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Federal Circuit Patent Bulletin: *Gilead Scis., Inc. v. Natco Pharma Ltd.*

April 22, 2014

"[A] patent that issues after but expires before another patent [will] qualify as a double patenting reference for that other patent."

On April 22, 2014, in *Gilead Scis., Inc. v. Natco Pharma Ltd.*, the U.S. Court of Appeals for the Federal Circuit (Rader, Prost, Chen*) vacated and remanded the district court's judgment that Natco infringed U.S. Patents No. 5,763,483 and No. 5,952,375, which related to antiviral compounds and methods for their use, and that the '483 patent was not invalid for obviousness-type double patenting over the '375 patent. The Federal Circuit stated:

The bar against double patenting was created to preserve that bargained-for right held by the public. If an inventor could obtain several sequential patents on the same invention, he could retain for himself the exclusive right to exclude or control the public's right to use the patented invention far beyond the term awarded to him under the patent laws. [T]he doctrine of double patenting was primarily designed to prevent such harm by limiting a patentee to one patent term per invention or improvement. . . . Federal courts for over a century have applied the principles of the doctrine as a means to preserve the public's right to use not only the exact invention claimed by an inventor when his patent expires, but also obvious modifications of that invention that are not patentably distinct improvements. [But a] terminal disclaimer should be a permissible means to overcome the prohibition on double patenting when it aligns the expiration dates of an inventor's several patents that claim mere obvious variations of the same invention to create a single term of limited exclusivity.

[I]t is a bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention. The double patenting doctrine has always been implemented to effectively uphold that principle. 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. That was the condition upon which the '375 patent was issued to the inventors. 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. The '483 patent, therefore, extends the inventors' term of exclusivity on obvious variants of the invention claimed in the '375 patent for an additional twenty-two months past the expiration of the '375 patent. That plainly violates the public's right to use the invention claimed in the '375 patent and all obvious variants of it after the '375 patent expires.

[F]or 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 [(Uruguay Round Agreements Act, Pub.L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994))] applies, because there are now instances, like here, in which a patent that issues first does not expire first. [I]t is the comparison of Gilead's patent expiration dates that should control, not merely the issuance dates. [I]f the double patenting inquiry was determined by issuance date for post-URAA patents, there could be a significant difference in an inventor's period of exclusivity over his invention (and its obvious variants) based on mere days' difference in the issuance of several patents to the inventor. . . . Such significant vacillations in an inventor's period of exclusivity over his invention and its obvious variants is simply too arbitrary, uncertain, and prone to gamesmanship. Congress could not have intended to inject the potential to disturb the consistent application of the doctrine of double patenting by passing the URAA. Looking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting. Permitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA guarantees a stable benchmark that preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires.

[L]ooking to the expiration date instead of issuance date is consistent with the PTO's guidance in the Manual of Patent Examining and Procedure . . . . Applied to the facts here, a terminal disclaimer would have been required for the '483 patent. We therefore hold that an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent under the circumstances here. In cases where such obviousness-type double patenting is present, a terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent. That disclaimer will most effectively enforce the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent's term expires. [T]he district court erred in concluding that the '483 patent could not be invalid for double patenting because the '375 patent could not qualify as an obviousness-type double patenting reference. We therefore vacate the judgment of the district

court and remand for further proceedings consistent with this opinion.