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Federal Circuit Expands Doctrine of Double Patenting

May 14, 2014

The Patents at Issue

Gilead Sciences, Inc. (Gilead) owns United States Patent No. 5,763,483 and United States Patent No. 5,952,375. The patents feature common inventors and disclose similar material in the field of anti-viral compounds. Natco Pharma Limited (Natco) filed an application with the FDA to market a generic version of a compound owned by Gilead and allegedly falling within the scope of the '483 patent. At the district court level, Natco argued invalidity of the '483 patent over the commonly owned '375 patent on the basis of obviousness-type double patenting. Gilead argued in turn that the '375 may not serve as a double patenting reference due to the fact that the '375 patent issued after the '483 patent.

The '375 patent was filed on February 26, 1996 and issued on September 14, 1999. The '483 patent was filed on December 27, 1996 and issued on June 9, 1998. The two patents feature priority claims to differing families of previously filed applications. Under provisions of the Uruguay Rounds Agreement Act (URAA), the differing priority claims produce differing expiration dates. The '375 patent expires on February 27, 2015, while the '483 patent expires 22 months later on December 27, 2016. Gilead filed a terminal disclaimer in the '375 patent but not in the '483 patent.

The District Court Decision

The district court sided with Gilead's position and granted summary judgment that the '375 patent does not qualify as a double patenting reference for the '483 patent. Natco appealed, and the Federal Circuit reviewed the judgment under the assumption that the claims of the '483 patent in fact comprise an obvious variant over the invention claimed in the '375 patent.

The Federal Circuit Decision

In its review the Federal Circuit addressed the following narrow issue: "Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?" (Slip Op. page 6). In a straightforward application of double patenting doctrine, the Federal Circuit answered in the affirmative. The Federal Circuit emphasized public policy underlying the patent system itself. In exchange for a patentee's time-limited right to exclude, the patentee fully discloses the invention to the public, which is then free to use the invention (and obvious variants thereof) upon expiration of the patent's term. The Federal Circuit then reasoned as follows:

And that principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention. Such is the case here. The '375 patent expires on February 27, 2015. Thus, come February 28, 2015, the public should have the right to use the invention claimed in the patent and all obvious variants of that invention. . . . But the public will not be free to do so. The '483 patent does not expire until December 27, 2016, and it (we assume for this appeal) covers obvious modifications of the invention claimed in the '375 patent. (Slip Op. 11-12)

The double patenting doctrine prevents a patentee from extending the patent term through successive applications on a single invention (and obvious variants thereof) by limiting the patentee's single invention to a single patent term.

Gilead argued that the '375 patent does not qualify as an obviousness type double patenting reference against the '483 patent due to the fact that the '483 patent issued first, i.e., that it is not a later issuing patent and therefore falls outside the scope of double patenting. However the Federal Circuit reasoned that:

for double patenting inquiries, looking to patent issue dates had previously served as a reliable stand-in for the date that really mattered—patent expiration. But as this case illustrates, that tool does not necessarily work properly for patents to which the URAA applies, because there are now instances, like here, in which a patent that issues first does not expire first (Slip Op. 13).

Accordingly, the Federal Circuit overturned the district court and held that a later issuing and earlier expiring patent may serve as an obviousness-type double patenting reference against an earlier issuing and later expiring patent.

If you have any questions or want to discuss how this decision could impact your business, contact your Baker Donelson attorney or one of the attorneys in the Firm's Intellectual Property group.