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CONTENTS

HOW BROAD CAN A NEGATIVE CLAIM LIMITATION BE?

By Weiwen Tan, Technical Specialist (wtan@ipfirm.com)

Imaginal Systematic, LLC v. Leggett & Platt, Inc., slip ops. 2014-1845 (Fed. Cir. Nov. 10, 2015).

Imaginal's U.S. Patent No. 5,904,789 (the "'789 patent") claims the use of a camera-based guidance in manufacturing a box spring so as to automate stapling coils. Imaginal's subsequent U.S. Patent No. 7,222,402 (the "'402 patent") is based on the '789 patent, but the '402 patent, via a negative claim limitation, purposefully removes a feature from claim 1 of the '789 patent by "moving the fastening tool without the use of a vision guidance system."

After losing the patent infringement case to Imaginal (*Imaginal Systematic, LLC v. Leggett & Platt, Inc.*, 496 F. App'x 997 (Fed. Cir. 2013)), Leggett & Platt (L&P) and Simmons redesigned their machine with another vision guidance system, avoiding the '789 patent. Afterwards, Imaginal once again filed suit for infringing the '402 patent in 2013 and asserted that "a vision guidance system" in claim 1 of the '402 patent specifically referred to the camera-based guidance system of the '789 patent. That is, the '402 patent was attempting to negate use of only one particular vision guided system, not all systems. The district court held that the accused redesigned machine did not satisfy one of the claimed

elements in '402 patent. Imaginal appealed, alleging that the L&P's redesigned machines themselves infringed the '402 patent.

The United States Court of Appeals for the Federal Circuit rejected Imaginal's contention based on the language of the claim and the specification in the '402 patent. The Federal Circuit held "the claims 'must be read in view of the specification, of which they are a part' . . . [w]e have said that the specification is always highly relevant to the claim construction analysis." With respect to the disclaimer of "moving the fastening tool without the use of a vision guidance system," the district court looked to the ordinary meaning of the words "vision" and "guidance" in dictionary definitions and concluded "vision guidance system" is a "system that uses a vision or sight based method to control or direct the movement or direction of something." Although the '402 patent "uses the '789 patent in its preferred embodiments as a general point of reference, it does not express any manifest exclusion or restriction as it pertains specifically to the meaning of 'vision guidance system.'

The Federal Circuit further stated that the claim excluded use of "a" system in general and not "the" specific system. Imaginal could have specifically pointed to the vision guidance system of the '789 patent if that was all they meant to exclude. Moreover, nothing in the claim language purports to restrict the term "vision guidance system" to a specific system. Therefore, Imaginal's attempt to narrow the negative claim limitation so that it disclaimed only one particular feature was not supported.

OBVIOUSNESS REJECTION IN PERSONALIZED MEDICINE

By Anthony Hom, Esq. (ahom@ipfirm.com)

Prometheus Laboratories, Inc. V. Roxane Laboratories, Inc. slip ops. 2014-1634, 2014-1635 (Fed. Cir. Nov. 10, 2015).

Prometheus Labs owns U.S. Patent No. 6,284,770 regarding a method of treating "diarrhea-predominant female IBS" by giving the patient "an effective amount of alosetron or a pharmaceutically acceptable derivative thereof." Prometheus sued Roxane Labs for infringement of the '770 patent.

The U.S. District Court for the District of New Jersey held the '770 patent invalid, finding that the claims would have been obvious over the prior art. The Federal Circuit affirmed.

The district court concluded that "[a]t best, the claims at issue are a combination of known elements, combined in a known way, to produce expected results." The '770 patent recites a species of the genus method claimed in U.S. Patent No. 5,360,800 ("the '800 patent"). The '800 patent claims the use of alosetron to treat patients suffering from irritable bowel syndrome (IBS). The '770 patent claims treating a subset of those IBS patients—those who (1) are women (2) with IBS-D (3) who have experienced symptoms for at least six months and (4) who have had moderate pain.

The Federal Circuit stated that "[i]t is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus." According to the Federal Circuit, the genus-species distinction may have particular relevance in the field of personalized medicine, where, for example, a particular treatment may be effective with respect to one subset of patients and ineffective to another subset of patients. Here, the subset is women.

Nevertheless, the Federal Circuit stated that, at the time of the '770 patent's priority date,

it would have been obvious to a person having ordinary skill in the art to treat women as a separate group of IBS patients. Notably, the Federal Circuit found that the "female" limitation was simply obvious since women represent half of the population and the majority of IBS patients, and the prior art taught differences between male and female reactions to the proposed treatment.

IS CERTIFICATE OF CORRECTION PROPER TO CORRECT CHEMICAL STRUCTURE BASED ON LATER DISCOVERY?

By Bernard Berman, Esq. (bberman@ipfirm.com)

Cubist Pharmaceuticals, Inc. V. Hospira, Inc., slip ops. 2015-1197, 2015-1204, 2015-1259 (Fed. Cir. Nov. 12, 2015).

Cubist Pharmaceuticals owns five patents that relate to the antibiotic daptomycin. Hospira sought authorization to sell a generic version of Cubist's daptomycin product, which led Cubist to file this action charging Hospira with patent infringement.

Daptomycin was developed by Eli Lilly & Co. ("Lilly"). The original patent to daptomycin expired in 2002. The five patents at issue in this case are all follow-on patents owned by Cubist. The first is U.S. Patent No. RE39,071 ("the '071 patent"), which is a reissue of U.S. Patent No. 5,912,226 is directed to antibiotic compounds, compositions, formulations, and methods of treating bacterial infections. The next two are U.S. Patent Nos. 6,852,689 and 6,468,967, which are directed to dosage regimens for administering daptomycin. The final two are U.S. Patent Nos. 8,058,238 and 8,129,342 which are directed to the purification of daptomycin compositions.

Following a bench trial, the United States District Court for the District of Delaware found that Hospira infringed Claims 18 and 26 of the '071 reissue patent and that some of the asserted claims of the other four Cubist patents are invalid for anticipation and that all of the claims of those patents are invalid for obviousness.

While this appeal by Hospira asked for reconsideration of the district court's entire holding, the main focus of the Federal Circuit panel was directed to Hospira's argument that the issuance of a certificate of correction by the United States Patent and Trademark Office was improper as the certificate of correction improperly broadened the scope of the claims at issue.

The certificate of correction is directed to correcting Formula 3 of the '071 patent to reflect the discovery that daptomycin actually is the D-isomer of asparagine rather than the L-isomer indicated in Formula 3.

The Federal Circuit, in reviewing the specification of the '071 patent, found that the specification describes the compound of Formula 3 in three ways. The first was as "an A-21978C cyclic peptide" which is described in Lilly's US Patent No. 4,208,403. The second was using Lilly's code name assigned to daptomycin, "LY146031". The third was structural Formula 3, which at the time the original patent application was filed and for several years after its issue, was believed to be correct.

The Federal Circuit found that since Cubist identified daptomycin as is described in Lilly's '403 patent and further used the Lilly code name that had been assigned to daptomycin and still further disclosed a synthetic route to daptomycin that produced the proper compound having the D-isomer, that it has been clear that Cubist possessed daptomycin at the time the original application was filed. Hence the entry of the Certificate of Correction was

proper.

"PROXIMATE END" LOCATION DOES NOT EXTEND TO A REGION 35% AWAY FROM THE EXTREME END

By Chang H. Yang, Patent Agent (chyang@ipfirm.com)

Advanced Steel Recovery, LLC v. X-Body Equipment, Inc. and Jewell Attachments, LLC, slip op. 2014-1829 (Fed. Cir. Nov. 12, 2015).

Advanced Steel Recovery, LLC ("Advanced Steel") sued X-Body Equipment, Inc. and Jewell Attachments, LLC (collectively, "X-Body") for infringement of US Patent 8,061,950 (the '950 patent). The district court granted summary judgment of noninfrigement to X-Body for both literal infringement and infringement under the doctrine of equivalents. Advanced Steel appealed.

The asserted claims of the '950 patent require that the piston-and-cylinder unit be connected to the "transfer base proximate end" and the "container packer *proximate end*." Meanwhile, the same container packer piston-and-cylinder unit in the accused device is connected to the bottom of the container packer at a location approximately 35% down its length.

The Federal Circuit agreed with the district court's claim construction that the "proximate end" is interpreted as "the extreme or last part lengthwise" based on a dictionary definition of "end" as the specification does not provide an express definition of the term "proximate end." The Federal Circuit further affirmed the district court's summary judgment of no literal infringement, because "the piston-and-cylinder unit in [the accused device] attaches to the floor, nearly 35% away from the extreme end, no reasonable jury could find that the [accused device's] piston-and-cylinder unit is connected to the container packer's proximate end." As to the infringement analysis under the doctrine of equivalents, the Federal Circuit found that "[w]hile the term "proximate end" by no means precludes some offset from the absolute end, we find no error in the district court's conclusion that "no reasonable jury could find this connection point to be equivalent to the 'container packer proximate end.'"

EXHAUST ALL OPTIONS ON THE RECORD BEFORE ASSERTING DENIAL OF PROCEDURAL RIGHTS

By Michael J. Steger, Esq. (msteger@ipfirm.com)

Belden Inc. v. Berk-Tek LLC, slip op. 2014-1575, -1576 (Fed. Cir. Nov. 5, 2015)

The predecessor of Berk-Tek LLC filed a Petition for *inter partes* review (IPR) of claims 1-6 of U.S. Patent No. 6,074,503, owned by Belden. The Patent Trial and Appeal Board (PTAB) instituted the IPR, rejected claims 1-4 for obviousness, and confirmed claims 5 and 6 – stating there was no apparent reason to combine the applied references.

During the IPR, Belden filed its patent owner response and attached a declaration from its expert, Clark. Berk-Tek submitted its Reply and attached a declaration from its expert, Baxter. Berk-Tek did not attach an expert declaration to the Petition for IPR. Belden argued that it had no opportunity to respond. The PTAB noted that Belden could cross-examine Baxter and move to file non-argumentative observations. Belden deposed Baxter and filed a motion for observations. Belden then moved to exclude the Baxter declaration, arguing that portions of the Baxter declaration were not responsive to the Clark declaration and that the Baxter declaration contained arguments and evidence necessary for the *prima*

facie case of obviousness. The PTAB denied Belden's motion to exclude. Belden appealed the cancellation of claims 1-4 and the denial of the motion to exclude. Berk-Tek appealed the upholding of claims 5 and 6.

On appeal, the Federal Circuit found that substantial evidence supported the PTAB's obviousness conclusion regarding claims 1-4. The Federal Circuit reversed the PTAB's finding with regard to claims 5 and 6, because the record was sufficient to find the requisite motivation to combine.

With regard to the PTAB's denial of the motion to exclude, the Federal Circuit stated that Belden had numerous, non-mutually exclusive, opportunities to respond. For example, Belden could have done one or more of the following:

1. cross-examined the expert and filed observations;
2. moved to exclude the declaration;
3. disputed the substance of the declaration at the oral hearing;
4. moved for permission to submit a surreply; and/or
5. requested that the Board waive or suspend a regulation Belden believed impaired its opportunity to respond.

The Federal Circuit stated that, because there was no concrete record indicating that the PTAB denied Belden of any of the opportunities to respond, and because Belden apparently chose to not pursue all of the available opportunities to respond, Belden was not denied a meaningful opportunity to respond to the grounds of rejection. Additionally, the Federal Circuit determined that the points addressed in the Baxter declaration responded to statements made in the Clark declaration. Furthermore, the Federal Circuit stated that there is no rule that requires a petition for IPR to be accompanied by a declaration, and as such, the Baxter declaration was not necessary to establish the *prima facie* case of obviousness. The Federal Circuit, accordingly, affirmed the PTAB's decision to deny Belden's motion to exclude.

BROAD CLAIM SCOPE REAFFIRMED

By Michael P. McComas, Esq. (mmccomas@ipfirm.com)

A Federal Circuit panel upheld a district court's claim construction and allowance of damages based on lost profits in the face of a challenge by Limelight Networks, Inc. ("Limelight"). *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, slip ops. 2009-1372, 1380, 1416, 1417 (Fed. Cir. Nov. 16, 2015).

The panel agreed with the district court that the term "tagging" in claims at issue in Akamai's U.S. Patent No. 6,108,703 should not be limited to "using a 'pointer' or 'hook' that either prepends or inserts a virtual server hostname into a URL" as asserted by Limelight. Agreeing with Akamai Technologies, Inc. ("Akamai"), the panel stated that the interpretation proposed by Limelight would improperly limit the claims to the preferred embodiment, citing Federal Circuit precedent from 2004. Also, because the two parties had stipulated to a broader claim interpretation at the Markman hearing and Limelight did not raise its challenge until jury instructions were read, Limelight was held to be bound by its prior stipulation.

The panel also denied Limelight's attempt to limit the interpretation of claim construction

language to which the parties had stipulated. The parties agreed that claim language "to resolve to a domain other than the content provider domain" means "to specify a particular group of computers that does not include the content provider from which an optimal server is to be selected," but disagreed over the interpretation of "an optimal server." The panel upheld the district court's interpretation as "one or more content servers," noting that choosing among multiple servers is a capability of the tagging system and that final server selection occurs while objects are being served, an operation separate from tagging.

With respect to Limelight's challenge to damages based on lost profits, the panel upheld the district court's decision to allow such damages, reasoning that Akamai's expert had presented sufficient evidence and analysis to counter Limelight's assertion that the parties operated in segmented markets. Limelight's questioning of the amount of the lost profits was considered to have been raised too late.

USING PATENT PROCESSES TO MAKE A PHARMACEUTICAL INVENTION

By David Beardall, Esq. (dbeardall@ipfirm.com)

Momenta Pharmaceuticals v. Teva Pharmaceuticals, slip ops. 2014-1274, 2014-1277, (Fed. Cir. Nov. 10, 2015).

Momenta Pharmaceuticals separately sued Teva Pharmaceuticals and Amphastar Pharmaceuticals alleging that they infringed a Momenta-licensed US Patent 7,575,886 (the '886 patent) by making the anticoagulant drug enoxaparin using the '886 patent (Teva and Amphastar) and by performing the method of the '886 patent in the United States. The First Circuit Federal District Court granted summary judgment in favor of Teva and Amphastar, dismissing Momenta's claims.

On appeal, the Federal Circuit ruled that producing enoxaparin using a patented process that assists in quality control of the final product does not qualify as "making" the drug under 35 USC §271(g). Momenta had argued that, under 21 C.F.R. § 210.3(b)(21), the FDA included testing and quality control of drug products within the scope of manufacturing and processing those drug products, so that any use of the '866 patent in making enoxaparin would infringe the '866 patent. However, the Federal Circuit noted that 21 C.F.R. § 210.3 specifically limits its definitions to application within the scope of 21 C.F.R. §§ 210, 211, 224, and 226. Thus, 35 U.S.C. §271 is not governed by the 21 C.F.R. § 210.3 meaning of "manufacture" and the plain meaning of "making" should be applied.

To "make" a drug means "to bring (a material thing) into being by forming, shaping or altering material." (Webster's Third New International Dictionary of the English Language (Philip Basbcock Gove et al. eds., 1986). A product is not "made by" a process patented in the United States where "the patented process [was] not used in the actual synthesis of the drug product." *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1377 (Fed. Cir. 2003). Summary Judgment for Teva was upheld.

The matter was remanded for further consideration of Amphastar's potential liability for performing the method of the '886 patent in the United States outside of the safe harbor of 35 U.S.C. §271(e)(1) after receiving FDA approval to market and sell enoxaparin in the United States.

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