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RECENT DEVELOPMENTS IN THE LAW OF OBVIOUSNESS

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I. STATISTICS

From October 2008 through December 2009, the Federal Circuit heard approximately 51 appeals involving dispositive issues of obviousness. In 21 of those, the Federal Circuit affirmed or affirmed-in-part determinations that one or more claims of a patent was obvious, compared with one where it reversed and six where it vacated. This reversal rate contrasts that for underlying determinations of nonobviousness as only nine were outright affirmed or affirmed-in-part, whereas eight were reversed. Again, six of such determinations were vacated. The Federal Circuit ultimately found claims obvious in the majority of the cases—57 percent. The court found claims nonobvious in only 20 percent of the cases. The rest of the underlying obviousness determinations—about 24 percent—were vacated. These statistics are set out in the chart below. The remainder of this article summarizes some of the more notable cases.

Federal Circuit Obviousness Determinations	Number of Opinions	Percent of Total
Total Opinions 10/08-12/09	≈ 51	_
Affirmed Obviousness Finding	21	41%
Affirmed Nonobviousness Finding	9	18%
Reversed Obviousness Finding	1	2%
Reversed Nonobviousness Finding	8	16%
Vacated Obviousness Finding	6	12%
Vacated Nonobviousness Finding	6	12%
Claims Found Obvious	29	57%

II. NOTABLE CASES

Perfect Web Techs., Inc. v. InfoUSA, Inc., 587 F.3d 1324 (Fed. Cir. 2009) (affirming summary judgment of obviousness)

Judges: Linn, J.; Dyk, J.; Prost, J.

Opinion: Judge Linn filed the opinion of the court.

Summary: Perfect Web filed suit against InfoUSA alleging infringement of a patent claiming methods of managing bulk email. Contemporaneous with claim construction, InfoUSA moved for summary judgment of invalidity. After conducting a claim construction hearing, but without issuing a formal claim construction order, the district court granted InfoUSA's motion. It assumed for purposes of summary judgment that Perfect Web's claim constructions were correct. The district court found that the first three elements of the key claim at issue were disclosed by a single reference and that the fourth and final element would have been obvious. This last element consisted of repeating the first three elements "until said calculated quantity [of emails] exceeds said prescribed minimum quantity."

On appeal, the parties narrowed their argument primarily to the single issue of whether the last step of the key claim would have been obvious. In particular, InfoUSA contended that this step was the "common sense" addition to the first three steps. In analyzing this argument, the Federal Circuit noted "Common sense has long been recognized to inform the analysis of obviousness if explained with sufficient reasoning." Accordingly, the Federal Circuit stated

We therefore hold that while an analysis of obviousness always depends on evidence that supports the required *Graham* factual findings, it also may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do not necessarily require explication in any reference or expert opinion.

The court found that evidence to support the district court's "common sense" reasoning appeared in the record: the fact that the last step of the claim recited repeating earlier steps. Separately, InfoUSA argued and the Federal Circuit found that the last step would have been obvious to try. The judgment of invalidity was affirmed.

Amgen Inc. v. Hoffman-La Roche, Ltd., 580 F.3d 1340 (Fed. Cir. 2009) (affirming-in-part and vacating-in-part findings that claims were patentably distinct)

Judges: Mayer, J.; Clevenger, J.; Schall, J.

Opinion: Judge Schall filed the opinion of the court.

Summary: Amgen brought a declaratory judgment action against Roche alleging that Roche's MIRCERA® would infringe Amgen's five patents covering human erythropoietin ("EPO") if imported into the United States. Following summary judgment proceedings, a jury trial, and JMOL, the district court entered judgment that four of Amgen's patents were infringed and not invalid, and that the remaining patent was neither invalid nor infringed. The court further granted Amgen a permanent injunction, enjoining Roche from marketing MIRCERA® in the United States. Roche appealed on multiple grounds,

including anticipation, indefiniteness, double patenting, and non-infringement. Amgen cross-appealed.

One of the key issues on appeal was obviousness-type double patenting. Amgen contended that three of its later-filed patents were protected by the § 121 safe harbor against double patenting for divisional applications. Roche argued that these patents were not entitled to safe harbor treatment because they did not issue from true divisionals; rather they issued from continuations of an earlier-filed parent application. While the PTO had issued a restriction requirement in the parent application, it was undisputed that the applications at issue were continuations. Nevertheless, Amgen posited that the applications qualified as divisionals under MPEP § 201.06 because they were (1) carved out of a pending application, (2) contained claims to distinct and independent inventions, and (3) disclosed and claimed subject matter disclosed in the parent application. In essence, Amgen argued that since the applications could have been filed as divisionals, they should be treated as such. The Federal Circuit was not persuaded. It found that because Amgen "checked the continuation application box," it could not now argue that the applications were divisionals. Accordingly, the district court's findings with respect to obviousness-type double patenting for Amgen's product patents were vacated and remanded.

Next, the Federal Circuit addressed the time frame for double patenting analysis of product claims. The court's earlier decision in *Takeda Pharmaceutical Co. v. Doll*, 561 F.3d 1372 (Fed. Cir. 2009), had allowed a patentee to rely on developments in the art as of the date of a later filed application to show that the product claims in that application were patentably distinct over earlier filed product-by-process claims. Roche argued the same rule should apply for any intervening art that shows a claim is not patentably distinct. The Federal Circuit found that such a rule would run contrary to § 120, by denying the patents at issue (all continuations) the benefit of their parent's filing date. In the end, the court limited the holding of *Takeda*:

Because of § 120, we read *Takeda* to stand for the limited proposition that an applicant can only rely on subsequent developments in the art up to the filing date of the "secondary application" in order to show that alternative processes to make the product render the product and the process for making that product patentably distinct.

The Federal Circuit, however, noted that *Takeda* is a two way street. If Amgen were to rely on intervening art to establish patentability on remand, Roche would be able to rely on its own intervening art to show that any alternative processes for making the claimed products do not render the claims patentably distinct.

The Federal Circuit then turned to Amgen's process patents. The district court had engaged in the proper analysis with respect to these patents by: (1) construing the claims and identifying any differences, and (2) considering whether the differences would have been obvious to one of ordinary skill in the art. The earlier filed patent had claimed transfecting Chinese hamster ovary ("CHO") cells with DNA coding for human EPO. The patents at issue claimed using these cells to produce therapeutically effective amount of EPO. Using an analysis analogous to that conducted under § 103, the Federal Circuit found that one of ordinary skill would not have had a reasonable expectation of success in isolating EPO after transfecting the CHO cells. Thus, it affirmed the district court's finding that the process claims were patentably distinct. After affirming and vacating various other aspects of the district court's judgment, the Federal Circuit ultimately decided not to disturb the district court's injunction.

In re Fallaux, 564 F.3d 1313 (Fed. Cir. 2009) (affirming BPAI finding that the two-way test for obviousness-type double patenting did not apply)

Judges: Schall, J.; Archer, J.; Moore, J.

Opinion: Judge Moore filed the opinion of the court.

Summary: The inventors of the Fallaux application appealed a decision by the BPAI affirming final rejections of various claims for obviousness-type double patenting. The rejections had found that the claims were unpatentable over certain patents to Vogels et al. by way of a single common inventor. In a footnote, the Federal Circuit noted:

Neither party raised or argued the question of whether a patent may be used as a reference for an obviousness-type double patenting rejection where the patent shares only a common inventor with the application, rather than an identical inventive entity or a common assignee. The Manual of Patent Examination Procedure (MPEP) allows such a rejection. This opinion should not be read to decide or endorse the PTO's view on this issue.

Despite this comment, the court analyzed double patenting over the Vogels patents, and ultimately upheld the rejection.

The key issue on appeal was whether the appropriate double patenting test had been used. In prosecution, the examiner had applied the one-way test to reject the Fallaux claims; the inventors argued that the two-way test should have been applied. Under settled law, the two- way test is only appropriate where: (1) a later filed application that has issued as a patent is used to frame rejections against an earlier filed application, and (2) the PTO is "solely responsible for the delay in causing the second-filed application to issue prior to the first." Substantial evidence supported the BPAI's finding that the inventors chose to file the Fallaux application after the Vogels patents had already issued. Hence the Federal Circuit found that the PTO was not solely responsible for the delay in examining the Fallaux application because the inventors could have included the claims in a parent application.

Perhaps more notably, the inventors further argued that the two-way test should apply because they were not seeking a time-wise extension of the patent right. Indeed, they had attempted to file a terminal disclaimer. This disclaimer was ineffective because the Vogels patents had been assigned to different entities and therefore were not "commonly owned." The court made no further reference to whether the lack of common ownership undermined the double patenting rejection itself. Rather, in addressing this issue, the Federal Circuit stated a second justification for obviousness-type double patenting: "harassment by multiple assignees," and affirmed the decision of the BPAI.

Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288 (Fed. Cir. 2009) (reversing-in-part JMOL of non-obviousness)

Judges: Newman, J.; Gajarsa, J.; Dyk, J.

Opinions: Judge Gajarsa filed the opinion of the court. Judges Newman and Dyk filed concurring opinions.

Summary: Fresenius appealed and Baxter cross-appealed a final judgment entered by the district court. The patented technology involved touch screen hemodialysis machines. Fresenius initially filed suit seeking a declaration that certain of Baxter's patents were invalid and not infringed. Baxter counterclaimed for infringement. Following claim construction, Fresenius admitted infringement, leaving validity as the only issue remaining for trial. The jury found that some of the claims were anticipated and that they all were obvious. But the district court granted Baxter's motion for JMOL and issued a permanent injunction, finding that substantial evidence did not support the jury's verdict.

The Federal Circuit addressed the issue of obviousness, analyzing the "implicit findings necessary to support the verdict" because the jury did not make explicit factual findings. For one claim, the issue was whether the jury could implicitly use anticipation evidence and opinion offered as to an independent claim to support its finding that a dependent claim was obvious. The Federal Circuit held that it could. The court also addressed the breadth of Markush claims, the use of demonstratives, and motivation to combine the prior art, finding support for the jury's obviousness findings. The Federal Circuit thus reversed the JMOL of non-obviousness for most of the claims. The court affirmed the JMOL with respect to six means-plus-function claims, however, because Fresenius had neither identified the corresponding structure for the claimed means, nor compared it to structures in the prior art. The permanent injunction was therefore vacated, so that it could be reconsidered in light of the court's holding.

While this case is an interesting example of how the court reviews obviousness decisions by both juries and judges, it is perhaps more interesting for the two concurring opinions, in which Judges Newman and Dyk debated the merits of stays pending reexamination. Judge Dyk joined the opinion "on the understanding that it does not foreclose the district court in its discretion from staying further proceedings pending the outcome of the reexamination before the U.S. Patent and Trademark Office." Judge Newman wrote separately to respond to Judge Dyk's proposal, noting that "at this stage in this protracted litigation, after full trial and decision in the district court, after full appeal and ruling of the appellate court and with only a modified remedy remaining on remand, such an action would be inappropriate." While she noted she is a "strong supporter of the principle of reexamination," Judge Newman analyzed the long pendency of stays pending reexamination, and concluded that a stay would be "contrary to the precepts of expeditious and just resolution of disputes" in the case at hand.

<u>Callaway Golf Co. v. Acushnet Co.</u>, 576 F.3d 1331 (Fed. Cir. 2009) (vacating jury verdict on obviousness and remanding)

Judges: Linn, J.; Dyk, J.; Prost, J.

Opinion: Judge Dyk filed the opinion of the court.

Summary: Callaway brought suit against Acushnet, alleging that it infringed four patents with claims covering golf balls. Acushnet stipulated that it infringed, leaving anticipation and obviousness as the issues for trial. A jury determined that all of the asserted claims were not invalid except for a single dependent claim, which the jury found invalid for obviousness. Notably, the jury found that an independent claim (from which the invalid claim depended) was not invalid. The district court entered final judgment on the jury's verdict.

On appeal, one key issue was whether the district court properly entered judgment on what Acushnet contended was an "irreconcilably inconsistent" jury verdict. The Federal Circuit reviewed the issues not unique to patent law under Third Circuit law. First, it found that that verdict was inconsistent because "[a] broader independent claim cannot be nonobvious where a dependent claim stemming from that independent claim is invalid for obviousness." Second, the court found that the verdict could not be read in such a way as to resolve the inconsistency; the evidence at trial supported either outcome and neither party was entitled to JMOL. The Federal Circuit therefore vacated the district court's judgment and remanded for a new trial on obviousness. After remand, a jury found all the asserted claims obvious.

In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009) (affirming BPAI finding of obviousness)

Judges: Rader, J.; Friedman, J.; Linn, J.

Opinion: Judge Rader filed the opinion of the court.

Summary: The inventors of the Kubin application appealed a decision of the BPAI, which found obvious their claimed DNA encoding a protein known as the "Natural Killer Cell Activation Inducing Ligand ('NAIL')." The key piece of prior art was the Valiante patent, which disclosed "a receptor protein called 'p38'" that is the same protein as NAIL. Thus, the prior art established that the protein encoded by the inventor's claimed DNA was previously known to exist. Valiante, however, disclosed "neither the amino acid sequence of p38... nor the polynucleotide sequence that encodes p38." Nevertheless, the BPAI found the claims at issue obvious in light of Valiante and a laboratory manual providing general methods for cloning genetic material.

The Federal Circuit affirmed the BPAI. In so doing, it overruled the longstanding precedent of *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), which had held that the results of cloning a gene of unknown sequence are non-obvious, even where there was a reasonable expectation of success: "Insofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim's constituent elements was 'obvious to try,' the Supreme Court in *KSR* unambiguously discredited that holding." The Federal Circuit noted that Valiante disclosed the protein of appellants' interest and suggested the protocol for cloning it. Thus, the court found that the claimed invention was "the product not of innovation but of ordinary skill and common sense." The Federal Circuit also considered how *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), limits "obvious to try" analysis, but found the case fell outside the purview of its exceptions.

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999 (Fed. Cir. 2009) (affirming denial of preliminary injunction on the basis of obviousness)

Judges: Newman, J.; Gajarsa, J.; Ward, J.

Opinions: Judge Ward (District Judge of the Eastern District of Texas, sitting by designation) filed the opinion of the court. Judge Newman filed a concurring opinion.

Summary: Altana sued several generic drug manufacturers for infringement of a patent directed to antiulcer medication after they filed ANDAs, seeking approval to market generic versions of Altana's proton pump inhibitor ("PPI") Protonix.* The defendants admitted infringement, but maintained that the asserted claims were invalid for obviousness. Altana

sought a preliminary injunction, which was denied. In denying the injunction, the district court found that Altana had not established a strong likelihood of success on the merits because Altana's prior art patent combined with two other references established a prima facie case of obviousness. The court also found that Altana had not shown the requisite irreparable harm. The denial of the injunction was affirmed on appeal.

In affirming, the Federal Circuit focused its analysis on Altana's likelihood of success on the merits. According to the court:

If the alleged infringer raises a "substantial question" of invalidity, the preliminary injunction should not issue. The burden on the accused infringer to show a substantial question of invalidity at this stage is lower than what is required to prove invalidity at trial. "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial."

Altana challenged the district court's finding that defendants had raised a substantial question of obviousness. Since the case involved a chemical compound, the court noted that the obviousness analysis could turn on the structural similarities between the claimed compound and the prior art: "Obviousness based on structural similarity may be proven by the identification of some motivation that would have led one of ordinary skill in the art to select and modify a known compound in a particular way to achieve the claimed compound." The Federal Circuit found that the district court did not abuse its discretion in determining that the patent at issue was vulnerable to obviousness attack; Altana's prior art patent used a structurally similar compound that one of ordinary skill could have pursued to develop PPIs. The Federal Circuit also found that the district court did not clearly err in its irreparable harm analysis. Judge Newman concurred in the opinion of the court, noting that she did not believe that the evidence established invalidity of Altana's patent but that deference to the district court was warranted because it had engaged in a discretionary action at a preliminary stage in the case.

Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc., 555 F.3d 984 (Fed. Cir. 2009) (reversing denial of summary judgment of obviousness)

Judges: Lourie, J.; Clevenger, J.; Linn, J.

Opinion: Judge Lourie filed the opinion of the court.

Summary: Ball sued Limited for infringement of a patent directed to a candle tin with a removable cover that also acts as a base for the candle holder. The district court denied Limited's motion for summary judgment of obviousness and *sua sponte* granted summary judgment of validity to Ball. The Federal Circuit reversed. On appeal, the key issue was whether a motivation to combine the various teachings of the prior art existed. The district court interpreted *KSR* to require that Limited's motivation to combine analysis "should have been made explicit." The Federal Circuit noted that this requirement applied to the district court's analysis, not that of the litigants. Since the problem the invention sought to address was known, and it was undisputed that all of the elements of the asserted claims were in the prior art, the court found that *KSR* compelled a grant of summary judgment of obviousness. Ball's showing of commercial success was not sufficient to outweigh the indication of obviousness from the prior art.

Boston Scientific Scimed, Inc. v. Cordis Corp., 554 F.3d 982 (Fed. Cir. 2009) (reversing denial of JMOL of obviousness)

Judges: Lourie, J.; Rader, J.; Prost, J.

Opinion: Judge Lourie filed the opinion of the court.

Summary: Boston Scientific brought suit against Cordis for infringement of a patent relating to drug eluting stents. At trial, the jury found that the asserted claim was infringed and not obvious. Cordis then filed a motion for JMOL and a new trial, which the district court denied, finding the jury verdict was supported by the evidence. On appeal, Cordis argued that the claim at issue was obvious over a single patent assigned to Medtronic. Boston countered that Medtronic failed to develop the claimed step until after the filing date of the patent at issue, suggesting the claimed invention was not obvious.

In assessing the parties' arguments, the Federal Circuit first addressed the standard of review. The court noted that it reviews the jury's conclusions on obviousness "without deference" and the underlying findings of fact for substantial evidence. The court further clarified:

While a jury may render a decision on a question of obviousness when it is considering any underlying fact questions, obviousness is ultimately a question of law that this court reviews *de novo*. When we consider that, even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, we may reverse its obviousness determination.

The court then reviewed the prior art references independent of the jury's implicit findings and found the claim at issue obvious over a single reference. That reference contained aspects of the claimed stent in two separate embodiments shown in different figures. According to the court, one of ordinary skill would have been motivated to combine these figures. The court dismissed Boston Scientific's evidence of secondary considerations due to the strength of the prima facie case. The judgment of the district court was therefore reversed.

Sundance, Inc. v. DelMonte Fabricating Ltd., 550 F.3d 1356 (Fed. Cir. 2008) (reversing JMOL of non-obviousness)

Judges: Dyk, J.; Prost, J.; Moore, J.

Opinion: Judge Moore filed the opinion of the court.

Summary: Sundance sued DeMonte for infringement of a patent directed to segmented covering systems. A jury found that the asserted claim was infringed but invalid for obviousness. Sundance moved for JMOL of non-obviousness, which the district court granted, finding that DeMonte had failed to show reasons to combine. The district court also noted that secondary considerations, such "long-felt but unresolved need" and "copying," supported a finding of non-obviousness. It denied DeMonte's request for reconsideration in light of *KSR*. On appeal, the Federal Circuit considered whether the court properly admitted the testimony of DeMonte's expert—a patent lawyer—on various issues, including obviousness. At trial, Sundance had moved in limine to exclude the

expert's testimony. The Federal Circuit found the district court abused its discretion in denying the motion in limine, explaining: "Unless a patent lawyer is also a qualified technical expert, his testimony on these types of issues is improper and thus inadmissible." As a result, the court found that there was no expert testimony supporting the jury verdict of obviousness. It decided that expert testimony was not required, however, because the technology at issue was "simple." Indeed, the Federal Circuit concluded that one of ordinary skill would have found it obvious to incorporate the features of the claimed invention into a cover system, barely addressing secondary considerations raised by Sundance. The court noted, "Secondary considerations of nonobviousness—considered here by the district court—simply cannot overcome this strong prima facie case of obviousness." Accordingly, the district court's judgment was reversed.

Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351 (Fed. Cir. 2008) (finding a verdict of non-obviousness does not foreclose a finding of anticipation)

Judges: Mayer, J.; Linn, J.; Prost, J.

Opinion: Judge Linn filed the opinion of the court. Judge Mayer filed a dissenting opinion.

Summary: Cohesive brought three related actions against Waters alleging infringement of two patents covering high-performance liquid chromatography columns ("HPLC"), which are used for separating, identifying, and measuring compounds contained in a liquid. In the first action, a jury found that one of Cohesive's patents was not invalid and that Waters's 30 mu products infringed. The court did not charge the jury on anticipation as requested by Waters. In the second action, the district court granted summary judgment that the same products infringed another of Cohesive's patents, and that this patent also was not invalid. In the third action, the district court granted summary judgment that Waters's 25 mu products did not infringe either patent.

On appeal, the Federal Circuit found that the district court was wrong to conclude that granting JMOL on anticipation would not harm Waters in light of the jury's opportunity to consider obviousness. The court explained:

Despite the often quoted maxim that anticipation is the "epitome of obviousness," novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103 are separate conditions of patentability and therefore separate defenses available in an infringement action. While it is commonly understood that prior art references that anticipate a claim will usually render that claim obvious, it is not necessarily true that a verdict of nonobviousness forecloses anticipation. The tests for anticipation and obviousness are different. For instance, the court noted that "secondary considerations are not an element of a claim of anticipation," so not every anticipated invention will also have been obvious. The Federal Circuit therefore remanded the issue of anticipation back to the district court. In dissent, Judge Mayer agreed that the district court should have submitted the issue of anticipation to the jury. He disagreed, however, that the case should be remanded in light of the jury's finding on obviousness. According to Judge Mayer, "The majority's assertion that a claim can be anticipated but not obvious flies in the face of a long line of precedent to the contrary."