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This section is intended to be a synopsis of recent developments and is not intended to be exhaustive. If any issue is referred to in this section is to be relied upon, specific advice should be sought. Please contact:

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Substantive Federal Circuit decisions concerning pharmaceutical companies

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In 2011, the United States Court of Appeals for the Federal Circuit ("the Federal Circuit") decided 15 cases relating to pharmaceutical companies. Of those cases, fourteen were substantive decisions and one was a *per curiam* affirmance pursuant to Fed. Cir. R. 36.[1] Of the fourteen cases, seven cases were unequivocally affirmed by the Federal Circuit, six of which were judgments granted by summary judgment. The other cases were reversed, vacated and/or remanded in whole or in part.

While some of these cases make new law (most notably, *Therasense v. Becton Dickinson*), they are also interesting for showing the wide variety of issues that can come into play, even in what the litigants might have initially thought were rather routine cases.

Summaries of these cases are below:

Centocor Ortho Biotech v. Abbott Laboratories[2]

On February 23, 2011, the Federal Circuit published its decision in *Centocor Ortho Biotech, Inc. v. Abbott Laboratories* reversing the district court's denial of Abbott's motion for judgment as a matter of law of invalidity. In doing so, the Federal Circuit invalidated Centocor's US Patent No. 7,070,775 based on lack of written description under 35 U.S.C. § 112, vacating a $1.67 billion jury verdict against Abbott Laboratories' Humira® product, which is an antibody used to treat arthritis.

Centocor developed a TNF-α antibody by identifying a mouse antibody to human TNF-α, then changing certain portions to make it more human. Abbott, on the other hand, developed a fully human antibody, which led to Humira®. After Abbott launched its product, Centocor filed claims to cover fully human antibodies, which was issued as the '775 patent. When Centocor sued Abbott for infringement, Abbott asserted that Centocor's fully human antibody claims lacked adequate written description.

Centocor argued that its patent satisfied the written description requirement of § 112 because it disclosed the antigen (TNF-α protein) and the PTO's March 24, 2008, Written Description Guidelines indicate that disclosing an antigen can provide § 112 support for any antibody that binds to that antigen. Centocor also pointed to a 2004 Federal Circuit case that stated "as long as an applicant has disclosed a 'fully characterized antigen' . . . the applicant can then claim an antibody by its binding affinity to that described antigen." *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004).

The Federal Circuit disagreed with Centocor and distinguished the *Noelle* case and PTO guidelines by stating that disclosing an antigen may provide written description § 112 support for an antibody, but only where creating the antibody is routine. In this case, creating the antibody was far from routine, and the claimed antibody had specific properties. Centocor did not establish that generating a fully-human antibody as claimed would be within the knowledge of one skilled in the art.

Accordingly, the Federal Circuit reversed the district court and held that Centocor's patent was invalid for lack of written description under 35 U.S.C. § 112.

Duramed Pharmaceuticals v. Watson Laboratories[3]

On March 25, 2011, the Federal Circuit published its decision in *Duramed Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, reversing-in-part, affirming-in-part, and remanding the case back to the district court.

Watson filed an Abbreviated New Drug Application (ANDA) seeking approval to make and market a generic

[1] Federal Circuit Rule 36 provides that the Court may enter a judgment of affirmance without opinion, citing the rule, when it determines that any of the following conditions exist and an opinion would have no precedential value:

a. the judgment, decision, or order of the trial court appealed from is based on findings that are not clearly erroneous;
b. the evidence supporting the jury's verdict is sufficient;
c. the record supports summary judgment, directed verdict, or judgment on the pleadings;
d. the decision of an administrative agency warrants affirmance under the standard of review in the statute authorizing the petition for review; or
e. a judgment or decision has been entered without an error of law.

[2] *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341 (Fed. Cir. 2011).

[3] *Duramed Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, 413 Fed. Appx. 289 (Fed. Cir. 2011).

equivalent to Duramed's extended-cycle combined oral contraceptive. Duramed filed suit and Watson stipulated to infringement. Duramed then moved for summary judgment of nonobviousness, which was granted by the district court. Watson then appealed.

On appeal, the Federal Circuit held that the district court erred in granting summary judgment of nonobviousness under 35 U.S.C. § 103. Specifically, the district court erred in assessing the content and scope of the prior art, leading it to incorrectly analyze each prior art reference in isolation without considering the prior arts' teaching as a whole in light of the creativity and common sense of a person of ordinary skill. The Federal Circuit stated that a reference "is prior art for all that it discloses, and there is no requirement that a teaching in the prior art be scientifically tested, or even guarantee success, before providing a reason to combine. Rather, it is sufficient that one of ordinary skill in the art would perceive from the prior art a reasonable likelihood of success."

Additionally, the Federal Circuit found that the district court had placed the burden of proof on the wrong party. The district court had incorrectly placed the burden of proof on the nonmoving party, Watson, to show clear and convincing evidence of invalidity as a matter of law. However, because Duramed had moved for summary judgment, the burden rested with Duramed to show that Watson had failed to come forth with clear and convincing evidence of an essential element of its *prima facie* case of obviousness.

The district court also failed to make any required finding on the level of ordinary skill in the pertinent art. The Federal Circuit noted that "in reviewing the record *de novo* on summary judgment and crediting Duramed's lower level of skill in the art, the district court on remand may well conclude that the claimed extended-cycle COC regimen would have been obvious as a matter of law." However, because Duramed did not have an opportunity to challenge Watson's *prima facie* case of obviousness or introduce any secondary considerations of nonobviousness, the case was remanded.

Lastly, the Federal Circuit held that the district court did not abuse its discretion in excluding certain expert testimony. Thus, the case was reversed-part, affirmed-in-part, and remanded.

Allergan, Inc. v. Athena Cosmetics[4]

On May 24, 2011, the Federal Circuit published its decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, reversing and remanding the case back to the district court.

Plaintiffs Allergan, Inc., Murray A Johnstone, MD, and Duke University brought suit for patent infringement and unfair competition against several cosmetic companies and doctors, i.e., defendants Athena Cosmetics, Inc., Pharma Tech International, Inc., Northwest Cosmetic Laboratories, Inc., Cosmetic Alchemy, LLC, Nutra-Luxe M.D., Stella International, LLC, Product Innovations, LLC, Metics, LLC, Peter Thomas Roth, Inc., Peter Thomas Roth Labs LLC, Lifetech Resources, LLC, Rocasuba, Inc., Global Mdrx, Cosmetic Technologies, Inc., Dmi, La Canada Ventures Inc., and Susan F. Lin, MD, for the manufacture, marketing, and sale of products that contained a prostaglandin compound that was approved for use in growing hair and eyelashes.

Defendants filed a motion for judgment on the pleadings under *Fed. R. Civ. P. 12(c)*, claiming that a cosmetics manufacturer that filed suit lacked standing to pursue its claim for unfair competition because the manufacturer did not allege an injury that was compensable by restitution. The district court granted the motion.

The district court concluded that Allergan had not sufficiently pled an injury that could be compensated by restitution. Earlier California precedent held that a party that failed to plead an injury compensable by restitution lacked standing under the unfair competition laws. Relying on this precedent, the district court found that Allergan lacked standing to obtain any relief. Finding that there was no just reason for delay in appealing this claim, the district court entered judgment pursuant to *Federal Rule of Civil Procedure 54(b)* and dismissed Allergan's claim for relief under the unfair competition laws as to all defendants with prejudice. Allergan appealed the dismissal of its unfair competition law claims. Allergan's patent claims remained pending before the district court, but the action was stayed until the outcome of the appeal.

The Federal Circuit relied upon two decisions from the California Supreme Court that issued after the district court granted defendants' summary judgment motion. The new cases made it clear that pertinent unfair competition laws required that a party need only allege an injury in fact that was caused by a defendant's unfair competition, and the plaintiffs' claims that it lost sales, revenue, market share, and asset value because of defendants' conduct met that standard. In view of the clear case law, the Federal Circuit reversed the district court's judgment and the case was remanded.

[4] *Allergan, Inc. et al. v. Athena Cosmetics, Inc. et al.*, 640 F3d 1377 (Fed. Cir. 2011).

In Re Brimonidine patent litigation[5]

On May 18, 2011, the Federal Circuit published its decision in *In Re Brimonidine Patent Litigation*. This case involved a dispute regarding Allergan's patents for its glaucoma drug Alphagan® P. The defendants, Apotex and Exela each filed an ANDA seeking permission from the Food and Drug Administration (FDA) to market a generic version of Alphagan® P. Allergan sued both Apotex and Exela for infringement. After an 8-day bench trial, the district court found that Allergan's asserted patents were not invalid and that Apotex and Exela infringed those patents. The district court enjoined both Apotex and Exela from making or selling the products described in each defendant's ANDA. Apotex appealed only the validity portion of the judgment against it, and Exela appealed only the finding of infringement.

Apotex's invalidity argument focused on two prior references, Stockel and Ratcliff. Apotex argued that Stockel disclosed the modifications that Allergan argues impart patentability, i.e., the use of stabilized chlorine dioxide (SCD) as a preservative. Allergan argued that Stockel taught away from the use of SCD as the only preservative because it would irritate the eye and recommends a combination of preservative agents.

The Federal Circuit agreed with Apotex that the asserted claims of one of the patents would have been obvious over a combination of Stockel and Ratcliff but found that the claims of the related patents would not have been obvious. The Federal Circuit rejected Apotex's other arguments and reversed the district court's determination that the asserted claims of the '078 patent were not invalid. The Federal Circuit also affirmed the district court's finding that Apotex failed to show that the claims of the related patents were invalid as a matter of law, and sustained the district court's injunction against Apotex.

Unlike Apotex, Exela only appealed the district court's finding of infringement. Allergan asserted only the '834 patent against Exela. Claims 7 and 16 of that patent recite a 0.15% brimonidine solution including SCD as a preservative adjusted to a pH of 7.0 or greater. The only issue was whether the product described in Exela's ANDA infringes that pH limitation. Both Exela and Allergan agreed that the highest pH at which Exela requests permission to manufacture and sell its proposed product was 6.7. The district court found that the lowest pH at which Exela requests permission to manufacture and sell its proposed drug at is 6.5. Both parties further agreed that to the extent the pH of the formulation changes over time, it will fall, not rise.

The Federal Circuit noted that neither party disputed that if Exela complies with its ANDA, it will never manufacture or sell a product at a pH above 6.7. As such, the Federal Circuit could not assume that Exela will not act in full compliance with its representations to the FDA, and accordingly reversed the district court's finding of infringement.

In sum, on Apotex's appeal, the Federal Circuit affirmed-in-part, reversed-in-part, and affirmed the entry of the injunction. With respect to Exela's appeal, the Federal Circuit reversed thereby lifting the injunction.

Therasense, Inc. v. Becton, Dickinson & Co.[6]

On May 25, 2011, the Federal Circuit issued its ruling in the *en banc* rehearing of *Therasense, Inc. v. Becton, Dickinson & Co.* In a 6-4-1 decision, the Federal Circuit held that, to establish inequitable conduct, the accused infringer must prove, by clear and convincing evidence, that: (i) the patentee acted with *specific intent* to deceive the PTO; *and* (ii) "*but for*" materiality, meaning that had the withheld reference or information been provided to the PTO, the PTO, more likely than not, would *not* have granted the claim. Further, the Federal Circuit held that, even if the accused infringer proves both intent and materiality, the "district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable."

Notably, the Federal Circuit rejected both the "sliding scale" approach that it had previously embraced, where a strong showing of either materiality or intent could lead to an inference of the other with a lesser showing, and the "materiality" standard as set forth in Rule 56 of the Manual of Patent Examining Procedure.

Therasense, therefore, makes it much more difficult to allege and prove inequitable conduct.

Boston Scientific v. Johnson & Johnson[7]

On June 7, 2011, the Federal Circuit published its decision in *Boston Scientific v. Johnson & Johnson*. The Federal Circuit affirmed the district court finding

[5] *In Re Brimonidine Patent Litigation - Allergan, Inc., v. Exela Pharmsci Inc. and Exela Pharmsci PVT., Ltd., and Apotex Inc. and Apotex Corp.*, 643 F.3d 1366 (Fed. Cir. 2011).

[6] *Therasense, Inc. (Now Known As Abbott Diabetes Care, Inc.) and Abbott Laboratories, v. Becton, Dickinson and Company, and Nova Biomedical Corporation, and Bayer Healthcare LLC*, 649 F.3d 1276 (Fed. Cir. 2011)(*en banc*).

[7] *Boston Scientific v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011).

that two patents directed to drug-eluting coronary stents were invalid due to lack of written description. Each of the patents contained limitations in the claims directed to an "analog of rapamycin"—limitations that were added years after the priority date for both patents. The district court found that the claims were broader than the disclosure in the patent.

On appeal, Boston Scientific argued that the specification was sufficient, but the Federal Circuit did not accept these arguments. Instead, the Federal Circuit relied on the holding in *Ariad*[8] stating that a "sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."[9] The Federal Circuit reasoned that in the patents, there were no descriptions or examples of "analogs" and the patents failed to disclose any sub genus of the types specifically claimed.

Judge Moore seemed particularly concerned with the lack of examples and stated that although examples are not always required to satisfy the written description requirement under Section 112, the lack of any examples should be considered when determining whether the claimed invention is adequately described.

Judge Gajarsa concurred with the majority but explained in a separate opinion that he believed the better analysis for invalidity of claims that are broader than the patent disclosure is under Section 112, paragraph 1, for enablement. The enablement requirement was more straightforward according to Judge Gajarsa, rather than parties and courts trying to determine "how the written description requirement applies to novel compounds as opposed to novel combinations of known elements."

Tyco Healthcare v. Mutual Pharmaceutical[10]

On June 22, 2011, the Federal Circuit published its decision in *Tyco Healthcare Group et al. v. Mutual Pharmaceutical Company, Inc. et al.*, affirming the district court's grant of summary judgment of invalidity due to obviousness of a pharmaceutical formulation patent.

Plaintiff Tyco sued Mutual for infringement of a patent that covered specific formulations for the insomnia drug temazepam—sold under the brand name Restoril®. The patent contained two claims directed to certain dosages of the crystalline form of temazepam. Mutual moved for summary judgment of invalidity, and the district court granted Mutual's motion holding that the claims of the patent were invalid for obviousness. The claims were held invalid as obvious in light of Tyco's prior patents claiming a range of dosages that included the claims at issue along with a 1983 edition of the British National Formulary (BNF).

On appeal, Tyco argued that the district court erred because all "the properties of a composition of matter relevant to patentability must be considered in evaluating whether that composition would have been obvious in light of the prior art and that the unclaimed property of effectiveness in treating insomnia renders the claims at issue nonobvious." Tyco argued that the BNF did not teach the 6–8 mg range recited in the patent because the BNF recommended a range of 5–15 mg, and that the BNF did not show that this range would be effective in the treatment of insomnia.

The Federal Circuit disagreed with Tyco's argument, reasoning that under Federal Circuit precedent, the discovery of a new use of a previously known composition, even when that use or property is not obvious, cannot "impart patentability to the known composition." The Court stated that the "recommendation in the BNF of a range of temazepam dosages that include the dosages claimed in the '954 patent renders obvious the claims to those dosages even in the absence of documentation in the BNF of the effectiveness of such dosages."

The Federal Circuit further found that the prior art did not teach away from the claimed invention, and that there were no unexpected results or commercial success. Accordingly, the district court's grant of summary judgment of invalidity due to obviousness was affirmed.

Reckitt Benckiser Inc., v. Watson Laboratories, Inc.[11]

On July 7, 2011, the Federal Circuit published its decision in *Reckitt Benckiser Inc., v. Watson Laboratories, Inc.* At issue in this case were pharmaceutical formulations comprising guaifenesin, an expectorant useful for relieving congestion. Reckitt obtained approval from the FDA to market its Mucinex® products, bilayer tablets containing guaifenesin in both immediate release (IR) and sustained release (SR) formulations. Reckitt listed the '252 patent in the FDA's Approved Drug Products with Therapeutic

[8] *Ariad Pharms., Inc., v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010)(*en banc*).

[9] *Boston Scientific v. Johnson & Johnson*, 647 F.3d at 1363.

[10] *Tyco Healthcare Group Lp And Mallinckrodt Inc., v. Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc.*, 407 Fed. Appx. 481 (Fed. Cir. 2011).

[11] *Reckitt Benckiser Inc., v. Watson Laboratories, Inc.*, 430 Fed. Appx. 871 (Fed. Cir. 2011).

Equivalence Evaluations (the "Orange Book") as covering Mucinex®.

The asserted claims recite "a modified release product having two portions…" The district court construed the term "portion" to mean "a discrete part of the product." The district court then determined that the generic's products did not infringe because they were non-layered, single-formulation polymer matrix tablets that did not contain separate portions.

On appeal, the Reckitt argued that the district court misconstrued the claim term "portion" in the asserted claims. The Federal Circuit concluded, however, that the district court did not err by construing the term "portion" to mean a discrete part of the product. The claim construction rested on a proper analysis of the claims and written description of the patent, as well as its prosecution history. The Federal Circuit held further that the district court had correctly concluded that the prosecution history demonstrated a disclaimer of single-formulation SR guaifenesin tablets, even if those tablets released some guaifenesin immediately upon ingestion.

Accordingly, the Federal Circuit affirmed the district court finding of no infringement.

Duramed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc.[12]

On July 21, 2011, the Federal Circuit published its decision in *Duramed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc*. In this case, the Federal Circuit affirmed the district court's grant of summary judgment of noninfringement.

The patent-in-suit claimed a pharmaceutical composition. During prosecution of the patent-in-suit, in response to a rejection by the Examiner, Duramed narrowed the patent claims to a certain moisture barrier coating, ethylcellulose. Paddock's accused product used a different coating, polyvinyl alcohol.

The district court held that Duramed's amendment of the patent claims to add the ethylcellulose limitation was substantially related to patentability and narrowed the scope of the asserted claims, thus triggering the *Festo*[13] presumption that Duramed had surrendered all territory between the original and amended claim scope.

The district court then held that Duramed had failed to rebut the *Festo* presumption based on an argument of, *inter alia*, the unforeseeability of the use of polyvinyl alcohol as an moisture barrier coating in a pharmaceutical formulation. Rather, based upon the evidence in the record, the district court held that polyvinyl alcohol moisture barrier coatings were foreseeable at the time of Duramed's narrowing amendment.

The Federal Circuit agreed with the district court's analysis and affirmed the grant of summary judgment holding that Duramed had not overcome the presumption of prosecution history estoppel.

Eli Lilly and Company, v. Actavis[14]

On July 29, 2011, the Federal Circuit published its decision in *Eli Lilly and Company, v. Actavis Elizabeth LLC*. In this case, each of the defendants filed an ANDA, accompanied by a Paragraph IV certification challenging the validity and enforceability and asserting non-infringement of the patent-in-suit. The patent-in-suit was directed to the use of the drug atomoxetine to treat attention-deficit/hyperactivity disorder (ADHD).

The district court sustained the '590 patent against the defendants' challenges on the grounds of inequitable conduct, anticipation, obviousness, and non-enablement, but held the claims invalid for lack of utility. The district court also held that if the claims were valid, the defendants would be liable for inducement to infringe but that they would not be liable for contributory infringement.

The defendants argued that the patent did not enable the full scope of claim 1, pointing out that the claim's words "administering to the patient an effective amount" were not limited to the formulations that were specifically exemplified in the specification. On this basis, the district court held all of the patent claims invalid for lack of "enablement/utility." The district court found that utility was not established because experimental data showing the results of treatment of ADHD were not included in the specification. The district court stated that "the court cannot conclude that a person of skill in the art would have recognized the method of treatment's utility in view of the specification and prior art."

On appeal, the Federal Circuit stated that patent applicants are able to submit data "either before or after the patent application was filed," where after-filed evidence "can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification." The Federal Circuit therefore reversed the district court decision, indicating that the district court

[12] *Duramed Pharmaceuticals, Inc., v. Paddock Laboratories, Inc.*, 644 F.3d 1376 (Fed. Cir. 2011).

[13] *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

[14] *Eli Lilly and Company, v. Actavis Elizabeth LLC, Sun Pharmaceutical Industries, Ltd., Sandoz, Inc., Mylan Pharmaceuticals Inc., Apotex Inc., Aurobindo Pharma Ltd. and Teva Pharmaceuticals USA, Inc.*, 435 Fed. Appx. 917 (Fed. Cir. 2011).

erred in finding that experimental data was required to be in the application as filed. The Federal Circuit stated further that an assertion of utility must be accepted as sufficient to satisfy the utility requirement unless there is "some reason" for the skilled worker to question the "objective truth" of the asserted utility. Thus, the Federal Circuit held that based on the entirety of the evidence, invalidity for lack of enablement/utility had not been shown by clear and convincing evidence, and therefore the holding of invalidity was reversed.

With respect to the infringement issues, the Federal Circuit affirmed the judgment that the provision of atomoxetine labeled solely for use to treat ADHD constitutes inducement to infringe the patent-in-suit. However, the Federal Circuit reversed the district court's finding of no contributory infringement.

The district court had held that liability would be avoided if the product has any "frequent" non-infringing use. Lilly argued that atomoxetine is not a "staple article of commerce suitable for substantial non-infringing use," the words of 35 U.S.C. § 271(c), for the only authorized use of atomoxetine is the patented use to treat ADHD, and Federal law prohibits the defendants from selling a federally regulated drug for unapproved uses.

The defendants responded that physicians may nonetheless prescribe atomoxetine for unauthorized use. The Federal Circuit disagreed with defendant's argument stating such unauthorized activity does not avoid infringement by a product that is authorized to be sold solely for the infringing use.

In sum, the Federal Circuit reversed the ruling of invalidity for lack of utility, and the ruling that there would be no contributory infringement, and affirmed district court's other rulings.

Mitsubishi Chemical v. Barr Laboratories[15]

On August 2, 2011, the Federal Circuit published its decision in *Mitsubishi Chemical v. Barr Laboratories*. In this case, Barr filed an ANDA to market a generic version of argatroban injection. Mitsubishi promptly filed suit against Barr, alleging direct and indirect infringement of the patent-in-suit. In the district court, the parties stipulated that the commercial manufacture, use, importation, sale, or offer for sale of the product described in Barr's ANDA would infringe all the claims of the patent-in-suit. Barr defended by contending that the asserted claims were invalid

The specification of the patent-in-suit explains that the solubility of argatroban increases dramatically when a saccharide and ethanol are added to an aqueous solution. Claim 1 recited a method for dissolving an arginineamide, comprising dissolving argatroban and/or its salt in a solvent containing ethanol, water, and a saccharide.

Barr made two invalidity arguments. It first contended that each of the claims was anticipated by a Japanese article published in 1986 by a Mitsubishi employee, Toshihiro Yamamoto. In the alternative, Barr argued that all of the claims would have been obvious over a combination of several references other than the Yamamoto article. The district court determined that Barr had not met its burden to show by clear and convincing evidence that the prior art references would have motivated one of the ordinary skill in the art to dissolve argatroban in a solvent containing ethanol, water, and a saccharide. In addition, the court concluded that secondary considerations such as commercial success and long-felt need supported its conclusion that the claims would not have been obvious.

The Federal Circuit agreed with the district court that Barr had failed to show that the claims of the patent were not anticipated and would not have been obvious. Accordingly, the district court's judgment was affirmed.

Unigene v. Apotex[16]

On August 25, 2011, the Federal Circuit published its decision in *Unigene Laboratories, Inc. and Upsher-Smith Laboratories, Inc. v. Apotex, Inc. and Apotex Corp.*

The patent-in-suit covers the pharmaceutical nasal spray Fortical® with the active ingredient salmon calcitonin. Fortical® is an alternative formulation of another salmon calcitonin-based drug, Miacalcin®. Unigene's NDA claims Miacalcin® as its reference drug. Upsher-Smith is the exclusive patent licensee, with rights to market and sell Fortical® in the United States. Fortical® treats, among other things, postmenopausal osteoporosis.

Both Miacalcin® and Fortical® use salmon calcitonin at a concentration of 2200 IU/mL as their active ingredient. Salmon calcitonin is a natural polypeptide hormone. Calcitonins help regulate

[15] *Mitsubishi Chemical Corporation and Mitsubishi Tanabe Pharma Corporation, and Encysive Pharmaceuticals Inc., and Glaxo Group Limited, Smithkline Beecham PLC, and Smithkline Beecham Corporation (doing business as Glaxosmithkline), v. Barr Laboratories, Inc. and Pliva-Hrvatska D.O.O.*, 435 Fed. Appx. 927 (Fed. Cir. 2011).

[16] *Unigene Laboratories, Inc. and Upsher-Smith Laboratories, Inc., v. Apotex, Inc. and Apotex Corp.*, 655 F.3d 1352 (Fed. Cir. 2011).

calcium ions in the blood and therefore address calcium-related conditions like osteoporosis. To be effective, polypeptides, like salmon calcitonin, must reach the bloodstream. Delivery to the bloodstream, however, is not easy because calcitonins are readily degraded by bodily fluids, are relatively unstable in pharmaceutical compositions, and are poorly absorbed through tissues. Miacalcin® and Fortical® are both nasal sprays.

Apotex submitted forty-plus pieces of prior art (also considered by the Patent Office during prosecution of the patent-in-suit). The district court found that none of the prior art teaches using 20 mM citric acid to achieve "both shelf stability and enhanced bioavailability" in a nasal salmon calcitonin formulation.

The Federal Circuit agreed with the district court that no reasonable juror could conclude that the patent-in-suit would give a person of ordinary skill sufficient reason or motivation to use about 20 mM citric acid in a liquid nasal salmon calcitonin composition. The Federal Circuit noted that the prior art '014 patent claimed a solid oral dosage of salmon calcitonin, not a liquid formulation, and that a person of ordinary skill would not glean from the '014 patent a reason to use about 20 mM citric acid in a nasal calcitonin formulation.

The Federal Circuit stated that the "about 20.0 mM citric acid" limitation alone supports the district court's grant of summary judgment of nonobviousness. With respect to another prior art patent, when citric acid was used as an absorption enhancer in the *'116 patent*, citric acid was one of over fifty options. Further, when the prior art used citric acid at about 20 mM, as in the *'315 patent*, it was used only as a buffer. The Federal Circuit thus concluded that there was no genuine dispute of material fact that a person of ordinary skill attempting to make a liquid composition to deliver salmon calcitonin into a human body through nasal administration would not have considered using about 20 mM citric acid with the narrowly claimed amounts of benzyl alcohol, phenylethyl alcohol, and polysorbate 80, because the formulation would not be expected to perform properly to meet the specificity of a pharmaceutical use. Thus, even accepting that there was a design need and market pressure to develop a pharmaceutical formulation that is bioequivalent to Miacalcin®, there was no evidence in the record that the patent claim would be an obvious solution to those motivations.

Accordingly, the Federal Circuit affirmed the district court's grant of summary judgment of nonobviousness and affirmsed the district court's denial of summary judgment of obviousness.

Teva. v. Astrazeneca[17]

On December 1, 2011, the Federal Circuit published its decision in *Teva Pharmaceutical Industries Ltd. v. Astrazeneca Pharmaceuticals LP and IPR Pharmaceuticals Inc.* In this case, the district court granted summary judgment for the defendants AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals Inc. invalidating the asserted claims of Teva's patent based on AstraZeneca's prior invention of the subject matter claimed therein.

AstraZeneca made an undisputed showing that, in mid-1999, it manufactured a 10,000-unit batch of a rosuvastatin calcium formulation containing the same ingredients in the same amounts as its commercial drug. On the basis of these undisputed facts, the district court found that "there is no genuine issue of material fact as to whether AstraZeneca arrived at the same [AstraZeneca drug] product formulations that Teva accuses of infringement-and made batches of those formulations-before Teva conceived of or reduced to practice the subject matter of the '502 patent."

On appeal, the Federal Circuit stated that because AstraZeneca conceded infringement for the limited purpose of its summary judgment motion, and because Teva maintains the allegation of infringement upon which its suit is based, it is undisputed for the purpose of this appeal that AstraZeneca's drug is an embodiment within the scope of the asserted claims.

The issue in the case was although AstraZeneca clearly had conceived and reduced its drug to practice before Teva's first conception of the claimed subject matter, it did not understand that crospovidone acted as a stabilizer in its drug prior to Teva's conception, if at all. The Federal Circuit noted that the applicable law requires a party seeking to establish prior invention to prove that it appreciated what it had made, but the prior inventor does not need to know everything about how or why its invention worked.

Here, there was no question that AstraZeneca appreciated that AstraZeneca's drug contained an "amount" of crospovidone, and because of AstraZeneca's limited concession of infringement, there is no question that the amount of crospovidone AstraZeneca's drug contained falls within the scope of the asserted claims as defined by the limitation "stabilizing effective amount." As such, AstraZeneca appreciated that its drug was stable, and it was not necessary for AstraZeneca to appreciate which component was responsible for the stabilization.

[17] *Teva Pharmaceutical Industries Ltd. v. Astrazeneca Pharmaceuticals LP and IPR Pharmaceuticals Inc.*, 661 F.3d 1378 (Fed. Cir. 2011).

Accordingly, the Federal Circuit affirmed the district court's judgment based on AstraZeneca's earlier development of the accused drug formulation.

Warner Chilcott Labs. v. Mylan Pharmaceuticals Inc.[18]

On December 1, 2011, the Federal Circuit published its decision in *Warner Chilcott Labs. v. Mylan Pharmaceuticals Inc*. In this case, the Federal Circuit vacated a preliminary injunction against Mylan granted by the district court. The litigation stems from Mylan's filing of an ANDA containing a paragraph IV certification seeking FDA approval to market a generic version of Doryx® (active ingredient - doxycycline hyclate), for which US Patent No. 6,958,161 ("the '161 patent"), that is directed to a tablet formulation of doxycycline, is listed in the Orange Book.

The district court construed the asserted claims in a *Markman* hearing, and thereafter advised the parties that the Court could not conduct a trial until January 2012 because of a murder trial that was set for fall 2011. One month before the 30-month stay was set to expire, in August 2011, Warner Chilcott filed a motion for a temporary restraining order and preliminary injunction against Mylan. In conjunction with this motion, the district court allowed arguments from counsel, but did not hold an evidentiary hearing and did not take testimony from any witnesses. The district court thereafter granted a preliminary injunction, but "did not address Mylan's arguments that the '161 Patent is invalid because of anticipation or obviousness, though it did acknowledge that those claims had been asserted." Mylan immediately filed a request for expedited briefing with the Federal Circuit and oral arguments were held on November 22, 2011.

In vacating the preliminary injunction, the Federal Circuit initially noted that a preliminary injunction "is an extraordinary remedy never awarded as of right." The Federal Circuit further noted that, when an accused infringer challenges the validity of a patent in response to a motion for a preliminary injunction, "the trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings."

The Federal Circuit noted that the claim construction, although not directly at issue in the appeal, was relevant to the "reasonable likelihood of success on the merits" element of the preliminary injunction test. The Federal Circuit additionally observed that the district court considered the "battle" of expert witness reports from both parties relating to the infringement question (but did not receive any testimony thereon), and moreover that the outcome of the "battle" was hardly definitive citing the district court's statement that there were "some serious factual disputes" between the parties' experts that would need to be resolved after "further testimony and examination and credibility" at trial. The Federal Circuit also observed that "the district court did not address Mylan's arguments that the '161 Patent is invalid because of anticipation or obviousness."

As such, the Federal Circuit held that:

> In this case, the district court abused its discretion in two ways. The court: (1) failed to hold an evidentiary hearing despite acknowledging that the decision turned on disputed factual issues; and (2) did not weigh the evidence or make any findings as to Mylan's invalidity challenge.[19]

Interestingly, however, the Federal Circuit noted that a temporary restraining order might be in order as follows:

> Although the district court's entry of the preliminary injunction in this case is contrary to controlling authority, we are mindful of the court's demanding schedule and desire to avoid duplicating its efforts with a soon-to-be-scheduled bench trial in this case. If doing so serves judicial efficiency, the district court may consider entering a temporary restraining order after this court's mandate issues, then consolidating the preliminary injunction hearing with the bench trial on the merits, assuming that can occur within the timeframes mandated by the Federal Rules of Civil Procedure.[20]

Conclusion

In the above cases, the patent-in-suit was found valid and infringed four times; the patent-in-suit was held invalid four times, the patent-in-suit was found not infringed three times; and the case was sent back to the district court for further proceedings four times. The Court addressed numerous issue of patent law, including direct infringement, contributory infringement, inducement to infringe, utility, enablement, written description, anticipation, obviousness, and inequitable conduct. These cases make clear that the district court does not always get it right, and also illustrate the oft-repeated mantra that no two patent cases are ever alike.

[18] *Warner Chilcott Labs. v. Mylan Pharmaceuticals Inc.* Appeal No. 2011-1611; 2011 U.S. App. LEXIS 24602.

[19] *Id.* at 10.

[20] *Id.* at 15.