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FEDERAL CIRCUIT CASES

Federal Circuit Reverses Summary Judgment of Noninfringement Under § 271(e)(1) for Consideration of Certain Post-FDA-Submission Activities, But Expresses Skepticism About Infringement

In a May 13, 2015 decision, the Federal Circuit agreed with the district court's conclusion that certain post-FDA-approval submissions did not infringe Classen Immunotherapies' business method claims because they were protected by the safe harbor provision of § 271(e)(1). Nevertheless, the court vacated the judgment of noninfringement and remanded the case to allow the district court to determine whether other post-submission activities infringed the patent. The asserted claims cover a method for identifying a new use for an existing drug and commercializing that new use. Classen accused Elan Pharmaceuticals of infringing the claims by submitting a supplemental new drug application (sNDA) to the FDA reflecting the results of a clinical trial studying the effect of food on the absorption of Elan's Skelaxin muscle relaxant, as well as engaging in other post-submission activities. The district court determined that Elan's conduct was protected under § 271(e)(1) because it was "solely for uses reasonably related to the development and submission of information" to the FDA, and granted summary judgment of noninfringement. With respect to Elan's sNDA submission, the Federal Circuit agreed with the district court. The court observed that the safe harbor in § 271(e)(1) "extends to all uses of patented inventions," and is not limited to activities related to seeking approval of a generic version of a drug. Noting that "post-approval studies serve similar purposes as pre-approval studies in ensuring the safety and efficacy of approved drugs," the court determined that Elan's post-approval sNDA submission was covered by § 271(e)(1). But the Federal Circuit found that certain other accused activities—namely Elan's filing of patent applications and its revision of the Skelaxin label—were not necessarily exempt, and reversed the district court's summary judgment of noninfringement. The court reasoned that, while FDA submissions and the dissemination of information learned in exempt clinical studies are clearly protected under the safe harbor provision, post-submission activities are not necessarily exempt. Accordingly, the court remanded the case so that the district court could determine if Elan's non-submission related activities constituted infringement. Although it left the issue for the district court to determine, the Federal Circuit observed that filing patent applications and placing information submitted to the FDA on product labels are not generally considered to be infringing conduct.

Classen Immunotherapies, Inc. v. Elan Pharm., Inc., 2014-1671 (Fed. Cir. May 13, 2015).

- Author: [Dan Moffett](#)

Federal Circuit Applies Single Entity Rule in Joint Infringement Analysis

The Federal Circuit, on remand from the Supreme Court, issued a 2-1 decision finding Limelight did not directly infringe an Akamai web content patent. Limelight performed some steps of the patent, while its customers carried out the other steps.

The court stated that "direct infringement liability of a method claim under 35 U.S.C. § 271(a) exists when all of the steps of the claim are performed by or attributed to a single entity," such as in a principal-agent relationship, in a contractual arrangement, or in a joint enterprise. Encouraging or instructing others to perform an act does not result in direct infringement. The court found that Limelight and its customers did not possess any of the identified relationships, thus Limelight was not liable for direct infringement.

In analyzing the facts, the court determined that Limelight's providing of written manuals to customers explaining how to operate Limelight's product did not create an agent-principal relationship. The customers direct and control their use of Limelight's CDN network and do not act as agents of Limelight. Also, the court rejected Akamai's argument that Limelight's standard form contract with content providers contracts out claim steps to be performed by the content provider. The court explained that the "customers decide what content, if any they choose to have

delivered by Limelight's CDN" and that the contract "does not obligate Limelight's customers to perform any of the method steps." (emphasis added). The court concluded that because the customers act for their own benefit, Limelight was not liable for the customers' action.

Judge Moore filed a dissenting opinion concluding that the majority's application of the single entity rule leaves "a gaping loophole in infringement liability." She explained, that "[u]nder the majority's reading of the statute, the patentee has no redress for the harm if two people act together to perform the patented method but does have redress if that identical method is performed by a single entity."

Akamai Techs., Inc. v. Limelight Networks, Inc., 2009-1372, 2009-1380, 2009-1416, 2009-1417 (Fed. Cir. May 13, 2015) (J. Linn).

- Author: [Ashley Edison Brown](#)

UNITED STATES INTERNATIONAL TRADE COMMISSION (U.S.I.T.C.) OPINIONS

USITC Finds Chinese Crane Co. Harmed Domestic Industry

In Inv. No. 337-TA-887, *Certain Crawler Cranes and Components Thereof*, the International Trade Commission (the "commission") affirmed Administrative Law Judge David P. Shaw's initial determination that Sany Heavy Industry Co. Ltd. (Sany) misappropriated trade secrets from Manitowoc Cranes LLC (Manitowoc), causing damage to Manitowoc's domestic industry. Additionally, the commission reversed in part Judge Shaw's determination that Sany had infringed U.S. Patent Nos. 7,546,928 and 7,967,158.

Complainant Manitowoc alleged that Respondent Sany misappropriated its trade secrets after John Lanning, a former Manitowoc executive, helped Sany build cranes using Manitowoc's proprietary information. Manitowoc alleged that it possessed trade secrets in its market analysis, pricing, and manufacturing processes. The commission rejected Sany's argument that Manitowoc's trade secrets were not legally protectable and highlighted the precautionary measures Manitowoc took. Further, the commission found that Sany had notice that Lanning had improperly obtained Manitowoc's trade secrets and that Sany failed to prevent the use of the information once Lanning shared it. Accordingly, the commission found that Sany had misappropriated Manitowoc's trade secrets.

Further, Manitowoc alleged that Sany's SCC8500 crawler crane infringed various method and apparatus claims of two patents directed to crane counterweight systems. The commission reversed Judge Shaw's initial determination of inducement of infringement of the method claims because it found that Manitowoc admitted that Sany had not performed certain claimed methods within the United States. Also, the commission found that no evidence showed that Sany's products directly infringed those method claims. Accordingly, it reversed Judge Shaw's initial determination of inducement of infringement of the method claims. However, the commission found that Sany's crane directly infringed the apparatus claims. Because it found direct infringement, it did not reach Judge Shaw's finding of inducement of infringement of the apparatus claims.

Accordingly, the commission affirmed in part Judge Shaw's initial determination and issued a limited exclusion order and a cease-and-desist order against Sany for 10 years.

Certain Crawler Cranes and Components Thereof, Inv. No. 337-TA-887, USITC (May 6, 2015) (Opinion of the Commission).

- Author: [Joseph Young](#)

PATENT TRIAL AND APPEAL BOARD

PTAB Denies *Inter Partes* Review Because Means-Plus-Function Claims Could Not Be Construed

In *Askeladden LLC v. iSourceLoans LLC*, the Patent Trial and Appeal Board (PTAB) declined to institute *inter partes* review of claims 1-20 of U.S. Patent No. 7,340,435, holding that the petitioner Askeladden had not identified sufficient structure for two means-plus-function claim limitations. Without sufficient structure identified, the PTAB determined that it could not construe the challenged claims and denied *inter partes* review accordingly.

The '435 patent is generally "directed to a system and method for processing mortgage loan data." Independent claim 1, the only independent claim challenged by the petitioner, was written in means-plus-function form. The PTAB focused on two particular means-plus-function limitations as dispositive: (1) "means for reviewing the loan application data to determine completeness" and (2) "means for completing the loan application whenever loan application data is incomplete by contacting the loan originator."

Under well-established Federal Circuit precedent, in computer-implemented inventions that use means-plus-function claiming, “the structure disclosed in the specification [must] be more than simply a general purpose computer or microprocessor.” *Eon Corp. IP Holdings LLC v. AT&T Mobility LLC*, No. 2014-1392, slip op. at 7 (Fed. Cir. May 6, 2015) (quoting *Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008)). As the structure corresponding to the “means for reviewing” and “means for completing” limitations in the challenged claims, the petitioner identified portions of the specification discussing “a computerized system with program software operable to perform” certain functions.

The PTAB found two flaws with the petitioner’s position. First, the PTAB determined that the cited passages spoke in general terms and did not adequately tie the claimed function to the disclosed structure: “The passages . . . discuss the computer components generally employed in various portions of the ’435 patent’s computer system, but are not linked to the recited ‘reviewing’ and ‘completing’ functions.” Second, the PTAB noted the rule that “the corresponding structure . . . must be more than simply a general purpose computer,” and concluded that “petitioner has failed even to establish that the structure corresponding to the recited ‘reviewing’ and ‘completing’ functions is a general purpose computer.” For these reasons, the PTAB was unable to construe the challenged claims and denied *inter partes* review.

Although the petitioner here lost its bid to challenge the claims at the PTAB, denial decisions like this may prove valuable in related district court litigation. For example, the PTAB’s determination that it cannot construe the asserted claims may support an argument that the claims are indefinite under 35 U.S.C. § 112 for the very reasons articulated by the PTAB.

Askeladden LLC v. iSourceLoans LLC, IPR2015-00134 (PTAB Apr. 15, 2015) (Rice, Daniels, & Plenzler, JJ.).

- Author: [Wesley D. Markham](#)

PTAB Attempts to Rein in Requests for Expanded Panels

The PTAB has designated two of its earlier decisions relating to expanded panels as “informative.” The PTAB panels had denied requests for expanded panels in both these decisions. Informative decisions are meant to illustrate board procedure.

Most PTAB decisions are made by three-judge panels, but in rare instances, the board has used expanded panels to address important issues. For example, a seven-judge panel was recently used to resolve the issue whether companies challenging patents can join multiple petitions that they have filed into one proceeding. Losing parties now regularly request rehearing of final written decisions, seeking an expanded panel review of such decisions. The intent of the two decisions designated informative last week is to discourage litigants from seeking expanded panels.

The first decision, *AOL v. Coho*, makes clear that only the board’s Chief Judge has the authority to expand a panel on a “suggestion” from a judge or panel. Accordingly, parties are not permitted to request, and panels do not authorize, panel expansion. The decision notes that the standard operating procedure of the board creates no legally enforceable rights for the litigants. The *AOL* order further explains that the decision to expand a panel “involves consideration of whether the issue is one of conflict with an authoritative decision of our reviewing courts or a precedential decision of the board, or whether the issue raises a conflict regarding a contrary legal interpretation of a statute or regulation.” The mere existence of a dissent in a decision does not entitle a party to an expanded panel on rehearing. Likewise, the second decision designated informative, *Unilever v. Procter & Gamble*, explains that “the members of the board deciding an institution matter are not authorized to select themselves or, of their own accord, select other board members to decide the matter, upon request of a party or otherwise.”

The board subsequently revised its standard operating procedure to clarify that, although a party may not request an expanded panel, a party is permitted to suggest the need for an expanded panel. Another important change to the SOP relates to the board’s pilot program allowing a single judge to make institution decisions, and subsequently adding participation of two additional judges for the trial and a final written decision.

AOL Inc. v. Coho Licensing LLC, No. IPR2014-00771 (PTAB Mar. 24 2015); *Conopco, Inc. dba Unilever v. Procter & Gamble Co.*, No. IPR2014-00506 (PTAB Dec. 10 2014); PTAB SOP 1 § III.C. (Rev. 14) (May 8, 2015).

- Author: [Ifiti Ahmed](#)

CONTACT INFORMATION

If you have any questions regarding this issue of *IP Newsflash*, please contact–

Todd Eric Landis
tlandis@akingump.com
214.969.2787

Michael Simons
msimons@akingump.com
512.499.6253

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