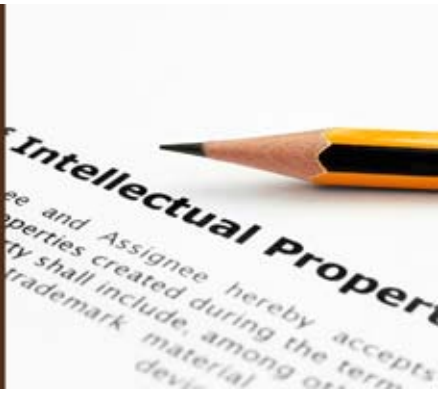
KING & SPALDING

Intellectual Property Newsletter



Clarification of the 'Vitiation Test" when applying the Doctrine of Equivalents.

Adam Conrad

Deere & Co. v. Bush Hog, LLC, No. 2011-1629 (Dec. 4, 2012).

http://docs.justia.com/cases/federal/appellate-courts/cafc/11-1629/11-1629-2012-12-04.pdf

A unanimous panel of the Fed Circuit reversed a grant of summary judgment of non-infringement, clarifying the limits of the "vitiation test" when applying the doctrine of equivalents.

Deere & Co's U.S. Patent 6,052,980 covers an improvement in rotary cutters of the type that are pulled behind a tractor for large-scale mowing. The cutters often accumulate debris and can rust as a result of moisture in the debris if not cleaned properly. The patented invention reconfigures the cutters to eliminate debris traps while maintaining cutting efficiency by having front and rear portions of an upper deck wall that are placed "into engagement with, and being secured to" a lower deck wall.

The district court construed the phrase "into engagement with" as requiring direct contact between the two deck walls. Because the deck walls in the accused products do not directly contact one another, the court granted summary judgment of non-infringement based on this construction. The district court also granted summary judgment as to the doctrine of equivalents, holding that, under its claim construction, deck walls are either in

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New York partners Bruce Baber and Katie McCarthy to speak at PLI's Annual "IP Enforcement and Litigation" seminar in New York and webinar on Feb. 1, 2013.

contact or they are not. In the district court's view, permitting a showing of equivalents in the absence of direct contact, would vitiate the claim language. The Fed Circuit vacated the district court's claim construction, concluding that the claim language and specification permit engagement through indirect contact as well as direct contact. The court therefore reversed the grant of summary judgment of literal non-infringement.

In addition to the erroneous claim construction, the Fed Circuit also criticized the district court's doctrine-of-equivalents analysis. The district court had construed "contact" to require "direct contact" and therefore concluded that allowing the upper deck wall to have indirect contact only with the lower deck wall would vitiate the court's construction of the "direct contact" term. To this, the Fed Circuit cautioned that courts should not shortcut the equivalence inquiry by "identifying a 'binary' choice in which an element is either present or 'not present.'" The vitiation test cannot be satisfied by simply noting that an element is missing from the claimed structure. By definition, the doctrine of equivalents applies where an element is literally missing. If it were otherwise, the concept of "vitiation" would swallow the doctrine of equivalents. The proper inquiry for the court is to ask whether an asserted equivalent represents an "insubstantial difference" from the claimed element or alternatively, "whether the substitute element matches the function, way, and result of the claimed element." In the present case, "a reasonable jury could find that a small spacer connecting the upper and lower deck walls represents an *insubstantial difference* from direct contact."

The "Success More Likely Than Not" and "Ordinary Observer" Standards for a Preliminary Injunction in design patent infringement.

Peter Dehlinger

Revision Military Inc. v. Balboa Manufacturing Co., case number 11-1628 (Nov. 27, 2012).

http://www.cafc.uscourts.gov/images/stories/opinions-orders/11-1628.pdf

Revision Military, Inc., manufacturer of protective eyewear used in the military and in law-enforcement, sought a preliminary injunction against Balboa Manufacturing Co. for selling eyewear that it alleged infringed two of its design patents. The district court denied the request for a preliminary injunction based on two determinations. First, the district court applied the Second Circuit's heightened standard of "clear or substantial likelihood of success" on the merits and concluded that Revision did not meet this standard. Second, the test for design patent infringement applied by the district court focused on features that "stand out as dissimilar," reciting particular distinguishing features of the Balboa glasses that differed from the Revision eyewear.

The Fed Circuit took issue with both standards applied by the district court. On the question of likelihood of success, the Fed Circuit was emphatic that "substantive matters of patent infringement are unique to patent law, and thus the estimated likelihood of success in establishing infringement is governed by Federal Circuit law." Revision need only meet the Federal Circuit's standard of whether "success is more likely than not," rather that the Second Circuit's heightened "clear or substantial likelihood" standard.

On the proper test for design-patent infringement, the "ordinary observer" test asks whether the designs at issue are substantially the same to the eye

of the ordinary observer, viewing the designs as a whole. Although the district court stated the correct standard, it failed to consider the background prior art in determining whether apparently minor differences between the two designs at issue would be recognized as distinguishable by an ordinary observer. That is, the district court failed "to consider the prior-art context in which the ordinary observer test is applied."

The district court's denial of preliminary injunction was vacated and the case remanded for redetermination in light of the "success more likely than not," and "ordinary observer" standards applicable to design-patent infringement.

eBay Revisited - A Normal Expectation of Injunction?

John Harbin

Edwards Lifesciences AG v. CoreValve, Inc., No. 2011-1215 (Nov. 13, 2012).

http://docs.justia.com/cases/federal/appellate-courts/cafc/11-1215/11-1215-2012-11-13.pdf

Edwards Lifesciences brought suit on its patent on a prosthetic device, called a "transcatheter heart valve," mounted on a stent and implanted in the heart by catheter, thus avoiding the risks of open heart surgery. The Federal Circuit affirmed the verdict for the patentee, but reversed the trial court's denial of injunctive relief and remanded, using some evocative language about when injunctions are appropriate.

The court affirmed the finding of enablement, rejecting the defendant-appellant's argument the claims were not enabled because the only testing had been done on pigs and not always successfully. The court noted the long-time recognition that, when experimentation on human subjects is inappropriate, as in the testing and development of medical devices, the enablement requirement may be met by animal tests or in vitro data. The court noted that the prosthetic device had been successfully implanted in pigs, in accordance with procedures described in the specification, and that pigs are a standard experimental animal, and cited evidence about the established use of porcine valves in humans.

The court also affirmed the infringement finding and affirmed, without any detailed discussion, the damages award of almost $74 million.

Most notably, the Federal Circuit vacated the trial court's denial of an injunction, holding that: "[a]bsent adverse equitable considerations, the winner of a judgment of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement." (Emphasis supplied.) The court noted the parties were direct competitors and that the trial court had erred in (a) finding that the patentee had already lost market share in the U.S., because the evidence showed the FDA had not yet authorized sales in the U.S.; and (b) finding that the patentee had given up its exclusivity by licensing the technology to another competitor because, as the defendant conceded, there was no such license. Also, the trial court had relied on the defendant's statements that it was immediately moving production to Mexico. The patentee argued on appeal and the defendant did not deny that it actually continued its production of infringing product in California. The court remanded the case for the trial court to reconsider the request for an injunction in light of subsequent events.

Judge Prost concurred with the decision to vacate the denial of the injunction but disagreed with the majority's statement quoted above, concluding that it deviates from the Supreme Court's four-factor test for an injunction in eBay:

> "Some complain of areas of patent law in which our guidance is mixed or muddled.

> This is not - or should not be - one of those areas after the Supreme Court's clear pronouncement in eBay … . We should take care to avoid possible misinterpretation of an otherwise clear Supreme Court standard."

Despite Judge Prost's admonition, it will be interesting to see if this case signals a shift by the Federal Circuit in favor of granting injunctive relief, where the parties are competitors.

Fed Circuit invalidates Intema patent under §101, but its reasoning highlights an inconsistency in Supreme Court's Prometheus decision.

Peter Dehlinger

PerkinElmer Inc. et al. v. Intema Ltd., case number 2011-1577 (Nov. 20, 2012).

http://www.cafc.uscourts.gov/images/stories/opinions-orders/11-1577.pdf

Intema's U.S. Patent 6,573,103 claims a method for determining the risk of Down's syndrome in a prenatal test that is less invasive and risky than amniocentesis. The method involves measuring the level of a sample or ultrasound screening marker in the first trimester of pregnancy, measuring the level of a second sample and/or ultrasound marker in the second trimester, and determining the risk of Down's syndrome by comparing the two marker levels with the observed relative frequencies of those markers in Down's syndrome and normal-fetus pregnancies.

When Intema brought suit against PerkinElmer for infringement of its '103 patent, the district court determined that the patent was drawn to patent-eligible subject matter under §101, but invalid as anticipated by and obvious over the prior art. On appeal, the Fed Circuit considered only the §101 issue, and concluded that the claimed invention did not meet the requirements of §101, applying the reasoning from the Supreme Court's *Prometheus* decision (*Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S.Ct. 1289 (2012)) and its own recent *Myriad* decision on rehearing (*Ass'n for Molecular Pathology v. PTO*, 689 F.3d 1303 (Fed. Cir. 2012)).

The Fed Circuit determined that the claimed assay method in Intema's patent embodied a law of nature -- in this case, a "natural law" that linked the value of certain first and second trimester markers with an increased risk of Down's syndrome -- and failed to meet any of the subtests that can rescue a law-of-nature from patent ineligibility. One subtest asks whether the process claim, apart from the ineligible natural law itself, contains more than "well-understood, routine, conventional activity previously engaged in by researchers in the field," that is, whether it contains an inventive concept sufficient to ensure that "the patent in practice amounts to significantly more than a patent upon the natural law itself." A second subtest asks whether the claimed process meets the machine-or-transformation test emphasized by the Fed Circuit in its *en banc Bilski* decision. A third subtest, and one applied in the Fed Circuit's *Myriad* decision, asks whether the claimed method requires a statutory machine, manufacture, or composition or composition for its operation?

In *Myriad*, a screening method for cancer treatment involved comparing the growth rates of cells transformed with a cancer-causing gene in the presence and absence of a test compound. Despite the fact the comparison step was a patent ineligible mental step, the claimed was redeemed as patent eligible because it required cells that were themselves patent-eligible under the *Chakrabarty* "hand-of-man" standard.

The third subtest would appear to be grounded in the language of 35 USC §101. A method that requires a patent-eligible machine, manufacture, or

composition of matter for its operation can be viewed as a "new and useful improvement thereof," bringing it within the ambit of §101. Or, as the court in *Myriad* stated, "once one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature."

Although the claimed process in *Intema* failed to meet any of the above subtests, it cannot have been lost on the court that its reliance on the third subtest in both its *Myriad* and *Intema* decisions was inconsistent with the Supreme Court's *Prometheus* decision. The process claims before the Court in *Prometheus* were to a diagnostic assay that required, as its first step, "administering a drug providing 6-thioguanine to a subject having [an] immune-mediated gastrointestinal disorder." The claimed method clearly requires the use of a 6-thioguanine drug, itself a patent-eligible compound. The Supreme Court's emphasis on the "law-of-nature" prohibition may have blinded it to the more salient fact that the claimed process in Prometheus is a new and useful improvement of a patent eligible drug (6-thioguanine) -- an improvement that allows the drug to be administered at an optimized dose when used in treating an immune-related gastrointestinal disorder.

Apparently Obvious, But Not: When Secondary Considerations Become Primary.

John Harbin

Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., No. 2011-1555 (Nov. 15, 2012).

http://www.cafc.uscourts.gov/images/stories/opinions-orders/11-1555.pdf

Transocean brought suit against Maersk to enforce its patents on an improved apparatus for offshore drilling. The Federal Circuit reversed the trial court's grant of JMOL to the defendant, Maersk, on obviousness even though, in a previous appeal, the Fed Circuit had found that two prior art references contain all of the elements of the asserted claims and provide a motive to combine so that a prima facie case of obviousness had been established. On remand, the jury found for the patentee, Transocean, on seven secondary considerations of non-obviousness: commercial success, industry praise, unexpected results, copying, industry skepticism, licensing, and long-felt but unsolved need. Hence, the court found, this was the rare case in which such considerations overcome a prima facie case.

Regarding the first factor, commercial success, Transocean presented sufficient evidence of both success and its nexus to the claimed invention. It showed its drilling rigs commanded a market premium over other rigs, introducing contracts that provided for reduced daily rates if the patented feature was not present and evidence that some customers expressly required that feature. Transocean also offered testimony from a Maersk employee that it added the patented feature to its drilling rig design because market surveys established customer demand for it, and testimony that the patented design had become the industry standard. Also, the court found the trial court had erred in considering a rejection of the claims by the European Patent Office.

Regarding the second and third factors, industry praise and unexpected results, Transocean presented numerous documents showing industry praise for the unexpected increase in drilling efficiency made possible by the patented technology, including a paper from a competitor and articles in a trade magazine, one describing the features of Transocean's rigs and characterizing the technology as being critical to the future. One of the inventors testified that industry members had doubted whether the claimed feature would increase drilling efficiency. Transocean's evidence also linked the

industry praise and the unexpected efficiency gains directly to the claimed feature.

As for the copying factor, Transocean cited an internal Maersk document stating it had to incorporate the patented feature, which the memo distinguished from the prior art. Also, the court noted, Maersk was aware of Transocean's patents when designing its accused rig and decided to incorporate the claimed feature anyway because it believed the patents were invalid over the prior art. Regarding industry skepticism, the two inventors testified that industry experts and Transocean's customers were skeptical of the claimed feature due to fears of an adverse operational side-effect.

Regarding licensing, Transocean established its licenses to customers and competitors were due to the merits of the claimed invention. The court rejected Maersk's contentions that Transocean's licenses were attributable instead to the threat of litigation and were not tied to the asserted claims, citing Transocean's assertions that the royalties exceeded any litigation costs. One party had paid a royalty of nearly $500,000 for one month of operations and at least three companies had taken licenses without any apparent threat of litigation.

Regarding the factor of long-felt but unsolved need, there was conflicting evidence but Transocean presented evidence that its technology satisfied a long-felt need for greater drilling efficiency, that the drilling industry had been operating in deep water since the 1970s, and that the industry tried another method that failed.

As to each of the seven factors, the court held, substantial evidence supported the jury's finding. The court noted that it has rarely found objective evidence sufficient to overcome a prima facie case of obviousness but also that few cases present such extensive objective evidence of nonobviousness. This, the court held, "is precisely the sort of case where the objective evidence 'establish[es] that an invention appearing to have been obvious in light of the prior art was not.'" (Citations omitted.) The court concluded that Maersk failed to prove by clear and convincing evidence that the asserted claims would have been obvious.

Interestingly, the court also reversed the trial court's conditional grant of new trial, even after holding that that the jury had erred in finding the prior art lacked certain elements of the claims. (As discussed, the Federal Circuit had expressly found in the prior appeal that all claim elements appeared in two prior art references.) Because its prior finding was the law of the case, the court found, conducting a new trial would serve no purpose. The court rejected the trial court's opinion that a new trial was needed because the jury's findings on secondary considerations may have been tainted by the court's failure to instruct the jury that the first three Graham factors already had been resolved in Maersk's favor. "These were discrete and separate fact questions on the special verdict. There is no reason to think that because the jury erred on one such fact finding, the other, unrelated fact findings are somehow tainted."

The court also reversed the trial judge's other JMOL decisions in favor of Maersk for lack of enablement and non-infringement. On the first issue, the court found substantial evidence supported the jury's verdict that Maersk failed to prove that undue experimentation would be required. Regarding infringement, the district court relied on the fact that the initial design that Maersk had sold had been changed to avoid infringement. But the jury's conclusion that what Maersk offered for sale and initially sold was infringing was supported by substantial evidence. The court noted that Maersk did not argue on appeal that the schematics in its contract were missing any of the limitations of the asserted claims.

Finally, the court reversed the trial court's grant of JMOL on damages after the jury awarded Transocean $15 million. Maersk argued that amount, equal to the upfront royalty customers had

paid for actual use of the invention, was too high because Maersk had only offered the feature and then modified its drill prior to delivery to avoid infringement. The court stated it was sympathetic with Maersk's argument but could not conclude that the jury's award lacked substantial evidence. The court cited Transocean's model license that includes an upfront fee of $15 million and a 5% running royalty when the licensee operates the rig where Transocean has patents; the fact that several companies had accepted these terms; and testimony that Transocean offered competitors such as Maersk less favorable terms than its other customers.

Hatch-Waxman's safe harbor provision is not limited to pre-approval activity.

Peter Dehlinger

Momenta Pharmaceuticals Inc. et al. v. Amphastar Pharmaceuticals Inc. et al., case numbers 12-1062, 12-1103 and 12-1104 (Aug. 3, 2012).

http://www.sunsteinlaw.com/media/2012_08_IP_Update_IASB.PDF

Momenta and Amphastar are generic drug manufacturers of the generic version of Lovenox (enoxaparin) a low-molecular weight version of heparin for use in preventing blood clots. The composition is produced by enzymatic digestion of heparin to produce a mixture of oligosaccharides. The molecular diversity of the product mixture raised potential problems in light of the FDA's abbreviated new drug application (ANDA) approval process, which requires an ANDA applicant to submit evidence to establish that its drug is bioequivalent to the reference approved drug.

Momenta and Amphastar both filed ANDAs for marketing approval of enoxaparin. The FDA, exercising its discretion in deciding the type of information required to make a finding of "sameness" of an active ingredient, identified five criteria or "standards for identity," that together provide sufficient information to conclude that generic enoxaparin has the 'same' active ingredient as Lovenox. Further, the FDA required generic manufacturers of enoxaparin to include in their manufacturing process an analysis of each batch of its enoxaparin, to confirm that it includes a defined percentage of non-naturally occurring sugar which includes a 1,6,-anhydro ring structure. Momenta received its FDA market approval in July, 2010, and Amphastar got approval more than a year later.

Two days after Amphastar received its FDA marketing approval, Momenta brought suit for infringement of its U.S. Patent No. 7,575,886. The patent covered methods for analyzing a heterogeneous population of sulfated polysaccharides, e.g., heparin and enoxaparin, and was useful, if not essential, in characterizing the levels of oligosaccharide components in enoxaparin, as required by the FDA in showing drug sameness, in particular, the percentage of sugar which includes a 1,6,-anhydro ring. Momenta alleged that Amphastar infringed its '886 patent by manufacturing generic enoxaparin for commercial sale using its claimed method.

The district court granted Momenta's motion for a preliminary injunction, based on the belief that Amphastar's quality-control testing infringed the '886 patent and that the infringing activity was outside the safe-harbor provision of Hatch-Waxman because "although the safe harbor provision permits otherwise infringing activity that is conducted to obtain regulatory approval of a product, it does not permit a generic manufacturer to continue in that otherwise infringing activity after obtaining such approval." The safe harbor provision of 35 U.S.C. §271(e)(1) provides that:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention… *solely for uses reasonably related to the development and*

> *submission of information under a Federal law* which regulates the manufacture, use, or sale of drugs or veterinary biological products.

In vacating the district court's grant of a preliminary injunction, a two-judge panel majority reasoned that that Amphastar, as a generic drug manufacturer, "cannot sell a batch of enoxaparin unless it has established that its strength and quality is consistent with the standards set forth in relevant official compendium." Here FDA regulations require that records associated with batch production of drugs be retained for at least 1 year after expiration of the batch, and these records "shall be readily available for inspection" by the FDA at any time. The panel majority concluded that "the requirement to maintain records for FDA inspection satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA."

The panel opinion had to distinguish the facts in the present case from those in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011). At issue in *Classen* were studies to evaluate the association between the timing of childhood vaccinations and the risk of developing certain immune-mediated disorders. The studies themselves were not mandated by the FDA, but any vaccine license holder was required to report to the FDA "adverse experience information," such as adverse side effects, it acquired as a result of vaccine studies. The court distinguished the *Classen* case on the grounds that the information submitted by the generic manufacturer in the present case was necessary both to the continued approval of the ANDA and the ability to market the generic drug.

In short, the safe harbor provision of 35 U.S.C. §271(e)(1) would seem to protect a generic drug manufacturer from infringing a patent being used to generate drug-product information, *even after FDA market approval*, if the information is mandated by the FDA for continued market approval.

When can Reissue be used to Cure Misconduct in Obtaining a Patent?

Peter Dehlinger

The American Invents Act (AIA) created a special procedure known as Supplemental Examination by which a patent owner can attempt to cure a multitude of prosecution sins and inoculate a patent against later charges of inequitable conduct. The Supplemental Examination offers the advantages in quick resolution and wide range of issues that can be addressed. It is also an expensive procedure and offers a patent owner limited options on appeal if the Examination leads to final claim rejections.

This note considers the question of whether and when a patent owner might be better served by curing prosecution misconduct through a patent reissue. Some obvious advantages of the reissue process are apparent from language of the reissue statute, 35 U.S.C. §251. Reissue allows a patent owner to correct a defective specification or claims, and to expand claim scope if the reissue request is filed within two years of the original patent issue date, unlike an SE. Also unlike an SE, a patent owner can terminate a reissue proceeding at will, restoring the patent to its original form (albeit with an added file history burden). A reissue proceeding is relatively inexpensive compared to an SE, and the average pendency during reissue is not much different from what the patent owner will encounter if the SE is converted to an ex parte reexamination (2-3 years average pendency in both cases).

The important questions for a patent owner considering a reissue are: what types of prosecution misconduct can be cured through reissue and is the "cured" reissue patent inoculated against inequitable conduct? The latter question stems from the apparently well-settled principle that "a

reissue proceeding cannot rehabilitate a patent held to be unenforceable due to inequitable conduct (the basis of the ruling in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals*, 525 F.3d 1334 (Fed. Cir. 2008).

Assume that the only "error" the applicant wishes to correct is to bring a pertinent reference before a patent examiner, without wanting to amend any of the existing claims. Under the reissue statute as amended by the AIA, it no longer matters whether the reference was originally withheld by deceptive intent. But does the reissue process allow for submission of new art that doesn't necessitate an amendment to the specification or claims? Probably not; the concept of "error" correctable by a reissue has not been understood to mean mere review of new information without amendment. This shouldn't be a significant hurdle, however, since *Ex Parte Tanaka* (BPAI, 2009) allows a patent owner to seek reissue if the only "error" was failure to include specific dependent claims. Once a legitimate "error" is established, e.g., a defect in the specification or drawings, or a "missing" dependent claim, any new art can be submitted as part of an applicant's duty of candor in reissue prosecution.

If an unamended independent claim is allowed over the newly cited art, the patent should be free of taint of inequitable conduct, since there has now been a determination that the newly-cited art is not material to the claims under the *Therasense* but-for standard.

In the case where the newly-cited art necessitates an amendment, it could be argued that the newly-submitted reference is material to the originally prosecuted claims, raising the specter of inequitable conduct in obtaining the original patent. However, this result would seem contrary to the purpose of the AIA amendment to §251, which was deliberately designed to allow correction of errors that may have involved deceptive intent.

The same analysis should apply to correcting an affirmative misstatement or misrepresentation made during original prosecution. The fact that the misstatement was made with deceptive intent would not prevent it from being corrected in reissue. If the claims are held to be allowable without amendment, the misstatement or misrepresentation could not have been material under *Therasense*, and no inequitable conduct should be found. Even if the correction necessitated a claim amendment, it would be hard to argue that any inequitable conduct hasn't been cured, since the reissue proceeding itself is indifferent to whether the "error" was made with deceptive intent.

A reissue procedure will not cure all forms of inequitable conduct, of course. Egregious misconduct, including deliberate fraudulent statements or actions made with the intent to deceive, are not absolved by the *Therasense* but-for standard of materiality, and would presumably not be cured by attempting to set the record straight in a reissue proceeding. It is also doubtful that a patent, once it is found unenforceable by reason of inequitable conduct, could be cured by a later reissue process, following the rule in *Aventis*, discussed above. The *Aventis* rule, however harsh, nonetheless finds an analogous restriction in a Supplemental Examination, which must be completed prior to the filing of a lawsuit where inequitable conduct may be raised as a defense, and must be filed prior to the inequitable conduct being alleged in a pleading.

News from the Biofuel Front: Hard Lessons in Patent Drafting.

Peter Dehlinger

The Fed Circuit affirmed denial of a preliminary injunction in a patent infringement suit brought by Butamax Advanced Biofuels against Gevo, Inc. (*Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 2012-1490, Nov. 16, 2012). The Butamax patent

covered a fermentation process for producing butanol by a transgenic yeast engineered to express five exogenous enzymes that form a biosynthetic pathway for converting an inexpensive carbon-source feedstock to butanol at elevated levels.

The district court denied a preliminary injunction on the grounds that the plaintiff had failed to show likelihood of success on either the infringement or validity issues. The Fed Circuit was unsympathetic to the lower court's analysis on claim construction and infringement, but agreed that the plaintiff's case for patent validity was shaky. The grounds for challenging the validity of the Butamax patent are captured in the rejection of claim 1 made in a then-pending reexamination proceeding. The main points from this rejection are:

"Claim 1 is drawn to a method of producing biobutanol by a recombinant yeast microorganism in fermentation medium. There is no specific limitation given on the amount of isobutanol produced by the yeast. The claim describes a biosynthetic pathway that is inherently present in yeast strains to produce isobutanol from pyruvate through a series of enzymatic reaction, pathway steps a, b, c, d and e" (of the claimed method)."

"Claim 1 only requires that the recombinant yeast is 'expressing an engineered isobutanol biosynthetic pathway.' There is not specific description of where and how this pathway is engineered."

"There is no requirement in the claim for any specific genetic alteration or introduction of specific nucleic acid sequences."

The lessons to be drawn from this rejection are pretty basic: (1) If the claimed reaction pathway is carried out by a native microorganism, though at a low level, the specification should support and the claims should reflect the elevated levels of product achieved by the engineered organism; (2) the specification should provide specific directions as to the type and extent of genetic engineering needed to achieve the claimed result; and (3) where the native microorganism contains the genes involved the claimed pathways, the claim should specify novel sequences and/or control elements that produce elevated levels of product.

Upcoming Events:

Ethan Horwitz is speaking at the Global IP Convention 2013, Jan 23 - 30 in Bangalore, India on "The Comparative Benefits of the ITC versus District Courts for Patent Infringement Actions."

http://www.iprconference.com/

Bruce Baber and Katie McCarthy are speaking at PLI's Annual "IP Enforcement and Litigation: Criminal and Civil Update" seminar in New York and webcast on February 1, 2013. Mr. Baber will speak on the Copyright Enforcement panel, discussing copyright protection for computer software with an overview of *Google v. Oracle*. Ms. McCarthy, a co-chair of the program, will moderate an in-house panel of trademark counsel from The Coca-Cola Company, Tiffany & Co., and Take-Two Interactive, discussing practical advice for stopping blatant infringements.

http://www.pli.edu/Content/Seminar/IP_Enforcement_and_Litigation_2013_Civil/_/N-4kZ1z12p7n?Ns=sort_date%7C0&ID=162245

Quiz- Identify the IP Case in Rap Disguise.

The Petitioner

I was hotter than flux, cooler than ice (yeah)
Captured the crux and kept the words precise
My solder was thin on alkaline earth
Dissing a claim as slim as Jack Sprat's girth
Just forgot the part about Jack's wax nose
(Talk about dressing up legal prose)

Now I'm graver, can't savor my dreamed-of elyseum
So much for manganese instead of magnesium

Court Majority

Hum along and dance with the Jackson six
It's time to do the equivalents fix
It's a breeze to seize the essence of invention
Stay light on your feet and get the quintessence
Does it do the same thing? (everybody sing)
Doesn't matter if it's grander or got bling bling
It's a cinch, you can clinch it in less than a minute
But that step alone is hardly going to win it
You also gotta spin so it works the same way
Don't hurry, no worry how the matter behaves
Just make some clatter and give your hands a wave
Now you've got the rhythm, but there's one last move
Do you get the same result, is it in the same groove?
Put it all together for the equivalents fix
Turning water into solder is just one of our tricks
Can't understand why the Dissent disapproves

Dissent

It's not the dance that gives us pause
It's how you've mangled the patent laws
The claim is there for all to read
No seed of doubt about what was freed
Manganese sure was, 'cause it's in the spec
Even shown in the art, but what the heck
Y'all go ahead, dance, have a good time
Don't give a glance to our earnest rhyme

Answer:

http://supreme.justia.com/cases/federal/us/339/605/case.html

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Our Intellectual Property Practice Group
King & Spalding offers clients a full-service intellectual property (IP) practice that combines proven first-chair trial and business lawyers with true scientific specialists. The firm's Intellectual Property Practice Group consists of more than 100 IP professionals, including more than 70 lawyers and patent agents with technical degrees, located in our Atlanta, Austin, Charlotte, Houston, New York, Silicon Valley and Washington, D.C., offices.

King & Spalding has specialized expertise in Section 337 cases before the International Trade Commission. Unique among firms, we have leading practices in the three disciplines necessary in Section 337 cases: we combine our broad-based patent litigation experience and technical expertise, international trade expertise and expertise in the ITC's procedures, and a strong governmental relations group. King & Spalding has been involved in some of the largest, most complex and precedent-setting Section 337 cases.

About King & Spalding
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