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Cases Update

International roundup of recently filed cases and noteworthy rulings

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*Endo Pharmaceuticals Inc.
v. Actavis, Inc.*

US Court of Appeals for the Federal
Circuit, March 31

In this ruling, the US Court of Appeals for the Federal Circuit vacated a denial of a preliminary injunction by the US District Court for the Southern District of New York, holding that the doctrine of legal estoppel does not grant an implied license to use patents that are not continuations of, or related to, licensed patents. The patent in question is related to oxymorphone, which is contained in Opana ER, a painkiller owned by Endo Pharmaceuticals. After Roxane Laboratories, Inc., Actavis, Inc, and Activis South Atlantic, LLC filed an Abbreviated New Drug Applications to market generic versions of Opana, however, Endo sued Actavis for patent infringement. These lawsuits settled after Endo granted Roxane and Actavis licenses and covenants not to sue on specified patents related to oxymorphone as well as any continuations, continuations-in-part and divisional applications claiming priority to those patents. After the agreement, two new patents were issued to Endo, and Endo acquired a third patent. None of these three patents is listed or defined in the earlier licenses. Endo sued Roxane and Actavis for infringing these three patents, and moved for a preliminary injunction to prevent the marketing and sales of Roxane's and Actavis' generic oxymorphone formulations. Roxane and Actavis opposed the preliminary injunction on the theories of express license and implied license by reason of legal estoppel, which the district court denied. The Federal Circuit vacated and remanded the district court's decision, where: the district court erred in concluding that defendants had the district court's order denying plaintiff's motions for a preliminary injunction to prevent defendants from marketing and selling their respective generic drug versions of Opana[®] ER during the pendency of this litigation, is an implied license to practice the asserted patents; and defendants do not have an express license.

Source: www.ca9.uscourts.gov/images/stories/opinions-orders/13-1658.Opinion.3-27-2014.1.PDF

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*Senju Pharmaceutical Co.
v. Apotex Inc.*

US Court of Appeals for the Federal
Circuit, March 31

The Federal Circuit affirms the district court's decision granting Apotex's motion to dismiss a second suit based on Senju's re-examined patent, US 6,333,045, an ophthalmic solution containing the drug Gatifloxacin and EDTA to allow a drug to pass into, and treat, the space between the cornea and the lens. In 2011, Senju filed a new action against Apotex alleging infringement of re-examined claims on the mentioned patent. However, the district court dismissed the second action because the re-examined claims "[did] not create any new cause of action that plaintiffs lacked under the original version of the patent." The Federal Circuit first concluded "the product in the second action completely overlaps with the product of in the first action" and "there is on that basis no new cause of action." They also stated that, "precisely the same patent rights were involved in both suits," and the Federal Circuit agreed with Apotex that "re-examined claims cannot create a new cause of action that did not exist before."

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/13-1027.Opinion.3-26-2014.1.PDF

*Shire Development, LLC v.
Watson Pharmaceuticals, Inc.*

US Court of Appeals for the Federal
Circuit, March 28

In this decision, the Federal Circuit reversed and remanded the district court's constructions of the terms 'inner lipophilic matrix' and 'outer hydrophilic matrix', finding that the defendant's product infringed the plaintiff's patent, which claims a controlled-release oral pharmaceutical composition of the patent relating to mesalamine in the treatment of inflammatory bowel disease. The district court decision was based on its determination of the meaning of the claims terms 'inner lipophilic matrix' and 'outer hydrophilic matrix' as "a matrix including at least one lipophilic excipient, where the matrix is located within one or more substances" and "a matrix of at least one hydrophilic excipient, where the matrix is located outside the inner lipophilic matrix," respectively. The Federal Circuit panel determined, however, that "[t]hese constructions do not reflect the ordinary and customary meaning of the claim terms in light of the evidence and are impermissibly broad." Regarding the 'inner lipophilic matrix', it found the district court erroneously focused "on the lipophilic properties of an excipient in the matrix, rather than the properties of the matrix itself." The Federal Court explained that these statements "do inform the claim construction" and ultimately concluded, based on "[t]he prosecution history, the structure of the claim itself, the ordinary meaning of the claim terms, including the Markush group limitations, and the patent's description of the invention that the inner lipophilic matrix is separate from the outer hydrophilic matrix."

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/13-1409.Opinion.3-26-2014.1.PDF

*Alcon Research, Ltd.
v. Barr Laboratories, Inc.*

US Court of Appeals for the Federal
Circuit, March 18

The Federal Court affirmed and reversed in part a district court's decision relating to two of Alcon's US patents relating to methods for making prostaglandin compositions (using polyethoxylated castor oil [PECO]) and holding those claims invalid for lack of enablement and written description. Alcon appealed the final judgment of the district court's decision that Barr does not infringe claims to two of its patents after Barr submitted an Abbreviated New Drug Application (ANDA) for a generic version of Travatan Z®. Alcon asserted Barr's ANDA filing was an act of infringement of the '287 and '062 patents even though they were not listed on the Orange Book. The district court construed the '287 claim term "enhancing

the chemical stability” to mean “to increase or increasing the ability of the prostaglandin to resist chemical change (as distinguished from merely increasing the physical stability of the prostaglandin or composition), i.e., ‘reducing or decreasing [travoprost] degradation’”. It also construed the claim term ‘prostaglandin’ to correspond to the written description “regarding the prostaglandins that may be used with the invention.” Barr was found not to infringe the patents because Alcon’s comparison study tested a significantly different composition from that proposed in Barr’s ANDA, which the Federal Court agreed. However, the Federal Circuit reversed in part and remanded the district court’s decision where the district court’s invalidity determinations as to the asserted claims of the ‘287 and ‘062 patents were not in accordance with law.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/12-1340.Opinion.3-12-2014.1.PDF

Council regulation (EC)
469/2009 concerning the
creation of a supplementary
protection certificate for
medicinal products dated
March 31, 2014 UKIPO

**Medical Devices are not protected
by SPC, Cerus cases (SPC/GB/07/043
& SPC/GB/07/044)**

The challenge for Supplemental Protection Certificate (SPC) for medical devices based on two European Design Examination Certificates (G7 02 05 16178 063 [SPC/GB/07/043] and G7 06 09 60562 004 [SPC/GB/07/044], related to platelet preparation) has been denied. These relate to medical devices that meet the criteria of Article 1(4) of Directive 93/42/EEC because the device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which acts upon the body with action ancillary to that of the device. Therefore, they fall within class III medical devices and the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in the medicinal products legislation (Directive 2001/83/EC). It was argued that Class III devices require explicit prior authorization with regard to conformity is required for such devices to be placed on the market since Class III devices have the highest risk potential in terms of the vulnerability of the human body, and as such. As a consequence of the need to assess the substance as part of the assessment of the device overall, the applicant argued that these EC Design Examination Certificates can, as a consequence, be considered to meet the requirements of Art 3(b) of the SPC regulation (i.e., they represent a valid authorization to place, on the market as a medicinal product, the product for which an SPC has been applied for). The decision held that “[as] ... these two SPC applications do not comply with the conditions for obtaining a certificate because the authorizations filed in support of these applications do not comply with Article 3(b) of the Regulation, which requires that the authorization is “granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC as appropriate.”

Sources: www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/141/14; www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/o14114.pdf

Hoffman-La Roche Inc. v. Apotex Inc. et al.

US Court of Appeals for the Federal Circuit, April 11

Patents directed to methods of treating osteoporosis through the once-monthly, 150 mg oral administration of a drug have been invalidated by the Court of Appeals for the Federal Circuit (CAFC), as being obvious over the prior art. The target drug is bisphosphonate sodium ibandronate (Boniva®), one of a class of compounds known as bisphosphonates, which was approved by the US FDA in 2005. The defendants, generic drug manufacturers, filed an Abbreviated New Drug Applications (ANDA) seeking approval to manufacture and sell generic versions of Boniva® before expiration of the plaintiff's patents, and the plaintiff sued under 35 USC § 271(e)(2) based on the defendants' ANDA filings. Roche moved for a preliminary injunction. The district court denied the motion, holding that Roche had failed to prove it was likely to succeed in defeating the defendants' obviousness challenge. The District Court found the claimed method of treatment obvious and the Federal Circuit affirmed. Specifically, the issue was whether it would have been obvious at the time of invention to select a once monthly oral dosing regimen of ibandronate to treat osteoporosis and to set that dose at 150 mg. The court held that "[conclusive] proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success" and held that "established at least a reasonable expectation that once monthly dosing of ibandronate could successfully treat osteoporosis and reduce fracture risk." Furthermore, regarding selecting the 150 mg dose was "it was reasonable to expect that a once monthly dose of 150 mg would have roughly the same efficacy as a daily dose of 5 mg. Safety and unexpected results were also considered; however, the patents were held invalid.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/13-1128.Opinion.4-8-2014.1.PDF

Hospira UK Limited v. Genentech Inc.

US Court of Appeals for the Federal Circuit, April 10

The England and Wales High Court held that EP 1 210 115 entitled 'Dosages for treatment with anti-ErbB2 antibodies' and EP 1 308 455 entitled 'A composition comprising anti-HER2 antibodies' covering Roche's blockbuster breast cancer drug Herceptin in UK are invalidated. Hospira wishes to sell a generic form of trastuzumab in the UK, but does not challenge the basic underlying patent held by Genentech on trastuzumab (EP 0 590 058). There is a supplementary protection certificate for that patent (SPC/GB04/015). This patent expires on July 28, 2014 and Hospira told the court it wanted to sell its version of the product, known generically as trastuzumab, after that date. Such a move would ramp up competition for a costly cancer treatment and could drive down prices. The issues are priority and obviousness for the 115 case. The key item of prior art is the FDA label for Herceptin, which was published when the product was approved by the FDA. During the dispute, Genentech made an application to amend the claim to include a reference to "intravenously". By the closing this was the only claim to be focused upon. The court concluded that "[claim 1] of the 115 patent would be obvious to the skilled team having regard to the FDA label in the light of the common general knowledge." The 455 patent is concerned with purifying trastuzumab. Hospira argues that claims 1, 2 and 4 lack novelty over a previous Genentech's WO 97/04801. Hospira also relies on slides presented at a Waterside conference containing analytical data in the context of Phase III trials. It was argued that the invention in 455 is obvious starting from these slides or from the common general knowledge alone. The court also found the 455 patent obvious and thus both patents have been invalidated.

Source: www.bailii.org/ew/cases/EWHC/Patents/2014/1094.html

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