Cases Update

International roundup of recently filed cases and noteworthy rulings

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Leo Pharmaceutical Products Ltd. v. Rea

US Court of Appeals for the Federal
Circuit, August 12

In this ruling, the CAFC ruled that the USPTO is no different from a district court in the requirement to assess objective indicia of nonobviousness in a patent re-examination proceeding. Leo Pharmaceutical Products appealed BPAI claim construction and obviousness findings regarding its US 6,753,013 patent relating to 'storage stable' compositions for treating skin conditions such as psoriasis by simultaneous treatment with vitamin D and corticosteroids. Leo recognized a storage stability problem (doctors were prescribing vitamin D and corticosteroids separately) and "*discovered that a new set of solvents, including polyoxypropylene 15 stearyl ether (POP-15-SE) solved the storage stability problem*", but that other ingredients (aqueous alcohol-based solvents, and propylene glycol/almond oil) did not. The Board construed the terms 'storage stable' and 'non-aqueous' and rejected Leo's claims as obvious over three prior-art references. The Federal Circuit therefore vacated the Board's construction, but declined to adopt an alternative construction as it was unnecessary to resolve the appeal.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/12-1520.Opinion.8-8-2013.1.PDF

Bayer Cropscience AG v. Dow Agrosciences LLC

US Court of Appeals for the Federal
Circuit, September 3

In this ruling, the Federal Circuit affirmed the District Court's decision on construing the term 'the biological activity of 2,4-D-monooxygenase' according to its plain scientific meaning. The patent at issue related to genetically modifying plants to confer resistance to the herbicide '2,4-D' by inserting a gene that is capable of turning the herbicide into '2,4-DCP.' During development, the scientists characterizing the process believed the enzyme to be a monooxygenase, which uses one oxygen atom in the process of breaking down the herbicide, and incorporates the other oxygen atom into a water molecule. As such, the initial patent application was drafted to include the term 'monooxygenase' in certain claims. During filing of the patent application, however, the Bayer scientists discovered that the enzyme responsible for the herbicide resistance was not a monooxygenase,

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but a dioxygenase. The patent claim language was not changed, and the patents were issued with the term ‘monooxygenase’. The court held that Bayer’s proposed construction ignored the strong accepted scientific meaning of the phrase ‘2,4-D monooxygenase’ and nothing in the intrinsic record supported such a broad construction. The court held that Bayer’s proposed construction ignored the strong accepted scientific meaning of the phrase ‘2,4-D monooxygenase’ and nothing in the intrinsic record supported such a broad construction.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/13-1002.Opinion.8-29-2013.1.PDF

St. Jude Medical, Inc. v. Access Closure, Inc.

US Court of Appeals for the Federal Circuit, September 11

The CAFC has revisited the issue of the safe harbor provisions of 35 U.S.C. § 121 from the judicially created doctrine of obviousness-type double patenting rejection. Previously, it has been held that the continuation or continuation-in-part applications could benefit from the safe harbor. In the subject case, however, the CAFC examined whether the effects of election-of-species requirements on whether there is consonance between claims in one patent over those on a related patent in which such a requirement is imposed. The patents in issue are US Patent No. 7,008,439, 5,275,616, and 5,716,375 are directed to sealing vascular puncture, and the patents relevant to the double patenting issues are a grandparent application, USSN 07/746,339 (USP5,391,183), a divisional application thereof, USSN 08/318,380 (USP5,830,130) and its two continuation applications (USSN 08/399,535 (USP7,008,439), and USSN 08/712,772 (USP5,725,498). The USPTO imposed a restriction requirement in the ‘339 application, wherein Group I was directed to apparatus claims and Group II directed to method claims, and an election-of-species requirement between Species A, B and C. In the ‘339 and ‘380 applications, the Applicant elected I/B for both and subsequently granted. The ‘535 application-in-suit contains I and II/C, whereas the ‘772 application contained II/no species election. The district court held that the safe harbor protected the subject case from invalidity under obviousness-type double patenting. The CAFC, however, reversed the District Court’s decision. It was argued that, “*the election of species did not affect the line because an election of species is inherently different from a restriction requirement.*” However, the CAFC found that “[*the*] election of species in the grandparent created a restriction”, and continued, “[*It*] makes logical sense that the election of species affected the line of demarcation when no claim was generic. If the election of species did not affect the line, double patenting would have prevented the Janzen applicant from obtaining valid claims directed to non-elected species. This result would be unfair since it was the examiner, not the applicant, who created the further division of the application with the election of species, and the examiner already stated on the record that the non-elected species were patentably distinct from the elected species. The unfairness of the result would violate the purpose of the safe harbor.” As such, the CAFC found that one of patents-in-issue was invalid under the doctrine of obviousness-type double patenting.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/12-1452.Opinion.9-6-2013.1.PDF

Pronova Biopharma Norge AS v. Teva Pharmaceuticals USA, Inc.

US Court of Appeals for the Federal Circuit, September 12

This decision is directed to a case where the Federal Circuit has invalidated the claims to Orange Book-listed patents, directed to Lovaza®, a formulation of specific omega-3 and omega-6 fatty acids for prevention of heart disease and other cardiovascular diseases. The subject case arises from ANDAs filed by Teva Pharmaceuticals USA Inc. and Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.. The District Court for the District of Delaware found the patents infringed, not proven invalid by clear and convincing evidence, and not unenforceable for inequitable conduct. The CAFC overturned the district court decision by holding that the Pronova's predecessor, Norsk Hydro, had permitted unrestricted use of formulations falling within the scope of the claims and disregarded Pronova's argument that public use was negated because there was insufficient evidence that the use was for the inventions' intended purpose. Specifically, the CAFC stated that the standard for public use is where *"a completed invention is used in public, without restriction,"* and citing from the case law *"[An] agreement of confidentiality, or circumstances creating a similar expectation of secrecy, may negate a 'public use' where there is not commercial exploitation"* (secrecy), and also stating *"public use may occur when 'a completed invention is used in public, without restriction', and 'a disclosure of some aspects of an invention, but not all, will likely preclude a finding of public use'"* (completeness) and insufficiency control. Finally, the Court also referred the *"sophistication of those to whom disclosure was made"* as a factor in the extent to which a use is a public use. Although the Court found that not all elements of the public use test have been shown, the Court dismissed the Pronova's arguments that the skilled in the art (Dr Skrinska) had not used the formulation for its intended use by stating *"...a compound is provided without restriction to one highly skilled in the art, that compound's formulation is disclosed in detail, and the formulation is subject to confirmatory testing, no other activity is needed to render that use an invalidating one. Once the formulation was disclosed in full to Skrinska, without any restriction on its use, it had been released into the 'public domain' for purposes of § 102(b)"*. As such, the CAFC reversed the District Court judgment and remand with orders to enter judgment in favor of Appellants.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/12-1498.Opinion.9-10-2013.1.PDF

Sunovion Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.

US Court of Appeals for the Federal Circuit, September 26

In this decision, the Federal Circuit reversed and remanded the district court's decision concerning Sunovion's patent, which is directed to pharmaceutical compositions of the single-enantiomer drug eszopiclone, the active ingredient in the chiral drug marketed as a sleep medication with the brand name Lunesta®. Sunovion appealed the district court grant of summary judgment to Dr Reddy's that it does not infringe claims 1, 2 and 8 of the '673 patent encompassing pharmaceutical compositions of the single-enantiomer drug (S)-eszopiclone. In approving Lunesta, the US FDA required it to contain not more than 0.3% of the corresponding levorotatory enantiomer, (R)-zopiclone. Following a *Markman* hearing, the district court construed the term 'essentially free' [of its levorotator isomer] of the disputed claims to mean *"less than 0.25% of [the] levorotatory isomer."* The district court found no plain meaning or definition in the intrinsic evidence but found Sunovion to be bound by the prosecution history (inventor declaration, amendments and arguments). Reddy's original ANDA specification requested approval for generic eszopiclone products with *"[n]ot less than 0.3% and [n]ot more than 1.0%"* levorotatory isomer. Ultimately, Reddy received approval for a product restricted to 0.0–0.6% levorotatory isomer. Reddy also submitted a declaration to the district court, but not the FDA, that it would not produce a product containing less

than 0.3% levorotatory isomer. The district court then granted summary judgment of noninfringement. The Federal Circuit agreed with the district court claim construction finding, for instance, that “[t]he term ‘essentially free’ appears only in the claims...and does not appear anywhere in the written description.” However, the panel disagreed with the district court regarding infringement, finding that “if a product that an ANDA applicant is asking the FDA to approve for sale [0.0–0.6%] falls within the scope of an issued patent [less than 0.25%], a judgment of infringement must necessarily ensue.” The claim construction determination was affirmed, but the infringement decision reversed.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/13-1335.Opinion.9-24-2013.1.PDF

*Genentech Inc. v.
The Commissioner of Japan
Patent Office*
IP High Court of Japan, September 30

This is a case concerning how to evaluate the scope of the claims when examining a patent term extension (PTE) application due to drug market authorization. The IP High Court of Japan (IPHC-J) held that even if the product in issue, which is subject to market authorization, does not literally fall within the scope of the patented claim(s), if the difference is due to obvious error and those skilled in the art would readily understand what the error is, and thus the product in issue would fall within the scope of the claims if the error were corrected, then a PTE shall be granted. In the subject case, the Plaintiff or patentee Genentech sought for a 5-year PTE for omalizumab, an antibody drug for asthma, due to the delay of market authorization or approval in Japan. However, the Japan Patent Office rejected this as the product in issue does not fall within the scope of the claims as the claimed invention has an additional two amino acids (residues 125 Lys and 126 Gly) inserted vis-à-vis the product in issue. However, Genentech argued that the two amino acid insertions are obvious error and in view of the specification and the common general knowledge in the art, then the claims should be interpreted taking such errors into account and, thus, such two amino acids should be deleted when properly interpreted. Specifically, the claim in issue is directed to a specific antibody (an antibody comprising a Fab H chain amino acid sequence and an L-chain amino acid sequence of humanized murine antibody humae11ver.1, set forth in SEQ ID NOs: 8 and 9, in which residue 60 is substituted with aspartate and residue 61 is substituted with proline and residue 67 is substituted with isoleucine.). On the other hand, the errors are found in the other portions of the antibody, which do not contribute the technical character of the patented invention in view of common general knowledge in the art. As such, the IPHC-J accepted Genentech's arguments and approved the 5 year PTE. The PTE judgment is related to the interpretation of a granted patent claim and, thus, may have an influence in the enforcement of a biotechnology patent.

Source: www.courts.go.jp/hanrei/pdf/20131002105019.pdf

*Sawai Pharmaceutical Inc. v.
Daiichi-Sankyo Inc.*

IP High Court of Japan , October 16

The subject case is directed to a combination drug of carvedilol, a nonselective β -blocker/ α -1 blocker or a congestive heart failure drug, with another drug selected from the group consisting of angiotensine-converting enzyme inhibitors, diuretics and cardiac glycosides. The issue is predictability of the claimed invention and evaluation of the effects attained by the claimed invention. The claimed invention is directed to long-term administration of carvedilol for at least 6 months, while the prior art only teaches short-term administration thereof such as 8 weeks at most. The Japan Patent Office (JPO) decided that the prediction was not readily available and, thus, the case is not obvious over the prior art. In terms of unexpected result of reduction in mortality, the JPO's original decision held that the result was unexpectedly low in view of the prior art. However, the IP High Court of Japan (IPHC-J) held that the result was to be expected because the results in the specification are 'exaggerated' in view of post-priority date evidence. In this regard, when evaluating the level of credibility of the specification, the IPHC-J employed evidence published after the priority date, wherein the IPHC-J also judged that such post-priority date evidence may be employed and considered when judging the credibility of the experimental data included in the specification. Additionally, this case has a complex litigation history wherein a correction appeal was filed and the patentee, Daiichi-Sankyo, prevailed and the IPHC-J previously held that the patent-in-issue is not obvious and thus should be patentable. The patentee argued that the subject case should be bound to the previous judgment of the decision; however, the IPHC-J held that the Court is not bound to such a decision, but only the JPO, and new arguments and evidence can be presented and considered. The case therefore raises warning to patentees that even if they prevail in the correction appeal, in which the JPO judges patentability, such a favorable decision does not always guarantee that the case will be patentable in the subsequent suits.

Source: www.courts.go.jp/hanrei/pdf/20131021100509.pdf

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