The Paragraph Four Report®
Court of Appeals Opinions by Case Name
Cases Numbered 02-XXXX through 06-XXXX

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Court of Appeals Cases by Case Name
Case Name, Case Number, Date Decided, and Synopsis

Abbott Laboratories vs. Andrx and Teva Pharmaceuticals, 05-1433, June 22, 2006. Court of Appeals vacated an order granting a preliminary injunction over Biaxin XL®(clarithromycin). The Court stated that in order to obtain a preliminary injunction, the party requesting it must show some likelihood of success on the merits, immediate reparable harm if injunction not granted, balance of hardships weighs in its favor, and the public interest is served. In reversing the trial court and vacating a preliminary injunction granted, the Court of Appeals concluded that Teva had raised substantial questions as to the validity of claims 2, 4, and 6 of the 6,010,718 patent and of claim 2 in the 6,551,616 patent. While Teva admitted infringement, it had claimed that the patents were invalid due to obviousness as established by prior patents and prior art. As such, the Court of Appeals concluded that Abbott did no show a likelihood of success and also that it would not suffer irreparable harm. Moreover, the balance of hardships may still have favored Abbott but the public interest was likely not served by enforcing patents that had substantial questions of validity. Judge Newman dissented.

Abbott Laboratories vs. Baxter Pharmaceuticals (Sevoflurane I), 02-1400, July 3, 2003. Court of Appeals reversed a ruling of summary judgment for noninfringement of Baxter's version of sevoflurane. The case turned on claims construction. The District Court restricted the claims construction of the amount Lewis Acid Inhibitor to maintain the product's integrity, but the Court of Appeals accepted the scientifically acceptable definition which was broader. The Appellate court remanded for further evaluation and also allowed Abbott to argue the doctrine of equivalents applies.

Abbott Laboratories vs. Baxter Pharmaceuticals (Sevoflurane II), 06-1021, November 9, 2006. After the case was remanded after "Sevoflurane I" (cafc 02-1400), the District Court ruled that Baxter's product did not infringe the 5,990,176 patent but that the patent was valid and enforceable. Baxter cross-appealed the finding of validity, and the Court of Appeals agreed, reversing the conclusion that the patent was valid. In deciding that the patent was invalid, the Court of Appeals stated that the prior art (the 5,684,211 patent) anticipated the '176 patent. While the prior '211 patent which noted the addition of water to sevoflurane, it was later discovered that the addition of water to sevoflurane prevented Lewis Acids from degrading the product. It had been previously believed that adding water to sevoflurane was not beneficial or desired. This discovery led to the '176 patent. In holding the '176 patent invalid due to the anticipation of the prior art, the Court of Appeals concluded that even though the benefit of the

addition of water was unknown, the '211 patent still serves to anticipate the '176 patent as it is the same use. As such, the '176 patent is invalid due to anticipation in the prior art, and the Court did not reach the other issues.

Abraxis Bioscience (formerly AstraZeneca) vs. Mayne Pharma, 06-1118, November 15, 2006. The Court of Appeals affirmed the finding of infringement. However, it agreed with the District Court that there was infringement under the doctrine of equivalents but disagreed with the finding of literal infringement. In its analysis, the Court of Appeals, taking a de novo review of the claims construction, concluded that the District Court's construction was "clearly erroneous" in that the court concluded that the edetate preservative in the Abraxis formulation should be read broadly to include all derivatives that would include the Mayne preservative EDTA (pentatate). However, as Abraxis was its own lexicographer, the Court of Appeals concluded that the patent language narrowed the definition of derivative so as not to include a structural analog such as EDTA. So, there would be no literal infringement. However, the standard for reviewing infringement under the doctrine of equivalents is "clear error." Using this standard, the Court of Appeals agreed with the conclusion that the Mayne formulation was substantially the same as the Abraxis and thus infringed under the doctrine of equivalents (that is, EDTA acted substantially the same as edetate).

ALZA vs. IMPAX, 06-1047, September 6, 2006 (dubbed "Mylan II" by the Court of Appeals.) This case was affirmed, simply due to the agreement between Alza and IMPAX to accept the rulings from the case below.

ALZA vs. Mylan, 06-1019, September 6, 2006 (dubbed "Mylan I" by the Court of Appeals.) This case came on appeal from a bench trial in West Virginia that found the Alza '355 patent invalid and also that the Mylan formulation was non-infringing. In affirming the judgment, the Court of Appeals agreed that the patent was invalid due to obviousness. In short, applying a principle of "motivation to combine" prior art, the Court concluded that, given the prior art of sustained release technology, it was obvious to combine the known prior art and apply it to oxybutynin for a once-a-day formulation. Also, the patent described the term "delivers" a certain amounts of oxybutynin to the blood stream over specific periods of time. During trial, Alza presented evidence that the Mylan formulation delivered the same amount of drug using [i]in vitro[/i] dissolution tests and total accumulation of drug in the bloodstream. The trial court, and the Court of Appeals, agreed that this was indirect evidence and did not show that Mylan's formulation infringed the patent as there was no evidence of *in vivo* rate of delivery which is how the patent should be construed.

ALZA vs. Mylan, 04-1344, December 10, 2004. The Court of Appeals agreed with the District Court that the patents involving Duragesic®(fentanyl) patch were construed properly and valid and that there was no intent to deceive during the prosecution that would warrant a finding of uneforceability due to inequitable conduct. The patent covering the fentanyl patch claimed fentanyl in a form that can permeate the skin but, as the District Court added, did not include fentanyl citrate. On appeal, Mylan conceded that its patch infringed the patent but argued inequitable conduct on the part of Alza/Janssen. The Court of Appeals made short order of the Mylan arguments stating that there was very little evidence, if any to conclude any anticipation between the two patents involved or deceit during the prosecution.

AstraZeneca vs. KV Pharmaceuticals (In Re metoprolol succinate), 06-1254, July 23 23, 2007. The Court of Appeals affirmed the finding of invalidity of the '154 patent for Toprol XL®(metoprol succinate) due to double patenting. In it, the claim of "metoprolol succinate" was simply a variation of a claim in a prior patent being the release of metoprol succinate from a core

of the compound through an inner coating and outer coating layers. It remanded the finding of inequitable conduct as intent to deceive the USPTO could not be inferred from the facts established on summary judgment.

AstraZeneca vs. Mutual Pharmaceuticals, 04-1100, September 30, 2004. The Plendil®(felodipine) case was a reversal of fortune for AstraZeneca as the Court of Appeals reversed the District Court's summary judgment without further remand. The case involved a extended-release formulation for felodipine, and the court concluded the patents valid and infringed by the Mutual formulation. The Court of Appeals agreed with Mutual's claims construction and concluded that the term "solubilizer" in the patent did not include a "co-solvent". In normal usage, a solubilizer would include a co-solvent, but given the patnet prosecution history, the Court concluded that it should be read more narrow to include only surfactants. As such, though the patent was valid, the Mutual formulation would not infringe. In addition, as AZ disavowed the use of co-solvents during prosecution, the doctrine of equivalents would not apply.

Aventis vs. Amphastar, 05-1513, April 10, 2006. Court of Appeals reversed summary judgment in favor of Amphastar and Teva. District Court concluded that certain omissions of data by Aventis during the patent prosecution were material, and had these data been disclosed, the patent would not likely have been granted. The data Aventis submitted was a comparison of half-lives of a product but at different dosage strengths which showed a significant difference. However, had they compared or disclosed similar dosage strengths, little difference could be shown, reducing patentability. The District Court also had inferred intent to deceive. In reversing, the Court of Appeals agreed that the omission of fact was material. However, Aventis had some evidence showing that no intent existed. As there was an issue of material fact, the Court remanded back to the District Court for fact resolution of intent.

Aventis and King vs. Lupin, 06-1530, September 11, 2007. Court of Appeals reverses finding of validity for the 5,061,722 patent covering Altace®(ramipril). In reversing, the Court of Appeals, citing the Supreme Court case of [u]KSR International vs. Teleflex[/u], noted that the standard for considering patent invalidity for obviousness is broader. Using this broader standard, it considered all of the prior publications regarding ACE inhibitors and the public knowledge about enalipril and captopril, including the patent applications. The Court of Appeals concluded that it would have been reasonably obvious to someone trained in the art that a 5(S) stereoisomer of ramipril, substantially free of other isomers would have been an effective ACE inhibitor, particularly considering the similarities of the chemical structures of these products.

Bristol-Myers Squibb vs. Pharmachemie B.V.(Teva), 03-1077, March 17, 2004. Court of Appeals reversed a summary judgment for BMS for Paraplatin®(carboplatin). The fact pattern gets complicated but can be boiled down to this: BMS made an application to the US PTO which the PTO set various restrictions. BMS made another application for the product, and the applications yielded two patents, the 4,140,707 and 4,657,927 patents. The patent infringement action was brought to defend the '927 patent, and Pharmachemie argued that it was invalid due to double-patenting. BMS invoked Section 121 of the Title 35 which basically states that when the PTO sets restrictions, thus requiring more than one application, that fact cannot be used against the applicant for defenses such as double-patenting. The case thus turned on whether the restrictions from the original application were in effect, thus forcing BMS into filing a second application. The District Court felt that the restrictions the PTO set forced BMS to file a second application, thus Pharmachemie could not use the double-patenting defense and thus infringed the patent. The Court of Appeals disagreed as it felt the facts before it did not adequately establish this conclusion and remanded for further proceedings.

Daiichi Sankyo vs. Apotex, 06-1564, July 11, 2007. Court of Appeals reversed judgment of infringement and validity of the 5,401,741 patent for Floxin Otic®(ofloxacin). In reversing, the Court of Appeals concluded that the patent was obvious in light of the prior art. Part of the district court's error was that it considered a general medical practitioner as someone who had "ordinary skill in the art" for the product which was an antibiotic for the ear that would not have negative side effects. The Court of Appeals figured that someone with special pharmaceutical formulation skills, particularly one with specialized knowledge of ear medications and treatment, would be the most appropriate standard. Given this standard as the ordinary skill in the art, the Court of Appeals concluded that someone with that level of knowledge would have known that these types of compounds are safe and effective to use in the ear, as was known in publications since 1986.

Eli Lilly vs. Teva, 05-1044, July 13, 2005. Court of Appeals affirms judgment of patent infringement and validity. In this case, the Court concluded that the sole patent covering Sarafem®(fluoxetine) (4,971,998) was properly construed by the District Court. The Court agreed that the claim "taken before a women's menstrual cycle (to alleviate symptoms of pre-menstrual syndrome)" did not limit the time frame as to when the drug should be taken. In addition, the use of fluoxetine to treat PMS was not invalid due to obviousness. While some in the scientific community thought it might be useful (about the time Lilly applied for the patent), these people were not of those "ordinarily skilled in the art." The average doctor treating patients for PMS had no indication that fluoxetine would help alleviate PMS symptoms.

Ely Lilly vs. Zenith Goldline, 05-1396, December 26, 2006. Court of Appeals affirms finding of patent validity and enforceability on inequitable conduct grounds. In this case, the Court of Appeals concluded that the 5,229,382 patent, covering the Zyprexa®(olanzapine) and its use in treating schizophrenia, was not obvious nor anticipated. In considering these defenses, it noted that the prior art (clozapine and its chemical family) did not suggest the use of a hydrogen component which the invention used, and, in fact, pointed away from using this component. Moreover, even if there were obviousness, Lilly overcame the defense by showing four of the five secondary considerations being long-felt and unmet need, failure of other compounds, industry acclaim, and unexpected results. In addition, Lilly's use of the product before the patent application was non-public; the way Lilly conducted the clinical tests were experimental and overcome the Section 102 Public Use Bar which prohibits the issuing of a patent if the invention was in public use for more than a year before application. The Court offers quick analysis of the inequitable conduct grounds. It notes that Lilly did not withhold any material information, particularly the publicized dog studies as it clearly stated to the USPTO that the results were not obtained from human studies.

Ferring vs. Barr Laboratories, 05-1284, February 15, 2006. Court of Appeals affirms summary judgment of unenforceability due to inequitable conduct for DDAVP®(desmopressin) Tablets. While it had been long known that desmopressin, a peptide, could be absorbed in the mouth and nasal mucosa, Ferring invented a compound and method of absorption in the GI tract for an oral solid formulation. The PTO rejected this claim because a prior patent referred to "peroral" administration which it considered to include GI absorption but also requested "non-inventor" statements to the contrary, and Ferring submitted declarations that "peroral" did not mean GI tract absorption which was then rejected. On appeal to the PTO Board, the Board once again rejected the claim and added that a prior publication noted the slow absorption of this particular peptide, suggesting that GI absorption was possible, thus rejecting the claim as obvious. After submitting additional declarations regarding the prior art issues, Ferring persuaded PTO to issue the patent. The trial court granted summary judgment on the grounds that four of the five declarants on

behalf of Ferring had either worked for Ferring or had received consulting fees from Ferring. These relationships were not disclosed. In affirming this ruling, the Court of Appeals concluded that the PTO's request for declarations was really a request for independent, disinterested declarations. As such, Ferring's failure to inform the PTO of the declarants' prior business relationships with Ferring amounted to material omissions. Further, because Ferring should have known of the materiality, failed to disclose the potential bias of the declarants, and failed to offer a rational explanation as to why it did not disclose, intent to deceive can be inferred. As a result, the Court concluded that these material omissions were made to deceive the PTO, thus rending the patent unenforceable due to inequitable conduct. There is a well-reasoned dissenting opinion.

Geneva Pharmaceuticals, et al vs. GlaxoSmithKline, 02-1439, November 21, 2003. Court of Appeals affirmed a ruling of summary judgment for patent invalidity for Glaxo's Augmentin®(amoxicillin clavulanate) for non-statutory double patenting. Glaxo argued that the claims in question had been restricted, but the argument failed. In commenting on the "Section 121" shield, the Court stated: "Specifically, § 121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance. The restriction documentation must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions." (page 18)

Glaxo Wellcome vs. Andrx Pharmaceuticals, 02-1348, September 22, 2003. Court of Appeals reversed a ruling of summary judgment for noninfringement of Andrx's version of bupropion (Zyban® and Wellbutrin, SR®). The case turned on claims construction. The District Court restricted the claims construction of a component to its specific weight and grade, but the Court of Appeals accepted the scientifically acceptable definition which was broader. "When a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification." (page 13) Thus, the Appeals Court remanded for further fact finding and ruling to the issues of infringement given the broader definition.

(Glaxo) SmithklineBeecham vs. Apotex, 04-1522, February, 24, 2005. The Court of Appeals, in a 2-1 decision, affirmed the ruling of summary judgment that a patent covering Paxil®(paroxetine) (6,113,944) was invalid. The '944 patent was a product-by-process patent that covered a different means of making paroxetine by a dry admixing process. The District Court concluded that this patent was invalid due to anticipation – the prior art (patent 4,721,723) covered the product itself. While GSK claimed that the process of the '944 patent limited the claims of it, the Appellate Court disagreed and affirmed. The Court of Appeals concluded that: "anticipation by an earlier product patent cannot be avoided by claiming the same product more narrowly in a product-process claim…While the process set forth in the product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. (page 11)." The Court also did not reach a second issue because GSK did not put the issue before the Appellate Court in its opening brief, thus procedurally did not preserve the issue on appeal. The dissent points out that claims must be narrowly construed and the majority opinion reads it too broadly and thus applies anticipation incorrectly.

(Glaxo) SmithklineBeecham vs. Excel Pharmaceuticals, 02-1581, January 29, 2004. Court of Appeals reversed a summary judgment of non-infringement of Glaxo's bupropion (Zyban® and Wellbutrin, SR®) and remanded the case to find further facts. In prosecuting the patent, Glaxo amended the patent to include the sustained release agent hydrogel polymer HPMC which had the effect of narrowing the claims. The Excel product included PVA as its agent, instead of HPMC. As the product did not literally infringe Glaxo's patent, the Court ruled that there was no infringement. Glaxo had also attempted to argue the doctrine of equivalents, claiming that PVA

and HPMC were essentially the same. However, the Court, noting the prosecution amended the agent to HPMC, concluded that prosecution history estoppel prevented Glaxo from invoking the doctrine of equivalents. While the Appellate Court agreed on this point, it also cited the Supreme Court's [u]Festo[/u] cases which held that, in certain circumstances, the presumption of history estoppel can be overcome if the patentee can show that the equivalency was not foreseeable at the time the patent was prosecuted. So, the case then turns on whether, at the time Glaxo was prosecuting the patent, HPMC and PVA were considered equivalents. If yes, then it was a foreseeable equivalent, and Glaxo would be barred from invoking the doctrine of equivalents because it had not claimed PVA in the patent. Because this fact was not clear in the record, the Court of Appeals remanded for further fact finding.

(Glaxo) SmithklineBeecham vs. IMPAX Laboratories, 03-1013, January 29, 2004. Court of Appeals affirmed a summary judgment of non-infringement of Glaxo's bupropion (Zyban® and Wellbutrin, SR®). In prosecuting the patent, Glaxo amended the patent to include the sustained release agent hydrogel polymer HPMC which had the effect or narrowing the claims. The IMPAX product included HPC as its agent, instead of HPMC. As the product did not literally infringe Glaxo's patent, the Court ruled that there was no infringement. Glaxo had also attempted to argue the doctrine of equivalents, claiming that HPC and HPMC were essentially the same. However, the Court, noting the prosecution amended the agent to HPMC, concluded that prosecution history estoppel prevented Glaxo from invoking the doctrine of equivalents. The Court of Appeals also cited the Supreme Court's [u]Festo[/u] cases which held that, in certain circumstances, the presumption of history estoppel can be overcome if the patentee can show that the equivalency was not foreseeable at the time the patent was prosecuted. So, the case then turned on whether, at the time Glaxo was prosecuting the patent, HPMC and HPC were considered equivalents. The Court of Appeals found ample evidence to support the fact that at the time of patent prosecution, it was reasonably well-known that HPMC and HPC were equivalent. As a result, Glaxo could not rebut the presumption that prosecution history estoppel barred invoking the doctrine of equivalents. Glaxo also made an attempt to argue "infectious estoppel" which the Court rejected outright.

(Glaxo) SmithKline vs. Apotex, 03-1285, April 23, 2004. Citing the public use bar, the Court of Appeals sided with Apotex in its infringing version of GSK's Paxil®(paroxetine). GSK was the owner of the 4,721,723 which covered the hemihydrate form of paroxetine. Apotex's version of the product was an anhydrous form. The case factually is convoluted, and the Court of Appeals decided not to get involved in the most circuitous facts. So, it made the claims construction that the hemihydrate form covered any amount of hemihydrate forms. Therefore, it agreed with the District Court that Apotex's anhydrous version would infringe because at times it would also contain trace amounts of the hemihydrate form of paroxetine crystal. (Apotex could not control the product during manufacturing to ensure no amounts of the hemihydrous forms would be present.) Inherent anticipation

(Glaxo) SmithKline vs. Apotex, 03-1575, July 27, 2004. The key holding from the Court of Appeals in the Ceftin®(cefuroxime) case is that the mere filing of an ANDA does not constitute willful infringement. In this case, the Appellate Court affirmed the claims construction of GSK's amorphous patents covering Ceftin and that Apotex's versions of cefuroxime infringed them. However, it did reverse the finding of willful infringement.

IMPAX Labs vs. Aventis, 05-1313, November 20, 2006. The Court of appeals affirmed the ruling that the 5,527,814 patent covering Rilutek®(riluzole) was enforceable and that there was no inequitable conduct in its prosecution. However, it reversed and remanded the district court's finding that the patent was valid (that is, not invalid due to anticipation.) The issue revolved

around a prior patent (5,236,940) that covered compounds that are useful for the treatment of amyotrophic lateral sclerosis (ALS), a neurological disease, as well as others. Of course, the compound riluzole led to patent '814 for the treatment of ALS. While the prior patent included riluzole as one of the compounds that were possibly useful in the treatment of ALS, and even went further to list possible dosage strengths, the trial court concluded that the prior patent did not anticipate the '814 patent because it did not state whether riluzole would actually be effective in the treatment of ALS. In reversing, the Court of Appeals held that effectiveness is not the standard to find anticipation but instead anticipation is broader and the question is whether the prior art would enable one skilled in the art to carry out the invention. So, it remanded the case back to the district court to "determine whether the '940 patent enables a person of ordinary skill in the art to treat ALS with riluzole. Effectiveness in treating ALS does not have to be established." (page 30.) There is a concurring opinion that dissents with the finding of antipation and concludes that there was sufficient finding of lack of anticipation in the district court's ruling.

In re Gabapentin, 06-1572, September 21, 2007. The District Court had ruled on summary judgment that the generic products did not infringe. In remanding, the Court of Appeals concluded that Pfizer had proffered enough evidence of pH testing that showed infringement. While the legitimacy of the testing is disputed, it raised genuine issues of material fact that needs trial

Janssen vs. Apotex, 08-1062, September 4, 2008. The Court of Appeals for the Federal Circuit affirmed the dismissal of Apotex's Declaratory Action. In short, Teva was first to file on this product which has three patents listed in the Orange Book. The compound patent (4,804,663) was upheld as infringed, valid, and enforceable in the tablet case, meaning that Teva could gain approval and launch before the expiration of the other two patents set to expire in a few years. Jannsen did not bring any litigation to defend those two patents. Along the course of events, Apotex had filed an ANDA and had stipulated to infringing the '663 patent, and Janssen had agreed not to sue Apotex on the other two patents. Apotex filed a declaratory action to see if it could get a judgment on the other two patents. The District Court in New Jersey dismissed this action, and the Court of Appeals, considering these facts, agreed that there was no "case or controversy" creating jurisdiction to hear the case. The idea here is that regardless of outcome, Teva would still be entitled to first to file exclusivity and a case declaring these patents invalid would not change that outcome or harm Apotex.

Janssen vs. Eon Labs, 04-1539, June 13, 2005. This case turned on claims construction, and the Court of Appeals issued this Opinion "as not citable as precedent." Anyway, Janssen manufactures and sells Sporanox®(itraconazole) which has one formulation patent (5,633,015) which covers the size of sugar cores used to make beads which are encapsulated. The patent refers to core sizes of 600-700 microns, or 25-30 mesh. Typically, formulation and manufacturing analysts refer to sizes of beads by the mesh screening technique. Eon used larger cores of 20-25 mesh though some cores might be smaller in the 600-700 micron range. The district court concluded that a person trained in the art would consider the mesh size critical, construed the mesh size to be controlling, and ruled that the Eon formulation did not infringe. The Court of Appeals agreed. Also, the Court of Appeals affirmed the ruling that the patent was not invalid due to prior use.

Knoll Pharmaceuticals vs. Teva, 03-1300, May 19, 2004. The Court of Appeals reversed and remanded the summary judgment ruling patent invalidity granted by the Court in Illinois Northern District concerning Vicoprofen®(hydrocodone/ibuprofen). The District Court concluded that the patent was invalid due to obviousness in that someone of ordinary skill in the art of pain management would conclude from prior teachings that combining an opioid with an

NSAID that is obvious. In reversing, the Court of Appeals felt that Knoll had presented enough evidence that combining these two particular molecules created unexpected effects. As such, there exists a dispute of material facts, preventing the grant of summary judgment.

McNeil PPC vs. Perrigo Corp, 02-1516, August 1, 2003. Court of Appeals affirmed a ruling of patent invalidity for McNeil's Imodium-AD®(loperamide/simethicone) for obviousness. The trial court had ruled that certain claims were obvious given the known prior art and that Perrigo's version did not infringe. However, the Court of Appeals reversed the awarding of attorney's fees to Perrigo. The Appellate Court did not believe that McNeil's conduct created an "exceptional case" where an award of attorney's fees would be justified.

Merck vs. HI-TECH Pharmacal, 06-1401, March 29, 2007. Court of Appeals affirmed a judgment on the pleadings. Here, Merck agreed to a terminal disclaimer of a patent (4,797,413) when the PTO was going to reject the application for double-patenting/obviousness. Merck agreed to have the patent expire the same day as the prior patent (4,677,115), and the patent was granted. However, Merck was able to obtain an extension under Patent Term Restoration, extending the term of the patent past the '115 patent. HI-TECH challenged on the argument that a patent subject to a terminal disclaimer cannot be extended. The Court of Appeals rejected this argument, stating the law "shall" allow for patent term extension even if it is subject to a terminal disclaimer.

Merck vs. Teva (Fosamax I), 03-1168, October 30, 2003. Court of Appeals affirmed a judgment for Merck for Fosamax®(alendronate) for infringement and validity of the 4,621,077 patent. The claim in the patent was the use of to compound containing "biphosphonic acid" for the method of treatment for urolithiasis and inhibiting bone reabsorption. Teva claimed that its product was a salt form, not covered by the patent, and that a prior patent (4,407,761) anticipated the '077 patent thus making it invalid for anticipation. In agreeing with the District Court, the Court of Appeals looked at the trial evidence that concluded that the term "biphosphonic acid" would include salt forms to those experts in the field and also that there was no evidence to support the anticipation claim. As such, Teva's salt form infringed a valid patent. As a last argument, Teva invoked the Patent Restoration Act which had given the patent an extension of 1,371 days. The Court rejected the argument noting that the acid salt form is contemplated by the Act and that deference be given the PTO. This case contains good discussion of standard of review, terms of art, and deference afforded to a federal agency.

Merck vs. Teva (Fosamax II), 04-1005, January 28, 2005. The second go-around was less favorable to Merck over Fosamax®(alendronate). While the District Court, after a bench trial, concluded that the 5,994,329 was valid and infringed by the Teva formulation, the Court of Appeals reversed. In construing the claims construction, the reversal was based on the word "about" and the conclusion that the patent was obvious in light of the prior art. The District Court ruled that the claims included the language "about 35mg" and "about 70mg" and that "about" really meant "exactly," as Merck, acting as its own lexicographer, so states. In reversing the claims construction, the Court of Appeals concluded that "about" really means "approximately." As such, two articles that had appeared in the non-peer reviewed magazine [u]Lunar News[/u] before the patent application discussed the use of alendronate on a weekly basis in dosages between 40-80mg. Because of the prior art, Merck's claims were obvious, thus invalidating the patent. There is a good discussion on the "lexicographer" rule in the dissent.

Novartis vs. Eon Labs, 03-1211, April 2, 2004. The Court of Appeals affirmed the ruling of summary judgment for non-infringement for Eon's version of cylcosporin. Novartis had developed a formulation that would administer cyclosporin as a hydrosol which was patented as

5,389,382. The Eon formulation used ethanol, and not a bit of water; however, when mixed with the waters in the stomach, Novartis argued that it became a hydrosol. In this case of claims construction, the Court of Appeals agreed with the district court that "hydrosol" should be limited to the medicinal preparation done outside of the body.

Ortho-McNeil vs. Caraco Pharmaceuticlas, 06-1102, January 19, 2007. The Court of Appeals affirmed the ruling of summary judgment for non-infringement for Caraco's version of tramadol and acetaminophen (Ultracet®). Caraco's ANDA covered an average ratio of tramadol to acetaminophen of 1:8.67 and not less than 1.75. The Court of Appeals agreed that the claim in Ortho-McNeil's patent that covered a ratio of "about 1:5" did not include any ratio reaching the 1:7.5 mark. So, given the context of the product and patent claims, "about" had to be read fairly narrow, and Caraco did not literally infringe nor did it infringe under a doctrine of equivalents theory.

Pharmacia vs. Par Pharmaceuticals , 04-1478, August 10, 2005. The Court of Appeals affirmed the judgment of the District Court in a case over Xalatan®(latanaprost). The District Court had found that one of the patents, the '368 patent, was unenforceable due to inequitable conduct because Pharmacia had not disclosed two prior publications. The publications contradicted one of the patent claims, were material, and the Court had inferred Pharmacia's intent to deceive the USPTO during the application process. While the '368 patent was unenforceable due to the inequitable conduct, it did not carry over to its sister patent, the '504 patent which was held enforceable and valid. By concluding that patents are independent by nature, the Court of Appeals affirmed the trial court because one cannot infer inequitable conduct from one patent to another.

Purdue vs. Endo Pharmaceuticals, 04-1189, February 2, 2006. The Court of Appeals remanded in part and affirmed in part the bench trial judgment of patent unenforceability due to inequitable conduct and infringement. In this case, Purdue had three patents covering Oxycontin®(oxycodone) ('295, '042, and '912) which all had nearly identical claims. When prosecuting these patents in succession, Purdue asserted a "surprising discovery" that the product had a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids. In prosecuting, Purdue was rejected for obviousness several times but continued to argue that these findings were "results" although no clinical studies had been done and the claim was based on insight alone. This case took a bizarre twist procedurally. On June 7, 2005, the Court of Appeals affirmed the trial court's judgment. However, the Court of Appeals reheard the case and changed its mind. It concluded that a court needs to consider the materiality (or importance) of the omission of fact to USPTO or deception and also consider intent. Then, a court needs to consider and balance equities before concluding a patent is unenforceable. Here, the Court of Appeals concluded that Purdue's omissions of fact were not all that material and that the trial court put too much emphasis on that fact as being highly material. In addition, the trial court needed to reconsider intent. While intent can be inferred, especially where the materiality of omission is significant, there needs to be some establishment that Purdue intended to deceive because the materiality was not all that significant in this situation. The court's prior reliance on the facts establishing intent were misplaced. So, the Court of Appeals sent the case back to the trial court. In addition, it then considered infringement and agreed with the trial court that "extended release" should be given an ordinary meaning and not restricted one. Hence, Endo infringes the patents at issue.

Pfizer vs. Dr. Reddy's Lab, 03-1227, February 27, 2004. This is the appeal of the 505(b)(2) case of the Dr. Reddy's formulation of Norvasc®(amlodipine besylate). Dr. Reddy had created a maleate form of amlodipine, and the District Court had ruled that its formulation was non-

infringing patent 4,572,909. Though the approved product was the besylate form, Pfizer had submitted data on both the besylate and maleate forms of the product, and the patent had been extended some 1,252 days by way of the Patent Restoration Act. Dr. Reddy's conceded that its maleate form was covered by the '909 patent but that the Extension/Restoration did not apply to the maleate form. In reversing the District Court, the Court of Appeals ruled that the compound is what in effect is "extended" by the Patent Restoration Act and that the extension covered amlodipine and any salts or esthers thereof.

Pfizer vs. Ranbaxy, 06-1179, August 2, 2006. This is the appeal of the decision that Ranbaxy infringed two patents that covered Lipitor®(atorvastatin). The Court of Appeals affirmed the decision that Ranbaxy infringed the '893 patent because the claims construction leading to this conclusion was appropriate and that "trans isomers" should not have been narrowly construed as Ranbaxy had argued. In addition, it also agreed with the district court that the patent term extension was appropriately granted, concluding that the correct, broader claims construction enabled the patent extension under 35 USC 156 and that statements regarding the other patent were irrelevant to the contention that Pfizer obtained the patent extension through inequitable conduct. However, the Court of Appeals reversed the finding that the '995 patent was infringed and valid. In reversing, the Court of Appeals invalidated the patent under 35 USC 112 (Para. 4). During the case, Pfizer only asserted Claim 6 of the patent regarding "hemicalcium salt of the compound." The claim was dependent on Claim 2. The problem here is that Claim 2 claimed acids, not the salt. So, as Claim 6 was not dependent on Claim 2, it is invalid. The Court noted that this is a bit of a technicality, but that is the way the section should be read.

Sanofi-Aventis v Amphastar and Teva, 05-1513, April 10, 2006 and 07-1280, May 14, 2008. Court of Appeals affirmed a finding of inequitable conduct against Sanofi Aventis regarding Lovenox®(enoxaparin). Back in July 2005, the District Court in Central California found that Sanofi-Aventis had omitted material facts to the US Patent and Trademark Office (PTO) when applying for the patent that was in dispute; as such, it ruled that the patent was unenforceable due to inequitable conduct. The issue revolved around a prior European patent EP'144 which was materially the same as the application. The PTO inititally rejected the application. Sanofi-Aventis gathered data around the product's half-life. The half-life of the enoxaparin was longer than the heparin chain of EP'144. This fact led to the unexpected innovation and ultimately the granting of the patent. However, Sanofi-Aventis failed to disclose the fact that the data it presented were for different dosage strengths than those embodied by EP '144. On the first go-around at the Court of Appeals (05-1513), the Court of Appeals agreed that there were omissions of material fact but remanded the case back to California because there was no real evidence that Sanofi-Aventis had any intent to deceive the PTO. After a trial on the issue of intent, the District Court (same court, different judge) concluded that there was an intent to deceive the PTO and once again ruled the patent unenforceable. This led to the Appeal (07-1280) decided May 14, 2008. In the second appeal, the Court of Appeals agreed with the District Court and concluded that the District Court did not abuse its discretion in finding intent to deceive. As a result, the patent is unenforceable due to inequitable conduct. The decision was decided 2-1 with one judge dissenting. The dissenting opinion notes that the concept of inequitable conduct is narrow and reserved for cases involving clear intent or fraud, elements not present here.

Sanofi-Aventis v Apotex (Preliminary Injunction Appeal), 06-1613, December 8, 2006. Court of Appeals affirmed a preliminary injunction in favor of Sanofi Aventis regarding Plavix®(clopidogrel). As background, after the settlement was rejected by several states attorneys general, Apotex launched its generic product and distributed a six month supply to the market. The Court in New York granted Sanofi-Aventis an injunction that prevented Apotex from distributing more product but did not require a recall. In affirming this decision, the Court of

Appeals, reviewing the case [i]de novo[/i], concluded that the trial court properly applied the four part injunction test and did not abuse his discretion in granting the injunction. The four part test includes: "the moving party may be entitled to a preliminary injunction if it establishes four factors: (1) a reasonable likelihood of success on its merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunctions impact…on the public interest." (pp 5-6) The Court of Appeals acknowledged that Apotex had stipulated to infringement, and thus considered its defenses. In weighing the four factors, the Court of Appeals concluded that Sanofi-Aventis had a likelihood of prevailing on the anticipation, obviousness, obviousness-double patenting defenses affecting validity as well as the enforceability argument based on alleged inequitable conduct. The Court in New York did not abuse his discretion in favoring Sanofi-Aventis when considering the other factors.

Schering v. Geneva Pharmaceuticals, et al., 02-1540, August 1, 2003. Court of Appeals affirmed a summary judgment of patent invalidity of Schering's Claritin®(loratadine) for anticipation. The Appellate Court agreed that the district court ruled that the prior compound patent anticipated several claims of the later-issued metabolite patent. "Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates
and invalidates." (page 11)

Syntex v. Apotex, 04-1252, May 18, 2005. Court of Appeals reversed a judgment of patent validity of Syntex's (and Allergan's) Acular®(ketoralac). During the District Court case the Court granted summary judgment on infringement and held a bench trial on invalidity and other issues, the District Court upheld the patent and rejected Apotex's claim of obviousness. At the root of the issue was a surfactant octoxynol 40 which helped to make soluable and stable the ingredients of the NSAID eyedrops. At first rejected by the PTO as being obvious to the prior art (patents 4,349,563, 4,559,343, and 4,454,151), the PTO acquiesced and issued the patent in dispute (5,110,493) because Allergan was able to show that the results of using octoxynol 40 over other surfactants were superior and unexpected. In reversing, the Court of Appeals found that the facts supporting the decision to uphold the '493 patent did not stand scrutiny and that the District Court should reconsider them on remand. For example, octoxynol 40 was well-known as a pharmaceutical ingredient though the District Court stated it was not; the prior patents did not "teach away" the surfactant though the District Court found as a fact that they did; and there was testimony that the combination was obvious. These facts lead to a conclusion that the patent is invalid for obviousness. However, it also affirmed the conclusion that there was no inequitable conduct during patent prosecution. Though the conduct was a bit questionable, there was no evidence to suggest there was an intent to deceive on the part of Allergan.
TAP Pharmaceuticals vs. OWL Pharmaceuticals, 03-1634, August 18, 2005. Court of Appeals affirmed summary judgment on several patents. The District Court had ruled that the '663, '020, and '021 patents of Lupron® Depot (leuprolide) were infringed by OWL but that OWL infringed the '721 and '228 patents which were also declared enforceable (OWL had claimed unenforceability due to inequitable conduct.) The case largely hinges on claims construction on all of these patents in question which the Court of Appeals agreed with the District Court's interpretation. The Court of Appeals dismissed OWL's argument that TAP acted inequitably by providing a reference cite to the USPTO late in the process. The Appellate Court concluded that the notification did not establish an intent to deceive and also that the prior art reference was not material to patentability.

Teva vs. Pfizer, 04-1186, January 21, 2005. In a very interesting ruling regarding Declaratory Actions, the Court set the bar high by affirming a dismissal of Teva in its dec action against Pfizer over Zoloft®(sertraline). Teva had filed a PIII/PIV ANDA against the product, and Pfizer

did not file a patent infringement action. Apparently, there were several other PIV applicants Pfizer chose not to sue, but Pfizer did sue IVAX and settled before this case was brought. Anyway, Article III of the Constitution requires that an "actual controversy" exist before a federal court has jurisdiction over a case. While Teva met the second part of this test (in that filing an ANDA was a potential act of infringement), Teva failed to show that it was had a reasonable apprehension of an explicit threat of being sued. The Court of Appeals agreed, rationalizing that the fact the Pfizer had sued IVAX, filed suits against others to defend other patents, and would not agree not to sue Teva, that was not enough to show an "actual controversy." The case may end up being of only historical significance as the Medicare Modernization Act of 2003 creates jurisdiction in these situations. Nonetheless, the Appellate Court refused to apply the act retrospectively to this case.

Teva Pharmaceuticals vs. Novartis, 06-1181, March 30, 2007. Here, Teva filed an ANDA with a PIV certification against all five of the Orange Book patents covering Famvir®((famciclovir). Novartis had sued Teva on only one of the five patents, and Teva filed a declaratory action on the other four. Applying [u]Teva vs. Pfizer[/u], the District Court dismissed the suit citing "no imminent threat of suit" However, before this Appellate decision was reached, the U.S. Supreme Court rejected this legal standard, and applying "all the circumstance," the Court of Appeals concluded that there is an actual case or controversy where an ANDA is filed with a PIV certification on Orange Book patents and also where the brand has filed an action against the ANDA filer.

Warner Lambert vs. Teva Pharmaceuticals, 04-1506, August 11, 2005. This case involves Accupril®(quinapril). The District Court in New Jersey issued three rulings. Under Summary Judgment, it ruled that the Teva formulation infringed the Pfizer product and also that the sole '450 patent was not invalid due to enablement. The enablement defense that Teva presented was that the claims of the patent are insufficient to describe the process of preventing degradation of the product to one trained in the art. In other words, the claims were too broad and vague which would require someone skilled in the art to use "undue experimentation" to figure out what the invention really was or how to reproduce its outcomes. After trial, the Court also favored Pfizer on the claim of invalidity due to inequitable conduct. This defense rested on Teva's claim of obviousness as the Pfizer formulation team reversed-engineered Merck's enalapril to help them figure out how to avoid product degradation through formulation excipients. The Court of Appeals affirmed the ruling of no inequitable conduct. However, it remanded the case under the summary judgment issues, citing that there was not enough evidence in the record to affirm summary judgment on the enablement defense and also that Pfizer did not produce enough evidence in the trial court that Teva's use of magnesium carbonate was to reduce the oxidative discoloration of the product. Pfizer would need to provide this evidence to show infringement.

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