



## **Federal Circuit: Obviousness-type Double Patenting Does Not Apply Where Licensor Retains Secondary Right to Sue**

Jul 17, 2017

Reading Time : **3 min**

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### **Background**

This case arose in litigation under the Biologics Price Competition and Innovation Act (BPCIA) over Erelzi<sup>®</sup>, Sandoz's biosimilar of Immunex's biologic drug Enbrel<sup>®</sup> (etanercept), used for reducing the symptoms of rheumatoid arthritis. The patents at issue, U.S. Patent Nos. 8,063,182 ("182 patent") and 8,163,522 ("522 patent") are directed to the fusion protein etanercept and the methods of making it, which is the active ingredient in Enbrel<sup>®</sup>.

The applications that eventually issued as the patents-in-suit were filed by Hoffman-La Roche Inc. ("Roche"). After obtaining FDA approval for Enbrel<sup>®</sup>, Immunex entered a license agreement for Roche's related patent applications and all patents that issued from them. Amgen later acquired Immunex, and in 2004, Amgen, Immunex and Roche entered into an "Accord and Satisfaction" agreement (the "Agreement") to eliminate the continuing obligations to pay royalties to Roche under the initial license agreement. Under the Agreement, Immunex received a paid-up, irrevocable, exclusive license to the patents-in-suit, as well as "the sole right to grant sublicenses and to make, have made, use, sell, offer for sale, and import products covered by the patent." Immunex also received "the exclusive right to prosecute patent applications in the U.S. patent family." Roche, meanwhile, retained a secondary right to sue and the right to practice the invention for internal, research purposes. The agreement also prohibited either party from assigning its rights to a third party without the written consent of the other.

In 2016, Immunex, together with Roche, sued Sandoz for infringement of the '182 and '522 patents under the BPCIA. Sandoz stipulated to infringement, but challenged the validity of the patents on multiple grounds. Following a bench trial, the district court found, *inter alia*, that Sandoz failed to show that Immunex owned the patents-in-suit, and thus refused to invalidate them for obviousness-type double patenting in view of other Immunex-owned patents.

### **Obviousness-Type Double Patenting**

On appeal, Sandoz challenged the district court's ownership determination based on the Agreement. Sandoz argued, borrowing the "all substantial rights" test used to determine standing to sue under 35 U.S.C. § 281, that even though the patents-in-suit are assigned to Roche, the rights conveyed to Immunex through the Agreement were tantamount to an assignment of ownership. Sandoz noted that Immunex held an exclusive license to the patents-in-suit, as well as the right to sue for infringement and to control prosecution, and was, therefore, the effective patentee. And, according to Sandoz, if a party is the effective patentee for the purposes of bringing suit, it should be viewed similarly for the purposes of applying the obviousness-type double patenting doctrine.

Immunex responded that obviousness-type double patenting requires common ownership "*at the time of the invention*," which did not exist here. And, in any event, obviousness-type double patenting should not apply because Roche retained some rights in the patent under the Agreement, including a secondary right to sue; the right to practice the patents for internal, non-clinical research; and the right to veto any assignment of Immunex's interest under the agreement to another party.

Regarding the appropriate test for common ownership for the purposes of applying obviousness-type double patenting, the Federal Circuit largely sided with Sandoz. That is, the court held that the "all substantial rights" test can be informative as to whether patents are commonly owned. However, the court refused to apply the test as a strict standard for determining common ownership. Instead, it held that the "all substantial rights" test aids in preventing unjustifiable issuance of claims that are patentably indistinct from claims already owned by that party *where one of the rights transferred is the right to prosecute the patents at issue*. The court rejected Immunex's assertion that ownership should be viewed at the time of the invention as inconsistent with precedent.

On the question of ownership, the court sided with Immunex, and held that the patents-in-suit were not owned by Immunex because Roche retained certain rights in the patents. In particular, Roche's ability to exercise a secondary right to sue and the fact that neither party could assign its rights to third parties without the written consent of the other demonstrated that Roche did not transfer all substantial rights in the patents to Immunex. And for this reason, the Federal Circuit affirmed the district court's finding that the patents-in-suit could not be invalidated for obviousness-type double patenting.

**Practice Tip:** This decision highlights the importance of considering specific provisions when drafting licensing agreements. In particular, when drafting a license that transfers substantial rights, including the right to prosecute patents, careful consideration should be given to the remaining rights and interests held by each party to the agreement in order to avoid later questions regarding validity.

*Immunex Corp. v. Sandoz Inc.*, No. 2020-1037 (Fed. Cir. Jul. 1, 2020).

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