

Adding to the Uncertainty of Obviousness-Type Double Patenting

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In *Immunex Corp. et al. v. Sandoz Inc. et al.*, the Federal Circuit found that there was no obviousness-type double patenting because there was no "common ownership" of patents under an agreement where Roche retained key rights to the patents-in-suit. *Immunex Corp., v. Sandoz Inc.*, ___ F.3d ___, No. 2020-1037 (Fed. Cir. July 1, 2020). As set forth below, this case has important implications for both the licensing and prosecution of patents.

To fully appreciate the import of this case, some factual background is necessary: Roche (the patent owner), Immunex (Roche's exclusive licensee), and Amgen (an exclusive sublicensee) sued Sandoz for patent infringement in the District of New Jersey pursuant to the Biologics Price Competition and Innovation Act. Roche's patents-in-suit related to the fusion protein etanercept, the active ingredient in Immunex's Enbrel®, which is used to reduce the symptoms of rheumatoid arthritis. Sandoz did not contest infringement, but instead argued that the patents were invalid. Interestingly, Sandoz sought to invalidate Roche's patents-in-suit for obviousness-type double patenting using Immunex's patents, not Roche's own patents as is typically the case. This argument was based on a novel theory of "common ownership," a prerequisite for a finding of double patenting.

Obviousness-type double patenting is a judicially created doctrine that prevents a party from obtaining an improper extension of the right to exclude through claims in a later-expiring patent that are not patentably distinct from claims in a *commonly-owned* earlier-expiring patent.

In the district court, Sandoz argued that Immunex effectively owned the patents-in-suit by virtue of a license agreement entered into by Roche, Immunex, and Amgen granting Immunex the exclusive right to prosecute the U.S. family of Roche's patents. Borrowing from 35 U.S.C. § 281, which uses an "all substantial rights" test to determine who may sue for infringement as a "patentee," Sandoz contended that the license agreement "transferred all substantial rights in the patents-in-suit to Immunex." The district court disagreed, upholding the validity of the patents, and Sandoz appealed.

On appeal, the Federal Circuit agreed that the "all substantial rights" test could be informative in determining common ownership for obviousness-type double patenting. That is, however, "only where one of the rights transferred is the right to prosecute the patent at issue." Under those circumstances, the Court concluded, the "all substantial rights" test achieves "the proper balance between deterring gamesmanship in prosecution, on the one hand, and avoiding any chilling effect on routine collaborations and licensing between parties working in the same field of research, on the other." To hold otherwise could allow an "effective patentee" to escape double patenting by using the "nominal label of licensee" to extend its patent term.

In this case, however, the license agreement did *not* transfer all substantial rights from Roche to Immunex, and there was thus no common ownership of the patents and no double patenting. Specifically, the license was not "effectively an assignment" because Roche retained several rights to the patents-in-suit, including the secondary right to sue if Immunex did not and the right to the entirety of any award of damages or lost profits. The retention of "such broad right[s]" was "thoroughly inconsistent" with a conclusion that the patents-in-suit were effectively assigned to Immunex. Roche's right to veto any assignment of Immunex's interest in the patents-in-suit further indicated that Roche transferred less than "all substantial rights" to Immunex.

This case illustrates an important practice point: it matters not whether the parties call the agreement a license or an assignment, what matters is the substance of the agreement and the rights conveyed. In diligencing licensed patents, consideration should now be given not only to the enforcement and alienation rights, but also to the right to prosecute the patents under the agreement when assessing double patenting risks. Indeed, a party could create common ownership, and thereby a double patenting risk, by in-licensing two different and unrelated patents on the same technology from two different and unrelated parties.

Conversely, this new double patenting test may provide a new mechanism for patent owners to handle double patenting invalidity arguments during litigation. If the patent owner acquired "all substantial rights" to a patent through a licensing agreement—including the right to control prosecution—it could potentially simply file a terminal disclaimer over its own patents or similar technology licensed from a third party.

This case, unfortunately, creates significant uncertainty for patent prosecutors. Double patenting is frequently raised by USPTO examiners, and the Federal Circuit in *Immunex* made clear that its ruling was intended to deter gamesmanship during prosecution. Does this decision mean that license agreements should now be disclosed during patent prosecution? Is a patent examiner really qualified to assess common ownership from a license, which often is only a small part of a much larger and complex collaboration agreement? Could a failure to disclose a license and thus the effective common ownership of patents be the basis for equitable conduct? These questions were not answered by the Federal Circuit in *Immunex* and will likely generate significant litigation in the years to come. In the absence of guidance from a court, one possible strategy to minimize the risk of an inequitable conduct claim is to obtain an opinion of counsel as to whether "all substantial rights" were indeed conveyed in the relevant license agreement. After all, in the absence of such a conveyance, there can be no common ownership and no double patenting.