Today’s Gilead Federal Circuit Decision Is a Significant Change to Double-Patenting Law

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Today, the Federal Circuit issued an opinion altering the law of double patenting in Gilead Sciences, Inc. v. Natco Pharma Limited, No. 2013-1418, in a manner that will likely have a significant impact on the pharmaceutical industry. Chief Judge Rader provided a vigorous dissent, and it remains to be seen whether the case will withstand petitions for rehearing en banc.

The Gilead case involved the question of whether the ‘483 patent-in-suit was invalid for obviousness-type double patenting over the ‘375 reference patent. The ‘483 and ‘375 patents had the same inventors and similar specifications, but did not share a common priority application. As shown by the below chart, the ‘483 patent was filed after the ‘375 patent, but issued before the ‘375 patent and has a later expiration date. As can be seen, the term of the patent-in-suit entirely subsumes the term of the ‘375 reference patent. Whether or not the claim scope was patentably distinct was not at issue on appeal. The relevant issue was whether the ‘375 patent could be an invalidating reference at all given the fact the ‘483 patent did not effectuate any time-wise extension of exclusive rights vis-à-vis the ‘375 patent.

In the ruling today, the Federal Circuit holds that the ‘483 patent is invalid for double patenting over the ‘375 patent. In other words, the court finds that a first-to-issue patent can be invalid for double patenting over a later-issuing patent.

Judge Rader explained in his dissent the error in this outcome. First, "based on changes implemented as part of the GATT and URAA [affecting] the term of a patent . . . a primary motivation behind the doctrine—preventing the effective extension of patent term—is largely no longer applicable." (Dissent, Slip Op. at 2.) In Judge Rader’s view, because this case "does not raise the policy concern regarding
subsequent extensions of patent term” and “does not involve the potential for harassment by multiple assignees asserting essentially the same patented invention,” the obviousness-type double-patenting doctrine is inapplicable. (*Id.* at 3-4.) Second, patentees that obtain longer patent terms through later priority applications already “subject [that] patent to intervening prior art.” (*Id.* at 4.)

We have observed a further anomaly in the outcome. In *In re Fallaux*, 564 F.3d 131 (Fed. Cir. 2009), the Federal Circuit found that the reverse set of facts was double patenting. Under *Fallaux*, therefore, the later-issuing patent can be invalid over the earlier-issuing patent — even with a shorter patent term — due to the theoretical potential for “harassment by multiple assignees.” *Id.* at 1318-19. Although apparently not argued to the court, combining the majority outcome in *Gilead* with the holding of *Fallaux*, both patents can be invalid over each other, which is of course an absurd result since *double* patenting prevents *two* patents, and does not mean *no* patent. In fact, such an outcome is contrary to the basic principle recognized by the Supreme Court over 100 years ago that double patenting does not eliminate both patents: “[t]he last [patent to issue], *not the first*, is void.” *Suffolk Co. v. Hayden*, 70 U.S. 315, 319 (1865) (emphasis added).

The majority suggests that the availability of a terminal disclaimer makes its holding uneventful. (Slip Op. at 16.) But this fails to recognize at least three significant problems: (1) if the patents are not commonly owned, no terminal disclaimer is available; (2) if the reference patent has expired, no terminal disclaimer is available, see *Boehringer Ingelheim Int’l GmbH v. Barr Labs.*, Inc., 592 F.3d 1340, 1347-48 (Fed. Cir. 2010); and (3) regardless, the patent term is often extremely valuable, and its loss can be significant. And if no terminal disclaimer is available, the possibility that both patents will invalidate each other is quite shocking.

Unless this situation created by this decision is rectified, patent owners should expect additional double-patenting challenges. They will also need to be prepared *now* to consider the difficult decision of whether to file terminal disclaimers: if the patent owner delays until the reference patent expires, and a court ultimately finds double patenting, it could be incurable through a terminal disclaimer. For this reason, unless this decision is reversed, pharmaceutical companies would be well advised to consider their patent portfolios for their important drug products and the relationships of the various patents to the others.

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