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Fed. Circ. Provides Clarity On Patent Term Questions

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In two decisions on Dec. 7, the Federal Circuit clarified the law of obviousness-type double patenting, or ODP, and provided certainty to biopharmaceutical patent owners. In Novartis AG v. Ezra Ventures LLC, the court held that ODP does not invalidate an otherwise valid patent term extension, or PTE, granted under 35 U.S.C. § 156 (extending the term of a pharmaceutical patent to compensate for regulatory delays). And in Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc., the court clarified that its holding in Gilead Sciences Inc. v. Natco Pharma Ltd.[1] i.e., that a later-issuing, earlier-expiring patent can invalidate an earlier-issuing, later-expiring patent for ODP, applies only to post-Uruguay Round Agreements Act, or URAA, patents. Under Breckenridge, where a later patent expires earlier only because of the URAA's change in patent term, the post-URAA patent is not an ODP reference against the pre-URAA patent. The two decisions put an end to post-Gilead ODP challenges to pre-URAA patents and patents with PTE based on term granted by Congress.

Gilead involved two post-URAA patents and what the Federal Circuit described as "gamesmanship" resulting in one patent expiring later than another. In its aftermath, patent infringement defendants have attempted to extend Gilead to a variety of different factual contexts. Patents have been challenged for ODP even when the longer patent term was expressly granted by Congress, such as through PTE under 35 U.S.C. § 156 or by the URAA's transition statute (giving pre-URAA patents the longer of 17 years from issuance or 20 years from the effective filing date for the patent).

Ezra Ventures involved one such post-Gilead challenge to PTE. In that litigation, a pre-URAA patent (the '229 patent) would have expired earlier than a later-issued post-URAA patent (the '565 patent) but for a five-year PTE obtained by Novartis. Section 156(c)(4) provides that the term of a single patent covering a U.S. Food and Drug Administration-approved pharmaceutical can be extended by PTE. As the court explained, PTE (part of the Hatch-Waxman Act) "was enacted to restore the value of the patent term that a patent owner loses during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency." Novartis chose to extend its '229 patent under the statute. In a motion for judgment on the pleadings, Ezra argued that the '565 patent, which expired before the '229 patent solely because of the '229 patent's PTE, invalidated the '229

patent for ODP. The district court denied the motion, finding that the expiration of the ’565 patent did not undermine the ’229 patent’s PTE.

The Federal Circuit agreed. Relying on the plain language of the PTE statute and its own earlier decision in Merck & Co. v. Hi-Tech Pharmacal Co.[2] — finding that PTE could validly extend the term of a terminally disclaimed patent — the court held that ODP “does not invalidate a validly obtained PTE” even though the PTE results in a later expiration for a patentably indistinct patent. The Federal Circuit explained that Novartis’s situation was no different than that in Merck, in which a “patent is terminally disclaimed to another patent to overcome an obviousness-type double patenting rejection and then term-extended under § 156.” In such a situation, “the term of patent protection afforded to the patentably indistinct patent to which the extended patent was terminally disclaimed is ... ‘effectively’ extended because of a PTE granted pursuant to § 156.” Ezra Ventures held that such an extension of term is not only authorized by Merck, but is precisely the result the PTE statute requires.

The Ezra Ventures court was untroubled by the policy concerns that motivated earlier ODP decisions. For example, as the court explained, PTE is not an unjustified extension of patent term (part of the reason the judge-made ODP doctrine exists). It is merely a “statutorily allowed” extension of term. And, there is no concern with “gamesmanship” from manipulated priority claims, the concern the Federal Circuit raised in Gilead. Instead, this case concerned application of the PTE statute to a single patent that would have expired earlier but for extension expressly authorized by statute.

In the companion Breckenridge case, the Federal Circuit considered whether ODP applies to two patents with different expiration dates solely because of the intervening change in patent term caused by the URAA. Before the passage of the URAA, patents received a term of 17 years from issuance. Congress passed the URAA to harmonize the United States patent terms with the rest of the world by providing patents with a term of 20 years from the earliest effective filing date. For patents filed prior to June 8, 1995, however, the URAA transition statute (35 U.S.C. § 154(c)(1)) guaranteed a term of 17 years from issuance or 20 years from filing, *whichever is longer.*

Pre-URAA, the ODP framework focused on relative issue dates (because term depended only on issue date). As a result, only a later-issued patent could invalidate an earlier-issued patent for ODP. In 2014, Gilead (involving two post-URAA patents) refocused the ODP inquiry on relative expiration dates (since term for post-URAA patents is not based on issue date). Under Gilead, a later-issued yet earlier-expiring patent can invalidate an earlier-issued yet later-expiring patent, where the later expiration date was an unjustified extension of term. The question presented in Breckenridge — a question presented to a number of district courts after Gilead — was whether Gilead applies to patents whose terms differed solely as a result of the URAA. The district court answered that question in the affirmative.

The Federal Circuit answered that question with an unequivocal “no.” It explained that Gilead is “limited to the context of when both patents in question are post-URAA patents” and “thus does not control the present situation.” In other words, for a pre-URAA patent, traditional ODP rules apply; a later-issued patent cannot invalidate a pre-URAA, earlier-issued patent. The court explained that Gilead “addressed a question that is not applicable here”; its holding was “limited to the post-URAA context.” The Federal Circuit stressed that the extra term of a pre-URAA patent “does not pose the unjustified time extension problem that was the case for the invalidated patent in Gilead.”

The court also explained that the “gamesmanship” concern that the Federal Circuit raised in Gilead was of no moment here. The difference in term for pre- and post-URAA patents in Breckenridge was “only due to the happenstance of an intervening change in patent term law.” When the pre-URAA patent

issued, it received the term the transition statute provided; there was no extension of term. As the court explained:

> Congress intended patent owners who filed patent applications before the transition date to the new patent term law to enjoy the maximum possible term available for their resulting patents under either patent term regime. Thus, to require patent holders to truncate any portion of the statutorily-assigned term of a pre-URAA patent that extends beyond the term of a post-URAA patent would be inconsistent with the URAA transition statute.

Conclusion

These two decisions clarify the law of ODP following Gilead and provide certainty to biopharma patent owners. They put an end to the flurry of post-Gilead challenges to term granted to patent owners by Congress.

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[1] Gilead Sciences Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014).

[2] Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317 (Fed. Cir. 2007).