

## Patent License Considerations After Fed. Circ. Enbrel Ruling

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(September 3, 2020, 4:36 PM EDT)

The recently decided *Immunex Corp. v. Sandoz Inc.* requires considering the prudence of conveying all substantial rights to a patent portfolio in a license agreement.[1]

In *Immunex*, the U.S. Court of Appeals for the Federal Circuit equated transferring all substantial rights to a patent to a licensee with transferring ownership. This analysis raises the possibility that, by virtue of the license terms, in-licensed patents could become prior art against the licensee's own patents and vice versa for an obviousness-type double patenting analysis.

Here, we provide an overview of *Immunex*, the interplay of the all substantial rights test and obviousness-type double patenting, and strategic implications for patent licensing negotiations.

### Immunex and Obviousness-Type Double Patenting

Obviousness-type double patenting, a judicially created doctrine, prevents patentees from improperly extending the term of their patent coverage by simply claiming an obvious variant of a patented invention in a later-filed application.[2]

Obviousness-type double patenting has typically been applied when the earlier and later filed patents or applications have at least one common inventor and/or are commonly assigned or owned.[3]

The Federal Circuit's decision in *Immunex* arguably extends the doctrine's reach to in-licensed patents in which all substantial rights have been conveyed to the licensee by the licensor.[4] Under such an analysis, an in-licensed patent could be subject to an invalidity attack under an obviousness-type double patenting theory based on another patent owned by the licensee. Alternatively, the licensed patent could be used as a reference patent to invalidate another patent owned by the licensee.

In *Immunex*, the applications that issued as the asserted patents were filed and assigned to Hoffmann-



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La Roche Inc.[5] After Roche filed the applications, Immunex Corp. obtained a license to all patents that issued from the applications.[6] As part of the license agreement, Immunex agreed to pay Roche royalties on the sales of Enbrel, Immunex's product encompassed by the asserted patents.[7]

In 2004, Immunex and Roche, as well as two nonparties, entered into an accord-and-satisfaction agreement concerning the same patent family to eliminate Immunex's obligations to pay royalties to Roche.[8] The accord sets out the following relevant rights and obligations:

- Immunex has an exclusive license to the patent family, the sole right to grant sublicenses, and the exclusive right to prosecute patent applications in the U.S. patent family;
- Roche is required to cooperate with Immunex regarding prosecution;
- Immunex has the first right to sue for infringement at its sole expense and under its sole control;
- Roche is obligated to cooperate in any suit brought by Immunex;
- Roche retains the right, but not the obligation, to sue for infringement if Immunex elects not to bring suit against an alleged infringer;
- Roche retains the right to practice the patents for internal, nonclinical research only; and
- Neither party may assign its rights to third parties without the written consent of the other.[9]

At trial, the defendants asserted that the patents-in-suit were invalid for obviousness-type double patenting over patents owned by Immunex.[10] The defendants argued that even though the patents-in-suit were assigned to Roche, Immunex effectively owns both the Immunex patents and the patents-in-suit because all substantial rights to the patents-in-suit were transferred to Immunex pursuant to the accord.[11]

The Federal Circuit agreed with the defendants "that the 'all substantial rights' test can be informative in determining common ownership in the obviousness-type double patenting context." [12]

However, the Federal Circuit concluded that the accord did not transfer all substantial rights from the assignee, Roche, to Immunex.[13] In reaching its decision, the majority focused on Roche retaining rights to enforce the patents if Immunex did not elect to sue,[14] as well as the fact that Roche had a right to veto any assignment of Immunex's interest in the patents-in-suit.[15]

### **Strategic Implications of Immunex**

Companies should keep in mind that licenses may be viewed as assignments under the all substantial rights test when negotiating exclusive licenses. Prospective licensees must balance obtaining sufficient dominion over in-licensed patent portfolios without inadvertently creating prior art by the terms of the agreement potentially subjecting both the in-licensed patents and the licensee's own patents to invalidity attacks under an obviousness-type double patenting theory.

Initially, as a due diligence exercise, a company interested in obtaining an exclusive patent license should substantively consider any obviousness-type double patenting threat the in-licensed patent(s) and the company's own patent(s) would have on one another if they were deemed commonly owned. In

such circumstances, the Immunex framework can be used as a guide to mitigate the likelihood of obtaining all substantial rights in the licensed patent(s).

To avoid being deemed the owner of a licensed patent for purposes of obviousness-type double patenting, companies should consider only obtaining rights that they reasonably need in the patent families they license while leaving others with the licensor. As discussed, in *Immunex*, the Federal Circuit found that all substantial rights were not conveyed where the licensor retained the right to enforce the patents if the licensee did not elect to sue and the right to veto any assignment of the licensee's interest in the patents.

## **Conclusion**

Application of the all substantial rights test to licensed patents for the purpose of invalidity attacks based on obviousness-type double patenting should be considered by in-house counsel when negotiating license agreements. Additional insights into this issue may arise from a recent appeal to the Federal Circuit after a district court refused to consider the all substantial rights test in the context of a patent licensee and obviousness-type double patenting.[16]

Further development of the case law related to this question will provide greater insight into the clauses and words that patent licensees should integrate into their licensing agreements to best protect themselves from inadvertently creating harmful prior art.

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[1] *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020).

[2] *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013).

[3] Manual of Patent Examining Procedure, 804, <https://www.uspto.gov/web/offices/pac/mpep/s804.html>, accessed 8/19/2020.

[4] *Immunex*, 964 F.3d at 1057.

[5] *Id.* at 1054.

[6] *Id.* at 1055.

[7] *Id.*

[8] *Id.*

[9] *Id.* at 1055, 1061.

[10] Id. at 1056.

[11] Id. at 1057.

[12] Id.

[13] Id.

[14] Id. at 1061.

[15] The dissent agreed with the majority adopting the "all substantial rights" test to determine ownership of a licensed patent for an obviousness-type double patenting analysis. Id. at 1069. However, the dissent focused on Immunex's control of prosecution. Id. Specifically, the dissent indicated that when Roche controlled prosecution for 10 years, the applications from which the patents-in-suit issued did not claim Immunex's product, but rather a different product; and once Immunex gained control of prosecution, Immunex amended the applications so that the claims covered its product. Id.

[16] *Onyx Therapeutics, Inc. v. Cipla Ltd.*, 2020 WL 2214443 (D. Del. 2020). Similar to the Accord in Immunex, the license agreement at issue indicated the licensee "had 'the first right and obligation to defend' the [licensed patent] against infringement or interference at its own expense." Id. at para. 83. Additionally, if the licensee did not sue an infringer within 60 days of notice, the licensor "reserved the right to pursue an infringement at its own expense, unilaterally settle such action, and terminate [the licensee's] exclusive license in the country where such action took place." Id. Further, similar to the Accord in Immunex, the licensee could not transfer its rights under the agreement without the licensor's written consent. Id.