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Last Month at the Federal Circuit

August 2010

Repeated Description of Mechanism in Specification Limits Scope of Claim Term, Despite Applicant's Statements During Prosecution Suggesting a Broader Construction

Telcordia Technologies, Inc. v. Cisco Systems, Inc.

Nos. 09-1175, -1184 (Fed. Cir. July 6, 2010)
[Appealed from D. Del., Chief Judge Sleet]

Filing Date of Provisional Application Can Have Patent-Defeating Effect

In re Giacomini

No. 09-1400 (Fed. Cir. July 7, 2010)
[Appealed from Board]

Obviousness, a Question of Law and Fact, Is Reviewable on JMOL in Certain Cases

Wyers v. Master Lock Co.

No. 09-1412 (Fed. Cir. July 22, 2010)
[Appealed from D. Colo., Senior Judge Babcock]

PDF version

Spotlight Info

Looking Ahead

Obviousness-Type Double Patenting Analysis for Patents Claiming a Compound Should Include an Examination of Any Utility Disclosed in the Specification of the Earlier-Issued Patent

Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.

No. 10-1105 (Fed. Cir. July 28, 2010)
[Appealed from E.D. Mich., Judge Steeh]

Federal Circuit Finds Listing Claim Elements Separately Clearly Implies Those Elements Are Distinct Components of the Patented Invention

Becton, Dickinson & Co. v. Tyco Healthcare Group, LP

Nos. 09-1053, -1111 (Fed. Cir. July 29, 2010)
[Appealed from D. Del., Chief Judge Sleet]

Abbreviations

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Board of Patent Appeals and Interferences
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law

MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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Last Month at the Federal Circuit

[Back to Main](#)

August 2010

Spotlight Info

In *Wyers v. Master Lock Co.*, No. 09-1412 (Fed. Cir. July 22, 2010), the Federal Circuit overturned the jury's verdict that Master Lock Company LLC ("Master Lock") failed to show by clear and convincing evidence that the asserted claims would have been obvious. The patents at issue relate to hitch pin locks that secure trailers to automobiles. Although the patents claimed improvements to prior art locks, the Federal Circuit found that the asserted claims represented no more than the predictable use of prior art elements according to their established function. The Court further found that it was a matter of common sense to combine those prior art elements to arrive at the claimed invention. Thus, the Court held that the claims were obvious as a matter of law and reversed the district court's holding that the asserted claims were nonobvious. See the full summary in this issue.

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Last Month at the Federal Circuit

[Back to Main](#)

August 2010

Looking Ahead

On August 9, 2010, in *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, Nos. 09-1306, -1396 (Fed. Cir. Aug. 9, 2010), the Federal Circuit affirmed that emsCharts, Inc. and Softech, LLC did not jointly infringe Golden Hour Data Systems, Inc.'s ("Golden Hour") patent for managing emergency medical transport services. The Federal Circuit also vacated a March 2009 ruling by the district court that Golden Hour's patent is unenforceable due to inequitable conduct, and the Court remanded that part of the case for additional findings on the company's intent. Judge Newman dissented. Please see the full summary in next month's edition of *Last Month at the Federal Circuit*.

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Last Month at the Federal Circuit

[Back to Main](#)

August 2010

Repeated Description of Mechanism in Specification Limits Scope of Claim Term, Despite Applicant's Statements During Prosecution Suggesting a Broader Construction

Elliot C. Cook

Judges: Rader (author), Lourie, Prost (dissenting-in-part)

[Appealed from D. Del., Chief Judge Sleet]

In *Telcordia Technologies, Inc. v. Cisco Systems, Inc.*, Nos. 09-1175, -1184 (Fed. Cir. July 6, 2010), the Federal Circuit affirmed the district court's grant of SJ of noninfringement of U.S. Patent No. 4,893,306 ("the '306 patent"), vacated the denial of Cisco Systems, Inc.'s ("Cisco") motion for JMOL that the '306 patent was invalid as anticipated and remanded the issue to the district court, affirmed the district court's denial of Cisco's motion for JMOL that U.S. Patent No. 4,835,763 ("the '763 patent") was invalid as indefinite, affirmed the district court's determinations that the jury verdict form provided damages for only past infringement and did not include prejudgment interest, affirmed the district court's grant of an accounting and prejudgment interest, and remanded to allow the parties to negotiate a reasonable royalty to the '763 patent and U.S. Patent No. RE 36,633 ("the '633 patent").

Telcordia Technologies, Inc. ("Telcordia") owns by assignment the '306, '763, and '633 patents, which relate to the transmission of data in telecommunications networks. The '306 patent describes a data transmission technique called Dynamic Time Division Multiplexing ("DTDM"), which is compatible with both the circuit transmission and the packet transmission formats. A system according to the '306 patent allocates discrete segments, or "frames," of a single transmission line to several sources (e.g., voice, video, and data). A train of DTDM frames is generated with occupied transmission overhead fields and empty payload fields, where the train has a bit rate that defines a basic backbone transmission rate for the system. A DTDM assembler inserts data packets to be transmitted into the empty payload fields of the DTDM frames so that the resulting DTDM bit stream contains packets from multiple information sources.

The '763 patent is directed to a survivable or self-healing ring network that can withstand a cut line or failed node. Two rings are provided, which carry identical multiplexed node-to-node communications in opposite directions. The nodes comprise controllers and selectors, and are capable of detecting a break in either ring by monitoring the arriving signals for defects. If a node detects an error, it inserts an error signal on the specific channels that were lost due to the break, which is detected by a selector in a node

that then selects the identical, error-free channels from the other ring to use.

Telcordia sued Cisco on grounds that certain Cisco routers and switches infringe the '306, '633, and '763 patents. The district court denied a Rule 54(b) motion by Cisco for entry of judgment of noninfringement of the '306 patent, despite Telcordia's concession that Cisco's accused products did not meet two claim limitations. But the district court then granted Cisco's motion for SJ of noninfringement of the '306 patent, finding that its accused products did not meet four claim limitations, in addition to the two limitations conceded by Telcordia. During the jury trial on infringement of the '633 and '763 patents, and the validity of all three asserted patents, the jury found that Cisco willfully infringed all asserted claims of the '633 and '763 patents, and that all three patents were valid. The jury awarded Telcordia \$6.5 million in damages. The district court granted Telcordia's motion for an award of prejudgment interest and an accounting of Cisco's prejudgment sales, and ordered the parties to negotiate the terms of a royalty for postjudgment sales. The district court also denied Cisco's motion for JMOL that the asserted claims of the '306 patent were invalid as anticipated, and denied Cisco's motion for JMOL that the asserted claims of the '763 patent are invalid as indefinite.

Telcordia appealed the district court's construction of six claim terms and SJ of noninfringement of the '306 patent. Cisco cross-appealed the district court's denial of its JMOL motions on validity of the '306 and '763 patents, and appealed the district court's damages awards.

The Federal Circuit first addressed claim construction. The district court construed the term "empty payload field" from the '306 patent to mean "a payload field that is empty of source data, but including bit signals of some kind, i.e. garbage bits." The Federal Circuit found that the district court's construction improperly relied on "an ad lib comment" from a judge during oral argument in *Bell Communications Research, Inc. v. FORE Systems, Inc.*, Nos. 02-1083, -1084 (Fed. Cir. Mar. 27, 2003), in which Telcordia's predecessor asserted the '306 patent against a different company. Rejecting the district court's construction, the Federal Circuit concluded that "empty payload field" means "a payload field that is empty of source data, but includes bit signals of some kind."

“By repeatedly describing the inventive DTDM mechanism as one that only allows one packet per frame, ‘the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest execution or restriction.’” Slip op. at 17 (citation omitted).

The Federal Circuit next considered the construction of the term "such that data in packetized format from any of said sources is written into any available empty payload field of any of said frames," as recited in the '306 patent. Agreeing with the district court's construction, the Federal Circuit affirmed the grant of SJ of noninfringement of the '306 patent. According to the Federal Circuit, "By repeatedly describing the inventive DTDM mechanism as one that only allows one packet per frame, 'the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest execution or restriction.'" Slip op. at 17 (citation omitted). Although during prosecution, the applicant implied that a payload field may contain multiple packets, the specification failed to support such a construction, and "[t]hese prosecution history comments cannot trump the plain language of the claims and the direct teaching of the specification." *Id.* Because Telcordia conceded that it could not prove infringement under this construction, the Federal Circuit affirmed the district court's grant of SJ of noninfringement.

The Federal Circuit next affirmed the district court's denial of Cisco's motion for JMOL that the '306 patent was invalid as anticipated. Because the district court denied Cisco's JMOL motion solely on the basis of the construction of the claim term "empty payload field" that the Federal Circuit rejected, the Federal Circuit remanded for reconsideration of Cisco's invalidity contentions under the revised claim construction.

Regarding Cisco's claim that the '763 patent was invalid because the "monitoring means" recitation was an indefinite means-plus-function limitation, the Court found that the patent's specification adequately disclosed structure (a "controller") corresponding to the "monitoring means." Accordingly, the Court affirmed the district court's denial of Cisco's motion for JMOL that the asserted claims of the '763 patent were indefinite.

Finally, the Federal Circuit affirmed the district court's damages determinations. The Court observed that the verdict form was unclear as to whether the jury compensated Telcordia only for Cisco's past infringement, or for both past and ongoing infringement. Noting that district courts have broad discretion in interpreting ambiguous verdict forms, the Court concluded that the district court did not clearly err in concluding that the jury's damages award did not compensate Telcordia for ongoing infringement or prejudgment interest. Thus, the Court affirmed the district court's ordering the parties to negotiate an ongoing royalty, and affirmed the district court's award of an accounting and prejudgment interest.

Judge Prost dissented-in-part with respect to the majority's finding that the '763 patent was not indefinite. According to Judge Prost, the claim term "monitoring means" was indefinite because the specification failed to reveal that the structure within the node that performs the monitoring task is the circuitry of the controller. The specification, therefore, did not "clearly link a particular structure with a claimed function." Prost Dissent at 2.

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Last Month at the Federal Circuit

[Back to Main](#)

August 2010

Filing Date of Provisional Application Can Have Patent-Defeating Effect

Sulay D. Jhaveri

Judges: Gajarsa, Dyk, Rader (author)

[Appealed from Board]

In *In re Giacomini*, No. 09-1400 (Fed. Cir. July 7, 2010), the Federal Circuit affirmed the Board's rejection of certain claims of U.S. Patent Application No. 09/725,737 ("the Giacomini application") as being anticipated under 35 U.S.C. § 102.

The Giacomini application was filed on November 29, 2000, entitled "Method and Apparatus for Economical Cache Population." The Board rejected certain claims of the Giacomini application as anticipated under 35 U.S.C. § 102 by U.S. Patent No. 7,039,683 ("the Tran patent"). The Board found, and Giacomini did not dispute, that the Tran patent teaches all of the claimed features in Giacomini's application. The central issue at the Board was the eligibility of the Tran patent to serve as prior art under 35 U.S.C. § 102(e). The Tran patent's filing date is December 29, 2000. However, the Tran patent claims priority to a provisional application ("the Tran provisional") filed on September 25, 2000. The Board held that the Tran patent had a patent-defeating effect as of the filing date of the Tran provisional. Giacomini appealed the Board's decision.

In its analysis of § 102(e), the Court noted that an application that a patent was "granted on" is the first U.S. application to disclose the invention claimed in the patent. The Court further noted that under 35 U.S.C. § 111(b)(8), "applications for patent" under § 102 includes both provisional and non-provisional patent applications. Slip op. at 4-5. Thus, the Court concluded that an applicant is not entitled to a patent if another's patent discloses the same invention, which was carried forward from an earlier U.S. provisional application or U.S. non-provisional application.

"[A]n applicant is not entitled to a patent if another's patent discloses the same invention, which was carried forward from an earlier U.S. provisional application or U.S. non-provisional application." Slip op at 5.

The Court found that the Tran provisional from which Tran claims priority under 35 U.S.C. § 119(e)

discloses Giacomini's claimed invention. The Court also noted that, although 35 U.S.C. § 119 requires that the provisional application provide written description support for the claimed invention, Giacomini never argued that the Tran provisional failed to do so and, therefore, waived the argument by failing to raise it below. Thus, the Court stated that Giacomini, who filed his application after Tran filed his provisional application, could not receive a patent covering the same subject matter under 35 U.S.C. § 102(e).

Giacomini contended that although the Tran patent claims the benefit of priority to the Tran provisional, the Tran patent did not have a patent-defeating effect as of the Tran provisional's filing date, citing *In re Hilmer*, 359 F.2d 859 (C.C.P.A. 1966). The Court rejected Giacomini's argument, stating that at the time of the *Hilmer* decision, Congress had not yet enacted § 119(e). Thus, the Court stated that the broad language in *Hilmer* concerning § 119 is not applicable to provisional applications. The Court also noted that *Hilmer* involved an earlier foreign application, while the present case dealt with an earlier U.S. provisional application.

Accordingly, the Court affirmed the Board's rejection of certain claims of the Giacomini application under 35 U.S.C. § 102(e), because the invention was described in a patent claiming priority to a U.S. provisional application filed before Giacomini's filing date.

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Last Month at the Federal Circuit

[Back to Main](#)

August 2010

Obviousness, a Question of Law and Fact, Is Reviewable on JMOL in Certain Cases

Maryann T. Puglielli

Judges: Lourie, Linn (concurring), Dyk (author)

[Appealed from D. Colo., Senior Judge Babcock]

In *Wyers v. Master Lock Co.*, No. 09-1412 (Fed. Cir. July 22, 2010), the Federal Circuit reversed the district court's JMOL of nonobviousness in favor of Philip W. Wyers and Wyers Products Group, Inc. (collectively "Wyers").

Wyers owns three patents directed to hitch pin locks that secure trailers to cars and sport utility vehicles. The hitch pin passes through aligned holes in the trailer hitch receiver, which is attached to the vehicle, and the draw bar, which is attached to the trailer. The hitch pin is barbell-shaped with a stop portion on one end, a locking head on the other end, and a shank portion that passes through the two holes. Two of the patents, U.S. Patent Nos. 6,672,115 and 7,165,426 (collectively "the sleeve patents"), claimed improvements to similar locks known in the art, those improvements dealing with a removable sleeve to cover the hitch pin's shank. Wyers did not claim that the removable sleeve improves the locking or towing function of the hitch pin lock, but rather that the sleeve was desirable because it allows for a single locking unit to be used for a number of varied size locking requirements, thus saving retailers the shelf space for locks having shanks of different sizes. The third patent, U.S. Patent No. 7,225,649 ("the seal patent"), claimed an improved locking device with an external seal designed to insulate the locking mechanism from contaminants such as dirt.

The use of a lock in a trailer hitch receiver was well known in the art. For example, U.S. Patent No. 5,664,445 ("the Chang patent") discloses a lock with a lock head, a shackle having a stop member, a shank, and a latch. The Chang patent also teaches a lock for use as a hitch pin lock. The use of barbell-shaped locks was also known in the art. U.S. Patent No. 4,711,106 ("the Johnson patent") shows a barbell-shaped lock used as a trailer hitch receiver lock. In addition, Wyers's own patent, U.S. Patent No. 6,055,832 ("the '832 patent"), teaches a barbell-shaped locking device comprising a locking head, a shackle with a stop member, a shank, and a latch, and teaches the use of that device as a hitch pin lock in a way very similar to the Johnson patent.

Master Lock Company LLC ("Master Lock") offered for sale locks that allegedly fell within the scope of Wyers's three patents. Wyers filed suit in district court, alleging infringement. At the close of evidence,

the district court granted Wyers's motions for JMOL of infringement. Master Lock argued that the allegedly infringed claims were obvious over the prior art. During trial, Wyers admitted that the Chang patent and the Johnson patent disclosed every element of the sleeve patent claims except the use of a sleeve to adjust the operative thickness of the shank. Similarly, Wyers did not dispute that its own barbell-shaped locks, on sale prior to the priority date of the sleeve patents, contained every element of the claims except for the removable sleeve. Master Lock argued that the claims of the sleeve patents would have been obvious in light of the Johnson and Chang patents in combination with U.S. Patent No. 3,963,264 ("the Down patent") or Master Lock's 37D padlock. Thus, the district court considered whether Master Lock presented clear and convincing evidence that the use of a sleeve to adjust the operative thickness of a shank would have been obvious.

Regarding the seal patent, Wyers conceded that the external seal was the only feature that distinguished the claims from the Chang patent and the '832 patent. Master Lock contended that the claims of the seal patent would have been obvious in light of either patent in further view of Master Lock's 6121 padlock, U.S. Patent No. 5,156,029 ("the Heald patent"), U.S. Patent No. 3,858,419 ("the Hampton patent"), and U.S. Patent No. 3,848,440 ("the Manuel patent"). Thus, the district court considered whether Master Lock presented clear and convincing evidence that the use of an external flat flange seal would have been obvious.

The jury considered the question of obviousness, finding that the claims of Wyers's three patents would not have been obvious and that Master Lock's products infringed these claims. After trial, Master Lock renewed its motion for JMOL based on obviousness and the district court denied the motion, upholding the jury's verdict. Master Lock appealed.

The Federal Circuit began its analysis of obviousness based on the *Graham* factors: (1) scope and content of the prior art, (2) the difference between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations, including commercial success, long-felt but unsolved need, and the failure of others. Finding that factors (1) and (3) were not in dispute, the Court focused on three specific factual issues: (1) whether the prior art references were in the same field of endeavor as the invention, (2) whether there was sufficient motivation to combine the references, and (3) the existence and significance of secondary considerations.

“Thus, in appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of ‘common sense,’ appropriate for resolution on summary judgment or JMOL.” Slip op. at 16.

Regarding the first issue, whether the prior art was in the same field of endeavor as the claims, the Court considered the Down patent in the context of the sleeve patents. The Court noted that the Down patent was specifically directed to a trailer-towing application adaptable to an automobile for towing by fitting a rear towing attachment for attaching the tow bar of a trailer. Based on this teaching, the Court concluded that the Down patent was clearly in the same field of endeavor as the sleeve patents. As for the seal patent, the Court focused on prior art relating to padlock technology. Given that the district judge instructed the jury that the relevant field of endeavor was locksmithing, the Court concluded that padlocks were part of the relevant prior art against the seal patent's claims. And, the Court reasoned, even if the padlocks were not in the same field of endeavor, they were reasonably pertinent to the problem that the

inventors of the seal patent tried to solve—preventing environmental contaminants from entering the locking mechanism. Thus, the Down patent and the padlock seals were pertinent prior art against the seal patent.

Regarding the second issue, whether sufficient motivation to combine existed, the Court began with *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), and its subsequent case law to show that motivation to combine could be addressed on JMOL. *KSR* instructs courts to take a more expansive and flexible approach in determining whether a patented invention is obvious, emphasizing the role of common sense in making that determination. Prior to *KSR*, the Court explained, the question of motivation to combine was treated as a question of fact. While *KSR* did not change that rule, it and subsequent Federal Circuit case law established that motivation may be addressed on JMOL. Specifically, in *KSR*, the Supreme Court explained that the ultimate judgment of obviousness is a legal determination. *KSR* and later Federal Circuit cases established that the legal determination of obviousness may include reliance on logic, judgment, and common sense in lieu of expert testimony, especially where the technology at issue was easily understandable. Citing *Sundance Inc. v. DeMonte Fabricating, Ltd.*, 550 F.3d 1356, 1365 (Fed. Cir. 2008), the Court noted that where the factual inquiries underlying the determination of obviousness are not in dispute, obviousness may be determined as a matter of law.

With this legal premise in mind, the Court considered whether there was motivation to combine a removable sleeve with the prior art barbell locks. Considering the teachings of the prior art, the Court concluded that it was a matter of common sense that Down's sleeve could be used with a barbell-shaped hitch pin lock to address the problem of different hole sizes. Likewise, the Court also concluded that one of ordinary skill in the art would have had a reasonable expectation of success in making this combination. In so doing, the Court rejected Master Lock's arguments.

The Court also considered whether there was motivation to combine the prior art locks with an external sealing mechanism. Both the '832 patent and the Chang patent disclose internal sealing mechanisms. In addition, the Master Lock 6121 series padlock and the Hampton patent include an external seal at the entry point of the shackle into the lock head or covering the lock head. The Heald patent also discloses an external flange seal that forms a weatherproof seal. Based on these teachings, the Court observed that there were two known ways to protect a lock's locking head, either by an external seal or an internal seal. Both design options were widely used in the prior art, and Wyers admitted that an external flange seal would work the same way on a padlock as it would on a barbell-shaped lock. Thus, the Court concluded, it was a matter of common sense that a flat external seal used in the prior art padlocks could be combined with a barbell-shaped hitch pin lock.

Regarding the final issue, the significance of secondary considerations, the Court considered evidence from Wyers as to commercial success, copying by competitors, and unexpected results. Wyers argued that Master Lock's success in selling its infringing product demonstrated commercial success. The Court, however, found that Wyers failed to establish a nexus between the success in sales and the specific claimed feature of an external seal or a removable sleeve. Wyers also failed to establish copying, as not every competing product that arguably falls within the scope of a patent is evidence of copying. Instead, copying requires more substantial evidence, such as internal company documents of the competitor, direct evidence of a competitor reverse-engineering an invention, or photographing the invention's features and using the picture as a blueprint to build a replica. Notably, the Court explained that secondary considerations of nonobviousness cannot overcome a strong prima facie case of

obviousness. In sum, the Court viewed Wyers's inventions as no more than the predictable use of prior art elements according to their established functions. As such, the Court reversed the district court and concluded that Wyers's three patents were invalid for obviousness.

In a concurring opinion, Judge Linn wrote to address concerns raised following the Supreme Court's decision in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), with respect to general verdicts relating to obviousness. Judge Linn stated that the Court has established precedent permitting the submission of obviousness questions to a jury for a general verdict, provided the jury has received proper instruction on the law. Judge Linn noted, however, that to facilitate review and reveal more clearly the jury's underlying factual findings, the Federal Circuit has encouraged trial court judges to provide juries with special interrogatories on obviousness. Absent any such special interrogatories, the Court must presume the "existence of findings necessary to support the verdict the jury reached." Linn Concurrence at 4 (citation omitted). Judge Linn added, "Because there is no way to determine from a general verdict on obviousness the specific findings of fact made by a jury on the factual questions underlying its verdict, the court in examining the first part of the obviousness question is left to infer whether substantial evidence existed from which the jury could have made the factual findings necessary to support the verdict." *Id.* at 4-5. In this case, Judge Linn concluded that the majority examined the record and, after considering the factual inferences, concluded that support was lacking and that the claims at issue would have been obvious as a matter of law. Accordingly, he concurred with the majority's analysis and conclusion.

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Obviousness-Type Double Patenting Analysis for Patents Claiming a Compound Should Include an Examination of Any Utility Disclosed in the Specification of the Earlier-Issued Patent

Jeffrey W. Abraham

Judges: Bryson, Gajarsa, Prost (author)

[Appealed from E.D. Mich., Judge Steeh]

In *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, No. 10-1105 (Fed. Cir. July 28, 2010), the Federal Circuit affirmed the district court's ruling that certain claims of Eli Lilly and Company's ("Lilly") U.S. Patent No. 5,464,826 ("the '826 patent") were invalid for obviousness-type double patenting in view of Lilly's U.S. Patent No. 4,808,614 ("the '614 patent").

The '614 patent claims the compound gemcitabine and a method of using gemcitabine to treat viral infections. The '826 patent claims a later-discovered method of using gemcitabine to treat cancer. Gemcitabine is the active ingredient in Gemzar®, which Lilly markets for the treatment of various forms of cancer.

The '614 patent, entitled "Difluoro Antivirals and Intermediate Therefor," was originally filed on March 10, 1983, as U.S. Patent Application Serial No. 473,883 ("the original '883 application"), and disclosed gemcitabine's antiviral utility. On December 4, 1984, a CIP was filed in the '614 family that added one paragraph to the original specification describing gemcitabine's newly discovered anticancer activity. On the same day Lilly filed the CIP, Lilly also filed the original application that issued as the '826 patent, entitled "Method of Treating Tumors in Mammals with 2',2'-Difluoronucleosides."

In 2006, generic drug manufacturer Sun Pharmaceutical Industries, Ltd. ("Sun") filed an ANDA with the FDA seeking approval to market a generic version of Lilly's Gemzar® and certified that both the '614 and '826 patents were invalid or not infringed. On November 29, 2007, Sun filed a DJ action against Lilly in the Eastern District of Michigan for invalidity and noninfringement, and Lilly counterclaimed for infringement of the '614 and '826 patents. On August 17, 2009, the district court granted Sun's motion for partial SJ that the asserted claims of the '826 patent were invalid for obviousness-type double patenting over the earlier '614 patent. Lilly appealed this ruling to the Federal Circuit.

On appeal, the Federal Circuit relied on its prior obviousness-type double patenting decisions in *Geneva*

Pharmaceuticals, Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373 (Fed. Cir. 2003), and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008). The Federal Circuit noted that in both *Geneva* and *Pfizer*, it found claims of a later patent invalid for obviousness-type double patenting “where an earlier patent claimed a compound, disclosing its utility in the specification, and a later patent claimed a method of using the compound for a use described in the specification of the earlier patent.” Slip op. at 7. The Court then considered whether the rationale of *Geneva* applied to single or multiple utilities. The Court noted that although *Geneva* only disclosed a single use for the claimed compound, the reasoning and holding of *Geneva* were not so limited. The Federal Circuit indicated that *Pfizer* disclosed more than one utility for the claimed compound—inflammation and inflammation-associated disorders—and that *Pfizer* invalidated the claims in the later patent that were separately directed to these multiple uses.

“[O]bviousness-type double patenting[] prohibits claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.” Slip op. at 6 (internal quotation marks omitted).

The Federal Circuit further stated that the “*Pfizer* decision shows that obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound.” *Id.* at 10. As a result, the Federal Circuit concluded that its obviousness-type double patenting analysis extends to any and all such uses disclosed in the specification of the earlier patent. Because the '614 patent described the originally disclosed antiviral utility and also contained the one paragraph mentioning the anticancer use that was added in the CIP, the Federal Circuit held the '826 patent, which claimed the method of using gemcitabine to treat cancer, invalid for double patenting.

Lilly's primary argument on appeal was that the double patenting analysis of *Geneva* and *Pfizer* did not apply to its later '826 patent claims reciting a method of using gemcitabine for cancer treatment because the original '883 application for the '614 patent did not contain any mention of the anticancer utility. In its briefs and at oral argument, Lilly argued that under *Geneva*, courts need to assess whether a compound and the utility necessary to make that compound patent eligible under 35 U.S.C. §§ 101 and 112 are being claimed in separate patents. Because the compound claims of the '614 patent were entitled to their original filing date under 35 U.S.C. § 120, the district court should have examined the original application to see what utility was necessary to make gemcitabine patent eligible under §§ 101 and 112. Because the anticancer use was not mentioned in the original application, as it had not yet been invented, it could not be the utility necessary to patent the compound claim, and *Geneva* double patenting thus could not apply.

The Federal Circuit rejected Lilly's argument that the district court should have evaluated the '614 patent's claim to gemcitabine based on the specification that existed as of the undisputed effective filing date of the '614 patent (the original '883 application). The Federal Circuit instructed that under its claim construction precedent, claim terms need to be construed in light of the entirety of the patent, including its specification, and that the specification to be consulted is that of the issued patent, not the original application.

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Last Month at the Federal Circuit

[Back to Main](#)

August 2010

Federal Circuit Finds Listing Claim Elements Separately Clearly Implies Those Elements Are Distinct Components of the Patented Invention

Troy A. Petersen

Judges: Gajarsa (dissenting), Linn, Mayer (author)

[Appealed from D. Del., Chief Judge Sleet]

In *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, Nos. 09-1053, -1111 (Fed. Cir. July 29, 2010), the Federal Circuit reversed the district court's denial of Tyco Healthcare Group, LP's ("Tyco") JMOL of noninfringement because the district court incorrectly construed the "spring means" limitation in the asserted claims.

Becton, Dickinson and Company ("Becton") sued Tyco for infringement of certain claims of U.S. Patent No. 5,348,544 ("the '544 patent"), directed toward a safety needle employing a needle guard. The guard is attached to the needle hub by a hinged arm. To facilitate the movement of the guard toward the needle tip, the '544 patent discloses a "spring means" for "urging [the] guard along [the] needle cannula" toward the tip of the needle. Slip op. at 3 (alterations in original). All the asserted claims contained this limitation. At trial, the district court instructed the jury that the spring means limitation required that "the 'spring means' must move the guard along the needle toward the needle tip." *Id.* at 6. The district court also instructed the jury that "[t]he spring is not required to move the guard all the way to the tip of the needle but must, by itself, move the guard some distance." *Id.* (alteration in original). The jury returned a verdict of infringement by Tyco's safety needles. The district court denied Tyco's motions for JMOL and Tyco appealed.

On appeal, the Federal Circuit agreed with Tyco that the unambiguous language of the asserted claims, as well as the disclosure in the specification, required an added spring element that moves the safety guard toward the tip of the needle. The Court found that because the asserted claims listed (1) a hinged arm and (2) a spring means "connected to" the hinged arm as separate elements, "[t]he unequivocal language of the asserted claims of the '544 patent requires a spring means that is separate from the hinged arm." *Id.* at 9. The Court noted that "[w]here a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention." *Id.* at 10 (second alteration in original) (quoting *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004)).

Additionally, the Federal Circuit determined that the specification confirmed the spring means as a separate element from the hinged arm, because the only elements disclosed in the specification as “spring means” for urging the guard forward were separate structures from the hinged arm and its hinges. The Court explained that Becton’s assertion that the spring means and the hinged arm could be the same structure rendered the claims nonsensical, as the claims describe the spring means as “connected to” the hinged arm. *Id.* at 11. The Court further noted that if the hinged arm and spring means in the claims were not separate structures, then the asserted claims would be invalid as obvious over the prior art, since the separate spring means is what distinguished the claimed invention.

“Where a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” Slip op. at 10 (alteration in original) (quoting *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004)).

Becton was not able to show that Tyco’s products had a spring means separate from the hinged arm. Because there can be no literal infringement where a claim requires two separate structures and one such structure is missing from an accused device, the Federal Circuit found no literal infringement by Tyco’s accused products.

Furthermore, the Federal Circuit found that even under the trial court’s erroneous claim construction, Becton adduced no credible evidence establishing literal infringement. Becton’s infringement argument was that the hinges in Tyco’s needles contain stored energy and that when the hinged arm is unlatched, the hinges act as “springs” that cause the guard to move down the needle cannula. But the Court noted that Becton did not provide any evidence that (1) the hinges in the accused devices contained stored energy, or (2) they moved the guard down the needle cannula. The Federal Circuit rejected Becton’s assertion that the fact that the jury was able to examine the accused devices provided sufficient support for the finding of infringement. The Court stated that the jury was not free to disregard the overwhelming record evidence showing that no movement of the guard occurred after the hinged arm was unlatched, and instead to infer that the hinges might contain some stored energy that might be capable of moving the guard down the needle cannula. The Court held that a jury verdict based on inferences wholly unsupported by the record cannot stand.

Becton also argued that Tyco’s accused needles did have springs that were separate structures from the hinged arm. In support, Becton asserted that the hinges in the hinged arm were separate structures from the hinged arm itself. The Federal Circuit found this argument unavailing. The Court found that even if Becton’s assertion were true, there was no evidence that the hinges function as springs that move the guard down the needle cannula.

Finally, the Federal Circuit rejected Becton’s argument that the district court erred in granting Tyco’s motion for an order in limine precluding Becton from presenting evidence that Tyco’s accused products infringed the ’544 patent during the manufacturing process. Because Becton’s argument was not properly raised during discovery, the Court found that the district court did not abuse its discretion in precluding Becton from presenting evidence regarding its theory at trial. Accordingly, the Court reversed the judgment of the district court.

Judge Gajarsa dissented from the majority opinion, indicating that the majority failed to conduct a claim

construction analysis to determine whether construction of the “spring means” limitation is a means-plus-function limitation governed by 35 U.S.C. § 112, ¶ 6. Judge Gajarsa further stated that the majority’s construction of “spring means” as requiring two separate structures was not supported in the record. While Judge Gajarsa agreed with the majority that the use of different terms in the claims like “spring means” and “hinged arm” connotes different meanings, he noted that “the use of two terms in a claim requires that they connote different *meanings*, not that they necessarily refer to two different *structures*.” Gajarsa Dissent at 7 (citation omitted). Judge Gajarsa also noted that it is well established that a single structure in an accused device may satisfy two different claim limitations, and in the absence of evidence requiring two structures, the claim language must be interpreted broadly to read upon an accused product containing the two claim terms, regardless of whether those elements are encompassed in one or two structures.

On the issue of infringement, Judge Gajarsa stated that had the majority correctly viewed the evidence in the light most favorable to Becton and properly analyzed the jury verdict, it would have concluded that there was substantial evidence in the record supporting the jury’s finding of infringement. Accordingly, Judge Gajarsa concluded that the district court was correct in denying the JMOL motion.

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