

Federal Circuit Patent Bulletin: *Senju Pharm. Co. v. Apotex Inc.*

March 31, 2014

"[I]n the absence of a clear showing that such a material difference in fact exists in a disputed patentable reexamination claim, it can be assumed that the reexamined claims will be a subset of the original claims and that no new cause of action will be created [for purposes of claim preclusion]."

On March 31, 2014, in *Senju Pharm. Co. v. Apotex Inc.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Plager,* O'Malley) affirmed the district court's dismissal of Senju's suit alleging that Apotex's Abbreviated New Drug Application for generic Zymar® and Zymaxid® infringed reexamined U.S. Patent No. 6,333,045, which related to an ophthalmic solution containing the antimicrobial drug Gatifloxacin and disodium edetate (EDTA), based on claim preclusion due to an earlier infringement action prior to the '045 patent reexamination. The Federal Circuit stated:

"[U]nder the doctrine of res judicata, a judgment 'on the merits' in a prior suit involving the same parties or their privies bars a second suit based on the same cause of action." . . . We look to the law of the regional circuit in which the district court sits for guidance regarding the principles of claim preclusion; however, whether a particular cause of action in a patent case is the same as or different from another cause of action has special application to patent cases, and we therefore apply our own law to that issue. Under Third Circuit law, the home circuit of the district court in this case, claim preclusion principles require: "(1) a final judgment on the merits in a prior suit involving[] (2) the same parties or their [privies]; and (3) a subsequent suit based on the same cause of action." . . .

In applying the policies expressed by the doctrine of claim preclusion, our court has identified certain significant factors to be considered in determining when a cause of action is the same. . . . One of the areas of factual overlap that we consider in a patent case involving claim preclusion is the overlap of the product or process accused in the instant action with the product or process accused in the prior action. If the products or processes are essentially the same, then claim preclusion may apply. We also consider whether the same patents are involved in both suits. Ordinarily, "[e]ach patent asserted raises an independent and distinct

cause of action.” Claim preclusion will generally apply when a patentee seeks to assert the same patent against the same party and the same subject matter. . . .

In its first suit, Senju alleged infringement based on Apotex’s ANDA No. 79-084 and its described Gatifloxacin ophthalmic solution. In its second suit, this case, Senju requested a declaratory judgment of infringement based on Apotex’s submission of the same ANDA (No. 79-084). Thus, both actions involve the same Gatifloxacin ophthalmic solution described in ANDA No. 79-084. Because the product in the second action completely overlaps with the product in the first action, there is on that basis no new cause of action.

The more difficult question is whether the same patent, or more precisely the same patent rights, were involved in both suits. Senju argues that the reexamination created a new cause of action because the reexamined patent claims are substantially different from the claims in the original ’045 patent. The reexamined claims are different according to Senju because they include the amount of Gatifloxacin or its salt, the pH range, and the amount of EDTA, none of which are included in the original claims. . . . Apotex responds that the district court correctly dismissed Senju’s case. According to Apotex, in order for Senju to comply with the statutory requirements for reexamination outlined in 35 U.S.C. § 305, the claim scope of its reexamined ’045 claims had to be the same as or narrower than the claim scope of the original ’045 claims. Since the claim scope of Senju’s reexamined ’045 claims was subsumed by the claim scope of its original claims, Apotex contends that the ’045 reexamined patent did not give Senju any additional rights against Apotex’s product that Senju did not already possess in its first lawsuit. Apotex argues [that] reexamined claims cannot create a new cause of action that did not exist before. According to Apotex, Senju has engaged in ‘claim splitting,’ and its second suit, the instant suit, is barred by claim preclusion.

On these facts we believe Apotex has the better argument. . . . [C]laims that emerge from reexamination do not in and of themselves create a new cause of action that did not exist before. We reach this conclusion because a so-called “reexamined patent” is the original patent; it has just been examined another time as indicated in its reexamination certificate. Reexamination does not involve the filing of a new patent application nor the issuance of a new patent. The reexamination process does permit some amendment of the patent and its claims, but any amendment that occurs during reexamination is statutorily constrained. For example, amendments to the disclosure cannot introduce new matter. Any change to the original patent is further constrained by 35 U.S.C. § 305, which states that “[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter.” We have strictly interpreted § 305 to prohibit any broadening amendments. The reexamined claim cannot be broader in any respect, even if it is narrowed in other respects. Therefore, while reexamination can make certain changes in the patent, such changes are strictly circumscribed by the original patent’s disclosure and claim

scope. As a result, a reexamined patent claim cannot contain within its scope any product or process which would not have infringed the original claims. Put another way, because the patent right is a right to exclude whose outer boundary is defined by the scope of the patent's claims, . . . reexamination does not provide larger claim scope to a patentee than the patentee had under the original patent claims. . . .

Whether it is possible that a reexamination could ever result in the issuance of new patent claims that were so materially different from the original patent claims as to create a new cause of action, but at the same time were sufficiently narrow so as not to violate the rule against reexamined claims being broader than the original claims, is a question about which we need not opine—that is not the case before us. We hold that, in the absence of a clear showing that such a material difference in fact exists in a disputed patentable reexamination claim, it can be assumed that the reexamined claims will be a subset of the original claims and that no new cause of action will be created. This applies whether the judgment in the original suit was based on invalidity of the claims or simply on non-infringement.