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ADDITIONAL DEVELOPMENTS—PATENT

BAYER AG V. HOUSEY PHARMACEUTICALS., INC.

340 F.3d 1367 (Fed. Cir. 2003)

The Federal Circuit held that the scope of protection provided by 35 U.S.C. § 271(g) is limited to physical products that have been manufactured. The definition includes products not directly made by the patented process and excludes the production of information.

Housey Pharmaceuticals, Inc. ("Housey") holds a number of process patents useful for screening products for use as drugs. Bayer AG and Bayer Corporation ("Bayer") sought a declaratory judgment of invalidity, unenforceability, and noninfringement of Housey's patents. Housey counter-claimed and alleged both direct and contributory infringement of its patents as well as infringement under 35 U.S.C. § 271(g), which prohibits importation of a product made using a process patented in the United States. Bayer filed a motion to dismiss, arguing that § 271(g) only applies to methods of manufacture and does not apply to methods of use. Housey argued that Bayer violated § 271(g) in two ways: 1) by selling an inhibitor or activator of a target protein that Housey's patent taught and 2) by importing information derived by using the patented process. The district court granted Bayer's motion to dismiss, holding that § 271(g) applies only to products manufactured using a patented process, and Housey appealed to the Federal Circuit.

The Federal Circuit focused on the meaning of the term "made" in the phrase "a product which is made by a [patented] process" in § 271(g). Housey argued that the information Bayer derived by using the patented process was "made" within the scope of § 271(g). In contrast, Bayer argued that "made" is synonymous with the word "manufactured" and that information is not a manufactured product. The court determined that the plain meaning of "made" was ambiguous and therefore looked to other sources for clarification of the meaning. The court first consulted other sections of the Omnibus Trade and Competitiveness Act of 1988, which was the bill that created § 271(g). The court found that all references in the bill suggested an understanding on the part of Congress that "made" referred to the manufacture of tangible goods. This interpretation was strengthened by two exceptions to § 271(g) that exclude products which have been "materially changed" or have "become trivial and nonessential components." According to the court, both of these exceptions contemplate the manufacture of tangible products rather than intangibles such as information. After looking to these statutory sources, the court explored the legislative history of § 271(g). The court found that "[e]ach and every reference to the provision that became section 271(g) describes it as directed to manufacturing." The court noted that if Congress intended § 271(g) to apply to information it should have made that intention explicit.

The court also held that § 271(g) allows infringement actions based on the importation of products manufactured using a patented process, even if the patented process is not used to directly produce the product. *See* Bio-Technology Gen. Corp. v. Genentech Inc., 80 F.3d 1553, 1561 (Fed. Cir. 1996) (making a protein using a cell line expressing the protein from a plasmid was infringement under § 271(g) when process for making the plasmid was patented). In this case, unlike *Genentech*, the court held that Bayer's use of Housey's process to screen compounds was not sufficiently involved in the process of manufacture of the accused product to constitute infringement.

The Federal Circuit affirmed the dismissal of Housey's claims of infringement.

ELI LILLY & CO. V. BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON

334 F.3d 1264 (Fed. Cir. 2003)

The Federal Circuit ruled that the Board of Patent Appeals and Interferences ("Board") committed no reversible error in interpreting 37 C.F.R. § 1.601(n). This regulation imparts a "two-way test" for deciding whether two inventions are the same for patent interference purposes. Under the two-way test, the Patent and Trademark Office (PTO) would declare an interference only if competing genus and species claims, regardless of presumptive seniority, anticipated or rendered each other obvious.

Eli Lilly filed a reissue application (No. 09/185,663 or "the '663 reissue application") of its U.S. Patent No. 4,775,624 ("the '624 patent") and requested an interference proceeding between the reissue application and U.S. Patent No. 5,302,529 ("the '529 patent") held by the Regents of the University of Washington. Since the '624 patent was filed earlier than the '529 patent, Lilly's reissue application would have been the senior party of the interference. Lilly's proposed count for the interference was claim 1 of the '529 patent, which claimed cDNA coding for a particular amino acid sequence. The Board found that whether claim 1 of the '529 patent was construed as a genus or as a species, it still did not define the same patentable invention as the claims in the '663 reissue application. The Board therefore rejected Lilly's interference request for a lack of interference-in-fact.

Lilly appealed to the Federal Circuit, claiming that the Board wrongly applied a two-way test in determining whether the two inventions were the same or not for interference purposes. Lilly argued that 37 C.F.R. § 1.601(n) only calls for a one-way test. The Federal Circuit disagreed.

The Federal Circuit noted that 35 U.S.C. § 135(a) indicated Congress' preference that declaration of an interference be left to the discretion of the PTO, and that the Director's interpretation of PTO regulations was controlling unless it was "plainly erroneous or inconsistent with the regulation." Focusing on the "same invention" definition of 37 C.F.R. §1.601(n), the Federal Circuit found that the Board's two-way test was consistent with the text of § 1.601(n), because it is not conclusively known which of the two inventions in the interference is the prior art, as mentioned in § 1.601(n). When both inventions can be prior art, the test for patentability should be conducted both ways. In addition, the court found that the Board's two-way test avoided the proliferation of unnecessary, wasteful interference proceedings and concluded that both parties were entitled to patents in situations in which the claimed inventions did not define the same patentable invention, but merely overlapped in scope.

Focusing on the genus-species context, the court noted that case law had firmly established that an earlier species claim prevented a later genus claim, but an earlier disclosure of a genus did not necessarily prevent later patenting of a species. Therefore, in this context, the two-way test was underinclusive (meaning an interference would not be declared when a species was in fact invented before the genus, resulting in the grant of an invalid genus patent), and the one-way test was overinclusive (meaning an interference would be declared when the genus was in fact invented before a species and when both can be patented, resulting in a waste of PTO resources). The court opined that § 1.601(n) could be reasonably interpreted to require an election of either a one-way or a two-way test. The Board's election of a two-way test was therefore reasonable.

OMEGA ENGINEERING, INC. V. RAYTEK CORP.

334 F.3d 1314 (Fed. Cir. 2003)

The Federal Circuit held that "means for causing" (or means-plus-function) claims must be given full ordinary meaning during claim construction and that prosecution history estoppel limits the claimed function, but it may not bar the inventor from claiming the function.

Omega Engineering, Inc. ("Omega") owns patents on a laser sighting system for infrared thermometers, which are also called radiometers. A radiometer measures an object's temperature remotely by assessing the amount of infrared radiation emitted from the object. To accurately measure the temperature of a target area, it is important to determine the target area within the radiometer's optical field of view, or the "energy zone." Written in means-plus-function format, the asserted claims cover a device using one or more laser beams to outline the energy zone. The accused devices have laser beams directed to the periphery as well as the center of the energy zone. The district court interpreted the phrase "to outline the energy zone" and equivalent phrases in the claims as precluding any laser beam from striking within the energy zone. Based on such a construction, the district court granted summary judgment of noninfringement in favor of defendants. Omega appealed.

The Federal Circuit reversed. The court rejected the district court's claim construction, holding that the claimed function is to cause at least one laser beam to strike the border of the energy zone and visibly outline it without adding significant heat that would affect the accuracy of the temperature measurement. The Federal Circuit held that the claim language must be given its full ordinary meaning and the patentee's express disclaimers are the only limits. It further found that district court erred in adding a negative limitation to exclude any laser beam from striking the *interior* of the energy zone, where the explicit claim language and the written description merely requires that the laser beam strike the *periphery* of the zone.

Where the patentee has expressly disavowed a particular meaning to avoid prior art, the doctrine of prosecution history estoppel prevents him from recapturing that meaning through claim interpretation. The Federal Circuit found that to overcome the Examiner's obviousness rejection, Omega repeatedly insisted that its claimed invention differed from the prior arts by not adding appreciable heat to the energy zone and thus not affecting the accuracy of the temperature measurement. The Federal Circuit ruled such a prosecution disclaimer added a limitation to Omega's claimed function, but not to the extent that Raytek argued. That is, the court found that Omega did not clearly bar itself from claiming an invention that directs a laser beam into the interior of the energy zone.

Based on its claim construction, the Federal Court found that a reasonable jury could reach a different conclusion as to whether the accused device adds any appreciable heat to the energy zone by directing a laser beam to the center of the zone. Thus, the court reversed the summary judgment of noninfringement.

SCHERING CORP. V. GENEVA PHARMACEUTICALS, INC.

339 F.3d 1373 (Fed. Cir. 2003)

The Federal Circuit held that a prior patent on a drug inherently anticipates broad compound claims to the metabolite, which is a compound formed by the human body upon ingestion of the drug.

Schering Corporation ("Schering") owned U.S. Patent No. 4,282,233 ("the '233 patent") on loratadine, which is an anitihistamine. Loratadine is the active component of CLARITIN TM, which treats allergic reactions without causing drowsiness. Schering also owned U.S. Patent No. 4,659,716 ("the '716 patent"), which issued six years after the '233 patent. The '716 patent covers a metabolite of loratadine called descarboethoxy-loratadine ("DCL"), which forms naturally in the body after ingesting loratadine. Upon expiration of the '233 patent, numerous pharmaceutical companies sought FDA approval to market generic versions of loratadine, whereupon Schering sued them for infringement of the '716 patent. At issue was the validity of claims 1 and 3 of the '716 patent, which are chemical compound claims to the structural formula of DCL, its fluorine analog, and their salts. The parties agreed to the district court's broad interpretation that claims 1 and 3 cover DCL metabolized by the human body as well as isolated and purified DCL. The district court invalidated both claims since it found that the prior art '233 patent anticipated them.

The Federal Circuit affirmed the district court's holding. The court ruled that a single prior art reference inherently anticipates a claimed invention that is "necessarily present" as a "natural result flowing from" the explicit prior art disclosure. Summary judgment was appropriate because there was "extensive" evidence supporting the district court's finding that consumption of loratadine by humans necessarily and naturally results in the production of the DCL metabolite in the human body. The court acknowledged that inherency had heretofore been needed to supply only a single missing feature of an otherwise express disclosure of claim limitations, and that the '233 patent lacked any explicit description of the later claimed DCL. However, since inherent disclosures place material in the public domain just as much as express disclosures do, the court concluded that a claim is invalid even if its entire subject matter, including all limitations, has been inherently anticipated. The Federal Circuit also ruled that inherent anticipation requires neither actual recognition in the prior art nor that a person of ordinary skill in the art would have recognized the inherent disclosure prior to the critical date of the '716 patent. Based on these considerations, the Federal Circuit concluded that the district court properly granted the defendant's motion for summary judgment.

The Federal Circuit clarified that its decision does not preclude patent protection for chemical products of "known drugs." The court stated that the drafter may claim the purified and isolated metabolite or the method for administering the chemical compound. It found that the '233 patent did not disclose isolation or administration of DCL and therefore claims 5-13 and 14-16 of the '716 patent are valid.