

SENJU PHARMACEUTICAL CO. v. APOTEX INC., Appeal No. 2013-1027 (Fed. Cir. March 31, 2014). Before Newman, Plager, and O'Malley. Appealed from D. Del. (Judge Robinson).

Background:

Apotex filed an Abbreviated New Drug Application (ANDA) requesting approval to make and sell a generic version of Senju's patented eye drops. Although the hypothetical ANDA product had not yet been made, the filing of an ANDA signifies an act of infringement by statute. Senju twice sued, alleging infringement of its patent claims.

In the first suit, the district court held that although the ANDA product infringed claims of Senju's patent, the claims were invalid as obvious. Before final judgment was entered in the first suit, Senju filed a request for reexamination, and the PTO issued a reexamination certificate. Still before final judgment in the first suit, Senju filed a second action against Apotex asserting that claims set forth in the reexamination certificate were infringed by the ANDA product. Final judgment was then entered in the first suit (which judgment was appealed to and affirmed by the Federal Circuit). Apotex filed a motion to dismiss the second suit as being barred by claim preclusion. The district court agreed and dismissed the second suit. Senju then appealed to the Federal Circuit in the second suit.

Issue/Holding:

Did the district court err in barring Senju's second action for infringement based on claim preclusion? No, affirmed.

Discussion:

Under the judicial doctrine of claim preclusion, a judgment on the merits will bar a second suit based on the same cause of action ("claim"). To determine whether the cause of action was the same in the first and second suits, the Federal Circuit examined (i) whether the accused product/process was the same in both suits, and (ii) whether the patent rights were the same in both suits. The conclusion was that (i) the hypothetical ANDA product was the same in both suits, and (ii) Senju's reexamined patent rights were the same as under the original patent.

Reasoning that claim scope cannot be broadened by a reexamination, the Federal Circuit determined that the reexamined patent claims were subsumed in the claim scope of the original claims, and thus the narrower reexamined claims' subject matter was necessarily at issue in the first suit. The Federal Circuit thus affirmed the district court and held that claims resulting from reexamination do not create a new cause of action that was not previously available, unless a clear showing is made that a material difference exists between the reexamined claims and the original claims.

Judge O'Malley's dissent pointed out that while the original claims were held invalid as being obvious, the reexamined claims are presumably valid as they were amended to avoid the prior art. Unlike the original claims, the reexamined claims may have actually conferred to Senju actionable legal rights. The dissent noted that amending previously obvious claims to be valid would seem to be in and of itself a "clear showing" that a material difference exists between the reexamined claims and the original claims, and thus new patent rights to consider were at issue in the second suit.