

When Does an Exclusive License Become Patent Owner for Obviousness Type Double Patenting? Sandoz Asks the Supreme Court to Weigh In

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Sandoz recently filed a cert petition in *Sandoz Inc. v. Immunex Corp.* asking the Supreme Court to reverse a split Federal Circuit decision holding that Immunex did *not* “commonly own” exclusively licensed patents for the purpose of obviousness type double patenting (ODP) because Immunex did not obtain “all substantial rights” to the patents under the license agreement. *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020). The Federal Circuit held that where one of the rights transferred is control of prosecution, then the “all substantial rights” test is the appropriate test for determining the effective patentee for ODP purposes. Within the Immunex agreement, the court focused on two features as evidencing a lack of transfer of all substantial rights: 1) the licensor’s retained right to sue and 2) licensee’s inability to assign to a third party without licensor’s consent.

Sandoz argues that the Federal Circuit’s decision as it stands is a “blueprint” for how to structure a license agreement to avoid ODP, thereby offering an exemption from the patent law’s rule against patenting the same invention twice. Sandoz tees up the issue for the Supreme Court presenting the question:

May the patent owner avoid the rule against double patenting by buying all of the substantial rights to a second, later-expiring patent for essentially the same invention, so long as the seller retains nominal ownership and a theoretical secondary right to sue for infringement?

The case highlights the potential for common ownership issues across exclusive licensing arrangements, with considerations for both patent validity and enforceability. Practitioners should consider the following when drafting and evaluating exclusive license agreements:

- The interplay of in-licensed IP with other IP owned by the exclusive licensee as in the *Immunex* case. If licensee obtains all substantial rights to the in-licensed IP, licensee should evaluate any potential ODP in view of other IP owned by licensee.
- The interplay of out-licensed IP with licensor’s retained portfolio. Do terminal disclaimers exist between the out-licensed IP and the retained IP? All parties should keep in mind that enforceability of terminally disclaimed patents requires maintaining common ownership.

Further details of the case:

The *Immunex* case arose out of BPCIA “biosimilar” litigation. Immunex sued Sandoz for infringing patents that Immunex exclusively licensed from Roche directed to Immunex’s biologic drug Enbrel®. Sandoz stipulated that its biosimilar product Erelzi® infringed the exclusively licensed patents, but asserted that the patents were invalid, including for the reason of ODP in view of earlier-expiring Immunex patents also covering the product Enbrel®.

ODP prohibits a party from obtaining an extension of patent term by claiming obvious variants of the same or similar subject matter in separate patents. The doctrine applies to all commonly owned patents. Sandoz argued that Immunex effectively owned the licensed patents based on the terms of the agreement, pointing in particular to Immunex's right to control prosecution of the licensed patents and therefore to determine the scope of the claims.

Before reaching the terms of the agreement, the Federal Circuit first considered the appropriate test for ownership-based ODP and concluded only within the circumstances of the case "*where one of the rights transferred is the right to prosecute the patent at issue*," that the identification of the effective patentee "is informative in evaluating whether the patents are commonly owned for purposes of ODP." The court unanimously held that under these circumstances, the "all substantial rights" test achieves the proper balance between gamesmanship in prosecution and avoiding a chilling effect on routine licensing, rejecting Immunex's argument that common ownership-based ODP arises only where inventions are owned by the same entity at the time of invention.

The court then turned to the question of whether Immunex had acquired "all substantial rights" to the exclusively licensed patents from Roche. The terms of the agreement provided Immunex with a paid-up, irrevocable, exclusive license, with the sole right to grant sublicenses, the exclusive right to control prosecution, and first right to rectify any suspected infringement by instituting suit or by giving a sublicense. Immunex further had the right to an assignment of the patents upon request and payment of \$50,000. Roche retained the right to practice the patents for internal, non-clinical use, and the secondary right to sue if Immunex failed to initiate an infringement action. Under the agreement, Immunex could not assign its rights to a third party without Roche's consent.

In a split decision, the Federal Circuit held that the license provisions did not effectuate a transfer of all substantial rights such that Immunex, not Roche, is the owner. The court focused on two features of the agreement: Roche's retained right to sue and Immunex's inability to assign to a third party without Roche's consent. The court explained that "the nature of the licensor's retained right to sue, is frequently the most important consideration," and that "restrictions on the ability to transfer patent rights are inconsistent with a transfer of all substantial rights."

Judge Reyna dissented, arguing that the licensor's enforcement and assignment rights were illusory and did not meaningfully interfere with Immunex's control and enforcement of the patents, as evidenced by Immunex's right to order Roche to assign the patents to Immunex upon payment of \$50,000. Under this backdrop, J. Reyna argued that Immunex effectively owned the licensed patents for ODP purposes.

In its Petition for Certiorari, Sandoz focuses on the extension of patent exclusivity over Enbrel® for "another decade," and the broader concern that Immunex's licensing structure will be "widely emulated" to evade the prohibition on double patenting.

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