IP Alert: Inherent Risks to a Common Prosecution Strategy

Inherent Risks to a Common Prosecution Strategy

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The U.S. Court of Appeals for the Federal Circuit affirmed the decision of the U.S. District Court for the District of Delaware, holding Sanofi's patents, U.S. 8,318,800 and U.S. 8,410,167, not proven invalid for obviousness and not proven narrowed by prosecution disclaimer. Sanofi v. Watson Laboratories (Case 16-2722, 16-2726). The court's November 9, 2017, decision affirmed the infringement of Sanofi's patents directed to cardiovascular drug dronedarone (Multaq®) compositions and methods of using it. The court held that Watson's proposed new generic version of dronedarone with its proposed label induces infringement.

In response to Sanofi's charge of infringement, Watson attempted to limit the scope of the '800 patent claims to exclude Watson's proposed formulation. Specifically, Watson urged the court to apply a limitation from a parent application's prosecution history as a prosecution disclaimer.

Sanofi employed a common prosecution strategy in pursuing the ’800 patent family. Rather than extensively arguing claims were distinct from the prior art, it added a limitation to claims in a parent application to satisfy an examiner’s objections. When the narrowed claims were allowed, Sanofi pursued the original broader claims, without the added limitation, in a continuation application. Sanofi was successful in obtaining claims in the continuation that did not have the added limitation.

Watson urged that the disclaimer of the parent application should be read into the continuation claims. In essence, it asserted that a negative claim limitation Sanofi omitted in the continuation claims should nonetheless be read into the claim.

The court declined to apply the disclaimer in this case because the purported disclaimer was directed to specific claim terms that had been omitted in the continuation application. The purported disclaimer was not directed to “the invention itself,” the court held, but only to the claims containing the limiting terms.

The court recognized that Sanofi’s prosecution strategy (narrow first patent followed by a broader second patent) “fit a familiar pattern.” It did not give any indication that this strategy was disfavored. However, there may be risks when using the narrow-first-patent-followed-by-a-broader-second-patent strategy.

First, as demonstrated in this case, an applicant risks creating a prosecution disclaimer or a prosecution history estoppel. These can occur when statements made in prosecuting a narrow claim are used to limit the construction of a claim or the scope of equivalents accorded to a claim. Second, a continuation application may put the term of a parent application at risk. Under Gilead Sciences, Inc. v. Natco Pharmaceuticals Ltd., 753 F. 3d 1208 (Fed. Cir. 2014), cert. denied, 135 S. Ct. 1530 (2015), an earlier expiring patent can serve as an obviousness-type double patenting reference against a later expiring patent. This can truncate the term of the later expiring patent. This may occur with any pair of commonly owned patents that do not have patentably distinct claims and do not share a common expiration date. Such pairs of patents may, for example, be a parent and child application, if one of them is accorded patent term adjustment. Alternatively, such pairs of patents may derive from different priority applications. If a narrow parent and a broad continuation have different expiration dates, an applicant may need to weigh the benefit of the longer term against the benefit of having a broader claim. This will be a very fact-sensitive decision.

Applicants must think of each of their patent families as a coherent whole rather than as separate and independent applications. Comments made during prosecution of one application may influence the scope of another application. Different patent expiration dates can truncate the longer term to the length of the shorter term. Thus, applicants would do well to review parent application file histories for any possible disclaimers by argument and/or amendment. Disclaimers may also be found in statements made in post-examination challenges in the Patent and Trademark Office or in

the courts. Applicants can affirmatively rescind any such possible disclaimers during examination of continuation applications. A coherent and consistent strategy in prosecuting and enforcing a patent family will help avoid these problems. Prescience would also be helpful.

Click here to download the decision in Sanofi v. Watson Laboratories.

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