approached with caution, because they limit the scope of the claims for purposes of infringement (see *Abbott Labs v. Sandoz*, 566 F.3d 1282, (Fed. Cir. 2009), but they do not limit the scope of the

claims for purposes of validity.

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