The Paragraph Four Report®
Court of Appeals Opinions by Case Name
Court of Appeals Cases Numbered 11-XXXX to 14-XXXX

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

Alcon Research v. Apotex Inc, 11-1455, August 8, 2012. The Court of Appeals for the Federal Circuit issued its Opinion regarding the Patanol case. The District Court in Indiana had found the sole patent in dispute 5,641,805 valid. However, when considering the obviousness defense, the Court of Appeals disagreed. In considering several of the claims of the patent –the ones covering the use of olopatadine for treating allergic eye disease by stabilizing conjunctive mast cells – the Court of Appeals concluded that the District Court had considered the application of the prior art in an obviousness defense too narrowly. In substance, the prior art article discussed the use of olopatadine at certain concentrations for the treatment of eye disease. Although it concluded that olopatadine was not an effective mast cell stabilizer, it nonetheless would have motivated one skilled in the art to use olopatadine in humans. Thus, most of the claims were invalid due to obviousness. However the Court did find two claims valid.

Alcon Research v. Barr, 12-1340, March 18, 2014. The Court of Appeals issued its Opinion which affirmed and reversed the District Court decision. The Court of Appeals affirmed the Delaware District Court ruling that the Barr formulation did not infringe the two patents in dispute (5,631,287 and 6,011,062). However, the Court of Appeals reversed on the issue of validity. The Delaware District Court had concluded that these two patents were also invalid due to lack of enablement and written description. In reversing, the Court of Appeals disagreed, finding that the patent was clear enough that someone skilled in the art could practice the teachings of the patent without undue experimentation. As such, the deicsion leaves these two patents (expiring this December) valid yet not infringed by Barr (Teva).

Allergan v. Apotex, 13-1425, June 10, 2014. The Court of Appeals for the Federal Circuit issued its Opinion in which it reversed the findings of the District Court in North Carolina over Latisse®(bimatoprost). The Court of Appeals examined the two patents at issue which the District Court had found to be valid and infringed. In affirming the anticipation findings, the Court of Appeals then examined the two patents in light of the obviousness arguments. For the 7,388,029 patent, the Court of Appeals concluded that the District Court failed to consider the entire scope of the patent, and in that context, the Appellate Court concluded that the prior art rendered the '029 patent obvious. As for the 7,851,404 patent, the Court of Appeals first disagreed with the District Court on priority – concluding that the patent was conceived after the publication of certain prior art. With this prior art, the Court of Appeals also felt that the '404 patent was obvious.

Allergan v. Sandoz 14-1275, August 4, 2015. The Court of Appeals for the Federal Circuit issued its Opinion, affirming the findings of the District Court of Eastern Texas. After a bench trial concluded, the Texas Court had concluded that the five patents at issue were valid and infringed. Four ANDA filers had asserted various defenses against the patents including obviousness, enablement, and written description.

The product is the 0.01% strength which is an improved formulation of the 0.03% strength which had the side effect of causing hyperemia and which patents covered the specifications of the new formulation and its uses. The Court of Appeals agreed with the Texas Court that the improved formulation was in essence unpredictable given the prior art which actually taught away from the 0.01% formulation. It also concluded that the other defenses were not viable, and thus upheld the three patents, the last of which expires in 2027.

Allergan v. Barr Labs,, 12-1040, January 28, 2013. The Court of Appeals issued its Opinion over Lumigan®(bimatoprost) Ophthalmic Solution, affirming the finding of the Delaware District Court of infringement and validity of the 5,688,819 patent (an additional patent found valid expired during the pendency of the Court of Appeals case.) The appeal boiled down to the expert witness of ANDA filers Teva and Sandoz. The Court of Appeals agreed that an expert witness was necessary in this case to evaluate the obviousness defense but that the expert witness lacked credibility during trial testimony.

Allergan v. Sandoz , 11-1619, May 1, 2013. The Court of Appeals for the Federal Circuit issued its Opinion. The District Court in Texas had concluded that the four patents at issue were infringed and valid, overcoming the obviousness defense. However, for the last-to-expire 7,323,463 patent, the Court of Appeals reversed. In disagreeing with the District Court, the Court of Appeals concluded that the prior art would have indeed motivated someone skilled in the art to combine a beta-blocker with an alpha2-agonist and would have reasonably expected success in doing so. As such, it concluded that the '463 patent was invalid. However, it agreed with the District Court that the 7,030,149 patent was valid (and not obvious). As that patent expires in 2022 with the other two in dispute, the Court of Appeals did not consider arguments about them.

Amgen v. Apotex, 16-1308. July 5, 2016.. The Court of Appeals for the Federal Circuit reiterated a key procedural provisions of the Biologics Price Competition and Innovation Act (BPCIA) which is the law allowing for approval of biosimilars in the Neulasta®(pegfilgastrim) case. Following the precedent from the Sandoz case below, it concluded that Apotex needed to wait until FDA approved of its biosimilar before providing Amgen its 180 day notice to market and that enjoining Apotex from launching until that time is appropriate.

Amgen v. Sandoz, 15-1499, July 21, 2015. The Court of Appeals for the Federal Circuit interpreted two key procedural provisions of the Biologics Price Competition and Innovation Act (BPCIA) which is the law allowing for approval of biosimilars in the Neupogen®(filgastrim) case. First, the Court of Appeals agreed with Sandoz that it did not have to disclose the contents of its application to Amgen for its filgastrim product Zarxio™ when it filed its aBLA. While the BPCIA allows for a biosimilar applicant to disclose its aBLA within 20 days of the FDA acceptance of the aBLA, such disclosure sets off one procedure for the two parties to proceed. If the aBLA applicant fails to disclose when FDA accepts its filing, the BPCIA sets off a different procedure allowing the BLA holder to file a patent infringement suit which Amgen did in California. As Sandoz followed the BPCIA procedures, the Court concluded that the state law claims (unfair competition, eg) Amgen asserted were properly dismissed. Second, the Court of Appeals interpreted the statute as to require the aBLA applicant to notify the BLA holder of its intent to commercially market its product (for at least 180 days) after its application received FDA approval. Sandoz had provided two notices – one in July 2014 before the product approval and also on the day of approval on March 6, 2015. As such, the Court of Appeals concluded that the appropriate notice under the BPCIA was the second one and enjoined Sandoz from launching until 180 days (September 2, 2015). Note also that this opinion was split, so each interpretation was a 2-1 decision and that the Court of Appeals remanded the case back to California consistent with its Opinion and allowed the underlying patent infringement case to proceed.

AstraZeneca vs. Apotex, 11-1182, February 9, 2012. On February 8, 2012, the Court of Appeals for the Federal Circuit issued an opinion in what is the second appeal filed in this case. When numerous generic companies filed ANDA's over Crestor, they submitted Paragraph IV filings over the RE37,314 patent but filed Section viii statements against two method of use patents (6,858,618 and 7,030,152) which "carve out" those indications covered by the use patents from the generic labels. AstraZeneca filed PIV cases on the '314 patent. AstraZeneca also filed a second set of infringement cases over the two use patents. These cases were dismissed. In affirming their dismissal, the Court of Appeals noted that the statute allows for generic companies to submit ANDA's with Section viii statements and their approved

products with carved-out labels. As such, AstraZeneca does not have a legal claim against the ANDA filers for infringing use patents that covers carved out indications.

AstraZeneca vs. Breath Ltd , 13-1312, October 30, 2013. On October 30, 2013, the US Court of Appeals for the Federal Circuit issued its Opinion, reversing and affirming the decision of the New Jersey District Court involving Pulmicort Respules®(budesonide) Inhalation Solution. The New Jersey Court had ruled on two patents concluding that: (1) the 7,524,834 patent was not infringed (by the four ANDA filers) and (2) the 6,598,603 patent was infringed yet invalid due to anticipation and obviousness. The Court of Appeals reversed and remanded the decision over the '834 patent. The Appellate Court concluded that the District court construed the term "micronized powder composition" to be limited to be "heat sterilized" compositions. The Court of Appeals remanded to the District Court to determine whether the ANDA's infringe the '834 patent given a broader meaning of "micronized powder composition" not limited to heat sterilization. However, for the '603 patent, the Court of Appeals affirmed the finding that it was invalid due to obviousness. The literature and prior art taught that budesonide could be administered through a nebulizer which covers the substance of the '603 patent, rendering it obvious.

AstraZeneca vs. Breath Ltd , 15-1335, May, 2015. On May 7, 2015, after this case's second trip to the Court of Appeals, the Court of Appeals for the Federal Circuit issued its Opinion. In the prior appeal, it remanded the case back to New Jersey for more invalidity analysis of the 7,542,834 patent, given a broader claims construction of "micronized powder formulation." The Court of Appeals agreed and affirmed the conclusion of the New Jersey Court on the remand opinion decided earlier this year. Essentially, a skilled artisan would have been motivated to develop a sterile budesonide powder and would have expected a reasonable expectation of success using any four of the five known sterilization techniques. As such, the '834 patent is invalid for obviousness, the Court of Appeals also dissolved its injunction against the four ANDA filers.

AstraZeneca vs. Hanmi, 13-1490, December 19, 2013. The Court of Appeals affirmed non-infringement. Hanmi had filed a 505(b)(2) NDA for esomeprazole strontium, a different salt than the magnesium used for Nexium®(esomeprazole). After the New Jersey District Court construed that AstraZeneca had disclaimed all but six salts (none of which was strontium) in the two patents at issue, the parties entered a Consent Judgment of non-infringement, and AstraZeneca appealed. In agreeing with the claims construction which yielded a conclusion of non-infringement, the Court of Appeals stated that the disclaimer was reasonably clear in the patent application and patents and that nothing in the record would mitigate this conclusion.

Aventis Pharma vs. Hospira, 11-1018, April 9, 2012. The Court of Appeals for the Federal Circuit affirmed the Delaware District Court. After bench trial, Judge Sleet ruled that certain claims in two patents (5,750,561 and 5,714,512) were invalid due to obviousness and unenforceable due to inequitable conduct. The Court further found that Hospira did not infringe claim 7 in the '512 patent. Having conceded that the patent was obvious given the two prior art references and the District Court's claim construction, Sanofi-Aventis argued the term "perfusion" should have been more limited. In affirming, the Court of Appeals noted that the term "perfusion" as construed by the District Court was appropriate and nothing in the patents or prosecution history could limit the term as Sanofi-Aventis requested on appeal. Given the claims construction, the Court of Appeals concluded that the patents were indeed obvious and infringed. In addition, the Court of Appeals agreed that the patents are unenforceable due to inequitable conduct because the inventor withheld the two prior art references which were material to the USPTO and that the District Court's finding that the intent to deceive was present given all of the evidence was not clearly erroneous.

Bayer v. Lupin Pharmaceuticals 11-1143, April 16, 2012. On April 16, 2012, the Court of Appeals affirmed a finding of non-infringement in favor of Sandoz, Mylan, and Lupin Yasmin(r)(drospirenone) case. The dispute arose over the claims of the method of use patent 5,569,652. The patent claimed a use for the combination of three effects while the label had one indication for the use of oral contraception. As the labels for the three ANDA's were also for the sole use, they were granted a dismissal as their labels were not infringing the method of use stated in the patent. In affirming, the Court of Appeals agreed that the indications section of the label controlled, and that the combination effects were not in the label. In the

dissent, Judge Newman agreed with Bayer that other portions of the label contained language and approval regarding the combination effect usage and that the district court should have considered these facts.

Bayer v. Watson 12-1397, April 16, 2013. Court of Appeals for the Federal Circuit reversed the judgment of the District Court of Nevada. In the Nevada case, Judge Kent Dawson granted summary judgment in favor of Bayer and held that the RE37,564 patent was valid, overcoming the obviousness defense asserted by Watson, Sandoz, and Lupin. The patent covered a 28-day dosing regimen of 24 or 25 days of a lower dosage strength of active oral contraceptive with fewer days (4 or 3) of placebo. However, the Court of Appeals considered all of the prior art and concluded that all of the limitations of the claims were previously disclosed and that someone skilled in the art would have been motivated by the information to create such a dosing regimen. As such, it reversed the District Court, finding the patent invalid due to obviousness.

Braintree Labs v. Novel Labs 13-1438, April 22, 2014. The Court of Appeals affirmed the finding of patent validity yet remanded the decision regarding infringement. The District Court of New Jersey, after constructing certain claims in the sole patent in dispute, issued a summary judgment of infringement. The case then proceeded to trial on several defenses, but the District Court found the patent valid. The Court of Appeals agreed that the patent was valid. However, it concluded that the District Court had improperly constructed certain terms in the patent though properly construed others. As such, it remanded the portion of the case back to New Jersey to consider infringement in light of the different claim construction. (Specifically, the Court of Appeals accepted the patentee's lexicography of "clinically significant electrolyte shifts" rather than the modified definition the New Jersey Court adopted.) The three panel court was also split. Judge Dyk concurred with Judge Prost's Opinion in all its parts but dissented on the one part regarding claims construction and would have concluded non-infringement as a matter of law. Judge Moore, while labeled as a "dissent" agreed with the Opinion except one part regarding a different portion of the claims construction and would have affirmed infringement. The end result is that the Court of Appeals considered the patent valid, but the New Jersey Court will need to reconsider the infringement issue given the different claims construction.

Bristol Myers Squibb v. Teva Pharmaceuticals 13-1306, June 12, 2014. The Court of Appeals for the Federal Circuit issued its Opinion in this case, affirming the District Court of Delaware. The District Court had concluded that the sole Orange Book patent was invalid due to obviousness. In agreeing with the finding of obviousness, the Court of Appeals concluded that the chemical structure of entecavir was an obvious and minor modification to a known lead compound (2'-CDG, a carbocylic nucleoside analog) and that while the unexpected results were perhaps more than what would have been anticipated, these secondary considerations were not enough to overcome the obviousness of the modifications to the chemical structure. The lone ANDA filer in this appeal was Teva which announced that it was awaiting final approval.

Cadence v. Exela 14-1194, March 23, 2015.The Court of Appeals for the Federal Circuit issued its Opinion in this case. The case and appeal focused on the formulation of ANDA filer Excela. The Court of Appeals agreed with the Delaware District Court that its formulation literally infringed the 6,028,222 patent as its use of sodium ascrobate was an infringing buffering agent. The Court of Appeals also agreed that Exela infringed the 6,992,218 through the doctrine of equivalents due to steps in its manufacturing process. The Court of Appeals finally concluded that the claims of the '218 patent were valid and not obvious as Exela raised on appeal.

Cephalon v. Watson, 11-1325, February 14, 2013. On February 14, 2013, the Court of Appeals for the Federal Circuit issued its Opinion, affirming and reversing this case. Cephalon and Watson had completed trial with Watson being found to not infringe the two patents at issue and that both were invalid due to lack of enablement. Taking the issue of enablement first, the Court of Appeals concluded that the trial court should have placed the burden of proof solely on Watson during trial. It also concluded that the primary evidence presented – expert testimony – was not sufficient to demonstrate that the invention could not be practiced without undue experimentation. In short, while there are many factors to consider when evaluating lack of enablement/undue experimentation, there was simply not enough evidence to establish

the defense. Thus the Court of Appeals reversed the trial court, finding the patents valid. However, it did agree with the district court that the Watson product did not infringe them, thus affirming that particular decision.

Galderma v. Tolmar, 13-1034, December 11, 2013. On December 11, 2013, the Court of Appeals issued its Opinion in the Differin®(adapalene) Topical Gelcase which was on appeal from the Delaware District Court. The Delaware Court had found the four patents in dispute valid, overcoming several defenses. In a 2-1 decision, the Court of Appeals reversed, finding the patents obvious. While the District Court had focused on the optimal strength of a prior formulation of 0.1%, this finding does not negate the fact that prior art supported the concept that the 0.3% concentration was suitable for the treatment of acne which 0.3% concentration is the essence of the patents in dispute. Moreover, there was not enough prior art that "taught away" from using a 0.3% concentration. As such, the District Court erred, and the patents are invalid.

Eli Lilly v. Teva Pharmaceuticals, 11-1561, August 24, 2012. The Court of Appeals for the Federal Circuit issued its Opinion, affirming the judgment of the Delaware District Court. Having found that sole patent at issue 5,334,932 was valid, the Court of Appeals considered the only legal defense at issue being obviousness-type double patenting. Teva had argued that the '932 patent was rendered invalid due to claims in two prior patents, all three of which stemmed from the same patent application. The two prior patents have expired. In rejecting the argument, the Court of Appeals concluded that the claims of the prior patents were "patentably distinct" from the claims in '932 patent, thus rendering the patent valid. The facts turned on the fact that the chemical structure in the '932 patent was not obvious from the prior patent nor was the use of pemetrexed as an intermediary.

Eurand v. Mylan Pharmaceuticals, 11-1399, April 16, 2012. The Court of Appeals issued three opinions. In the Amrix case, the District Court of Delaware had concluded that Mylan (and Par) infringed two patents (7,387,793 and 7,544,372) but that the patents were invalid due to obviousness. In addition, Judge Robinson enjoined Mylan from marketing its product pending appeal. Cephalon appealed the finding of invalidity, and Mylan appealed the injunction ruling. In reversing the finding of obviousness, the Court of Appeals noted that the District Court relied too much on the fact that the development of the extended release formulation relied on the known bioequivalence profile while everyone agreed that the relationship between the pharmacodynamics and pharmacokinetics was unknown and the result reached not really anticipated. So, after considering other facts supporting patent validity, the Court of Appeals reversed the finding of patent invalidity. In addition, the Court of Appeals affirmed the best mode ruling of the District Court (finding patent validity). It also dismissed the injunction portion of the appeal and kept the injunction in place pending further consideration of the District Court as there are a few claims remaining to be considered.

Ferring v. Apotex and Watson, 14-1377 and 14-14-1416, August 22, 2014. On August 22, 2014, the Court of Appeals for the Federal Circuit issued Opinions in two appeals involving Lysteda®(tranexamic). The first appeal involved Watson. After trial, the Nevada District Court concluded the three patents at issue were not obvious as there was no prior art that would have suggested increasing the dose to the present 650mg. The three patents also outlined dissolution rates, and the Nevada District Court concluded that the Watson infringed the patents in a sealed opinion. While the Court of Appeals agreed that the patents were valid, it concluded that the dissolution rates of the Watson product, along with the composition, did not infringe the rates and composition established in the patents. Likewise, in the Apotex appeal, the Nevada Court had dismissed the case as moot after Apotex had amended its ANDA to establish its dissolution rates were not within the parameters established by the patents and thus was non-infringing. The Court of Appeals affirmed the order of mooting the case for non-infringement.

G.D. Searle v. Lupin Pharmaceuticals, 14-1476, June 23, 2015. On June 23, 2015, the Court of Appeals issued its Opinion which represented the second trip to the Court of Appeals for Celebrex®(celecoxib). Back in 2007, the Court of Appeals invalidated one of the Celebrex patents for double patenting. Pfizer then was able to get this patent re-issued and filed a PIV case against five ANDA filers in Virginia. The Virginia Court invalidated the reissued patent. While the Court of Appeals did not reach the issue of

whether the reissued patent was properly reissued, it focused on whether Pfizer could rely on the Section 121 "safe harbor" defense which would enable Pfizer to raise a defense against the double-patenting ruling. The Court of Appeals rejected the safe harbor defense. The Court of Appeals concluded that the safe harbor defense was not available to Pfizer because the reissued patent did not stem from the correct patent application and, during the convoluted patent prosecution history, "new matter" was introduced to the patent.

Gilead v. Natco Pharma, 13-1418, April 22, 2014. The Court of Appeals for the Federal Circuit remanded this case back over Tamiflu®(oseltamavir to New Jersey. Given the timing and changes in the law of patent terms, this case is a bit unique. Two patents are at issue. The first (5,952,375) was applied for at the USPTO. The second (5,763,483) was applied for after the '375 but was issued before the '375 patent was issued. However, while both were nearly identical, different patent terms applied to these patents, and the '375 patent expired before the '483 patent. Gilead filed its PIV suit against Natco on the later-to-expire '483 patent, but Natco claimed that the '483 patent was invalid due to double patenting as it was nearly identical to the '375 patent. The New Jersey District Court concluded that because the '375 patent issued after the '483 patent, it could not be used as the double patenting reference. The Court of Appeals disagreed, concluding that, assuming the '483 patent was an "obvious variant" of the invention claimed in the '375 patent, the expiration dates controlled the analysis because the effect of the '483 patent term was to extend the '375 patent – assuming they are basically the same patent. As such, the '375 patent could be used as a double patenting reference and sent the case back to New Jersey for further consideration. There was a dissenting opinion which noted that this analysis of allowing the expiration dates to control is basically new law and argued that the application issuance dates are the controlling considerations.

GlaxoSmithkline v. Banner Pharmacaps et al, 13-1593, February 24, 2014. On February 24, 2014, the Court of Appeals for the Federal Circuit issued its Opinion over the single patent at issue 5,565,467. After the defendants had stipulated to infringement, the District Court in Delaware had concluded that the patent was valid, overcoming four defenses. On appeal, the ANDA filers narrowed the appeal to the one defense of lack of written description, claiming that the word "solvate" is not adequately described in the patent. In rejecting this argument, the Court of Appeals concluded that the term "solvate" adequately described what was invented to a person of ordinary skill in the art and that further identifying the possible characteristics of the possible solvates was not necessary.

Hoffman-La Roche v. Apotex Inc et al 13-1128, April 11, 2014. On April 11, 2014, the Court of Appeals for the Federal Circuit issued its Opinion in the Boniva®(ibandronate) case. Through a series of summary judgment rulings, the District Court of New Jersey had concluded that two patents (7,718,634 and 7,410,957) – covering the once-monthly, 150mg formulation of Boniva – were invalid due to obviousness. In affirming the District Court, the Court of Appeals agreed that the plethora of prior art references would at the very least encourage a formulator to try to develop a once-monthly, 150mg strength of Boniva. As such, the patents were obvious. However, the Court of Appeals was split with Circuit Judge Newman dissenting, pointing out that none of the prior art references disclosed the critical protocol that led to the once-monthly formulation, that it took Hoffman-La Roche 12 years to develop, and that the 150mg dosage strength was thirty times the strength of the 5mg strength FDA had rejected as too toxic.

Insight Vision Inc v. Sandoz, Inc 14-1065, April 9, 2015. On April 9, 2015, the Court of Appeals affirmed the findings and conclusions of the New Jersey District Court in the Azasite®(azithromycin) Ophthalmic Solution Case. The New Jersey District Court had concluded that the four patents at issue were valid, overcoming an obviousness defense. After accepting how the District Court framed the question regarding whether the inventions leading to the patents would have been obvious to a person skilled in the art, the Court of Appeals affirmed the conclusion that the four patents were not obvious and hence valid.

The Medicines Company v. Hospira 14-1469, July 2, 2015. The Court of Appeals issued its opinion in the Angiomax®(bivalirudin) case, reversing the Delaware District Court. In the district court case, the court found that the two patents at issue were valid yet not infringed by the Hospira product. Both Medicines Company and Hospira appealed their adverse rulings. The patents covered a product-by-process that reduced impurities. Focusing on the sole issue of the "on-sale bar," the Court of Appeals concluded

that a commercial "sale" had occurred when Ben Venue manufactured pharmaceutical batches using the patented product-by-process for the Medicines Company. The on-sale bar requires the inventor to apply for its patent within one year of the patented subject's commercial use or sale. As the sale of the batches and commercial use of the invention occurred more than one year before Medicines Company applied for the patents, the on-sale bar invalidates the patents. The Court of Appeals did not reach the other issues on appeal. (But see below)

The Medicines Company v. Hospira 14-1469, July 11, 2016. The Court of Appeals for the Federal Circuit (en banc) issued its Opinion examining the issue of whether the patents in this case were invalid due to the "on-sale" bar (that is, a patent can be found invalid if the subject of the patent was found to be offered for sale more than one year before the patent was applied for.) Here, the Medicines Company had contracted with Ben Venue to produce batches of product which were delivered to Medicines (and stored) more than one year before Medicines applied for their patents. Last July, the Court of Appeals concluded that this transaction constituted a commercial sale and invalidated the patents. However, it vacated the decision in favor of an "en banc" hearing in front of all of the appellate judges (as discussed in the April 2016 [i]Quarterly Note[/i].) In reversing this decision, the en banc Court of Appeals noted that there was no transfer of title and that the contract between Ben Venue and Medicines was confidential. So, the transaction did not have the hallmarks of a commercial sale and can best be described as a contract manufacturer simply providing batches of product that the inventor (Medicines) stored before offering it for sale. As such, it agreed with the original District Court Opinion and found the patents were valid (that is, not invalid due to the on-sale bar.) However, it remanded the case back to the Court of Appeals panel to consider the other issues on appeal.

The Medicines Company v. Hospira 14-1469, February 6, 2018. The Court of Appeals for the Federal Circuit issued an Opinion in an appeal process that began in August of 2014. After the first appeal was issued, the Court of Appeals issued an opinion [i]en banc[/i] (that is, it reconsidered the first opinion with all of the judges involved.) The [i]en banc[/i] panel sent the case back to the original Court of Appeals panel to consider whether Hospira infringed the patents at issue and whether a distribution agreement Medicines entered into was a "commercial sale." In this most recent decision, the Court of Appeals agreed with the original Delaware District Court decision and concluded that the process by which Hospira makes its ANDA product did not infringe the two patents as the Hospira process did not perform "efficient mixing" as set out in the claims. However, it reversed the Delaware decision regarding the distribution agreement. The Court of Appeals concluded that the Agreement met all the requirements of being a "commercial sale" which, in turn, could invoke the one-year "on sale bar" (preventing a patent from issuing if the patented subject matter was offered for sale longer than one year before application.) However, the Court of Appeals remanded the case back to Delaware for it to determine whether the patents are in fact covered by the distribution agreement.

Novartis Pharmaceuticals Corporation v. Watson Laboratories et al 14-1799 and 15-1061, May 21, 2015. The Court of Appeals issued its Opinion in two separate cases involving Exelon Patch. The Delaware District Court concluded in the case against Watson infringed the two patents at issue (the only remaining Orange Book patents) and that these were also valid, overcoming an invalidity defense. However, the same court concluded that the Par formulation did not infringe the valid patents. In affirming these two decisions, the Court of Appeals agreed that while the prior art discusses the addition of an antioxidant with rivastigmine, the prior art does not teach that oxidative degradation of rivastigmine was a known problem. Thus, someone skilled in the art would not have been motivated to add an antioxidant to the formulation to stabilize it, and thus the invention and patents were not obvious. The Court of Appeals also agreed that the Par formulation was non-infringing as it uses acetaldehyde which was not shown to actually act as an antioxidant.

Novo Nordisk v. Caraco, 11-1223 and Novo Nordisk v. Paddock, 12-1301. On June 18, 2013, the Court of Appeals for the Federal Circuit issued opinions in two companion cases involving Prandin. The primary case against Caraco had seen a prior trip to the Court of Appeals and even the US Supreme Court.

However, this Opinion decided the traditional PIV issues and should be the end of the Caraco litigation. The District Court in Michigan had concluded the sole patent (6,677,358) at issue was both invalid due to obviousness and unenforceable due to inequitable conduct. The Court of Appeals affirmed the obviousness ruling, agreeing with the district court that using repaglinide with metformin rather than as monotherapy was obvious. However, it reversed on the inequitable conduct issue. While the Court was troubled by some of the omissions in the statements to the USPTO, the Court felt that these were not material. The companion case against Paddock had been tried in Minnesota which conformed its ruling to the Michigan court. The Court of Appeals also affirmed and reversed but remanded that case on the issue of infringement.

Otsuka v. Sandoz et al, 11-1126, May 7, 2012. the Court of Appeals for the Federal Circuit affirmed the decision of the New Jersey District Court. In the Opinion, the Court of Appeals considered whether the 5,006,528 patent was invalid due to obviousness and/or double patenting. In rejecting both possibilities, the Court of Appeals noted that the obviousness argument was premised primarily on hindsight and that at the time of the invention, it would not have been obvious to develop aripiprazole based on the lead compounds of the time. Moreover, the chemical composition of the invention is structurally different than the prior art and other patents; thus, the patent is not invalid due to double patenting.

Par Pharmaceutical v. TWi Pharmaceuticals, 14-1391 December 3, 2014. On December 3, 2014, the Court of Appeals issued its Opinion. The District Court of Maryland had concluded that the 7,101,576 patent which covered the use of megestrol nanoparticles to improve body mass was invalid as obvious. When Par developed the nanoparticle formulation, it found that it greatly reduced food effect and allowed for better bioabsorption when taken in a fasting state which was a benefit to the patient population. While the Court of Appeals agreed with much of the analysis of the Maryland District Court, it remanded the case to find further facts. The facts established that the prior art ANDA filer TWi relied upon did not disclose the food effect limitations. As such, the Maryland District Court had proceeded on the "doctrine of inherency," the idea being that even though the prior art did not disclose the limitations of the food effect, the prior art could still render the patent obvious if the claim limitation in the prior art is "the natural result of the combination of elements explicitly disclosed in the prior art." (Page 16). Finding that these facts had not been established in the Maryland Court and noting that the standard is rather high to establish in obviousness defenses, the Court of Appeals remanded the case to Maryland for further fact finding, that is, to see whether TWi has presented "clear and convincing" evidence that "demonstrates the food effect as claimed is necessarily present in the prior art combination." (Page 17).

Pfizer v. Teva Pharmaceuticals et al 12-1576, February 6, 2014. The Court of Appels for the Federal Circuit issued its Opinion, affirming the decision of the Delaware District Court. While the District Court held that the four patents at issue were infringed and valid, against eight ANDA filers, all of the parties agreed that the appeal hinged on Claim 2 of the 6,197,819 patent and thus narrowed the appeal to a review of this claim. In considering this Claim, the Court of Appeals agreed with the District Court and Pfzier that the claim covered the general compound and not limited a specific racemic mixture. A such, the patent remains infringed, and with the broader claim construction, the Court of Appeals likewise affirmed the validity of the patent overcoming defenses of enablement, written description, and obviousness.

Pozen v. Par Pharmaceuticals , 11-1584, September 28, 2012. The Court of Appeals affirmed the judgment of patent validity and infringement in the Treximet®(sumatriptan and naproxen) Tablets case. The Court concluded that the prior art did not establish or teach one skilled in the art to use the product in combination. There was a dissenting opinion which disagreed with a portion of the infringement finding.

Prometheus Laboratories v. Roxane Laboratories , 14-1634, On November 10, 2015. The Court of Appeals for the Federal Circuit issued its Opinion in this case. The patent at issued (6,384,770) is the sole remaining Orange Book patent and covers the method of using alosetron to treat irritable bowel syndrome in women whose predominant symptom is diarrhea. In the prior proceeding in New Jersey, the District Court concluded that this use was obvious considering the claims in the other Orange Book and expired patent and that it was also invalid due to double patenting. In affirming this decision, the Court of Appeals agreed with the District Court that the method of use claims of the '770 patent were obvious given the prior patent

and then-current knowledge of irritable bowel syndrome and the standards for treating it. As such, it affirmed the finding of obviousness and did not consider the double-patenting ruling. .

Pronova v. Teva Pharmaceuticals 12-1498, September 12, 2013. The Court of Appeals reversed the district court in the Lovaza®(omega-3 acid ethyl esters) case. The Delaware District Court had concluded the two patents at issue (5,656,667 and 5,502,077) were infringed and valid, overcoming several defenses. In March, 2013, the '077 patent expired. However, in assessing the '667 patent, the Court of Appeals concluded that Pronovo's predecessor Norsk Hydro had made the inventions claimed in the patent public accessible. Specifically, Norks Hydro had sent both vials and capsules of the product for unrestricted, non-experimental use and not under any confidentiality to certain physicians starting as early as September 1987. Given these circumstances, the Court of Appeals concluded that these were a "public use" and that these took place more than a year before the patent application was filed. So, the Court invalidated the patent on these grounds, leaving the other issues moot.

Purdue v. Epic Pharma 14-1294, February 1, 2016. The Court of Appeals issued its Opinion in what may be the end of nearly 15 years of PIV litigation over this product. Since 2001, there have been several PIV cases involving OxyContin® with the most recent wave of cases involving the latest – and currently marketed – reformulation. The underlying New York District Court trial was decided two years ago and involved Teva where Judge Stein concluded that the three patents designed to reduce impurities ("low ABUK") were invalid due to obviousness and that the two abuse deterrent formulation patents were invalid due to anticipation. After this decision, there was much legal wrangling over three pending cases involving ANDA filers Mylan, Epic, and Amneal. The same New York Judge dismissed these cases in favor of the three ANDA filers on the legal grounds of collateral estoppel, the idea being that Purdue could not fundamentally re-try the same cases again. In this appeal, the Court of Appeals simply recited and agreed with the rationale of the District Court. In essence, the prior art disclosed many of the chemical processes that would lead to the reduction of the alpha, beta unsaturated ketones (ABUK) rendering the three low-ABUK patents obvious. Likewise, prior art clearly anticipated the abuse deterrent crush resistant tablets encompassed by the sole abuse-resistant formulation patent on appeal as the reference disclosed each and every limitation in the asserted claims in the patent.

Research Foundation v. Mylan, 12-1523, August 7, 2013. On August 7, 2013, the Court of Appeals for the Federal Circuit issued its Opinion, affirming the decision of the Delaware District Court. In Delaware, Judge Stark considered argument surrounding five Orange Book patents. While ruling that four of them were not infringed, he concluded that two of the four were valid yet that the other two were invalid due to anticipation. However, more importantly, Judge Stark concluded that the fifth, last-patent-to-expire was not only infringed but also valid. The Court of Appeals affirmed this decision and most of the other conclusions of the District Court. However, it vacated and remanded the portion of the decision pertaining to the two invalidated patents. The Court of Appeals concluded that the District Court had not made enough findings of fact regarding the patents to establish anticipation, particularly the prior art and the relationships between the patents' dependent and independent claims. As the last-to-expire patent remains infringed and valid, the return to the Delaware Court is a bit academic, and we might anticipate the parties reaching a settlement.

Reckitt Benckiser v Watson Laboratories, 11-1231, July 7, 2011. The Court of Appeals affirmed a finding of non-infringement. The Reckitt patent (6,372,252) covered a modified release product having two portions that were an immediate and sustained release forms. However, the Watson formulation was a non-layered, single-formulation polymer matrix. In agreeing with the District Court, the Court of Appeals construed the formulation as being in two distinct parts, and as the Watson formulation was in one part, it did not infringe the patent literally or under the doctrine of equivalents.

Sandoz Inc. v. Amgen, 14-1693, December 5, 2014. On December 5, 2014, the Court of Appeals affirmed the California District Court's decision to dismiss this case for lack of jurisdiction. The facts revealed that Sandoz is developing a biosimilar product for etanercept under the Biologics Price

Competition and Innovation Act (BPCIA). The Act represents new territory as it provides a mechanism and pathway for manufacturers to develop biosimilars. Sandoz had begun its Phase III studies – and had not yet filed an application for approval with FDA – when it filed a declaratory action against Amgen over two patents. The case (and this appeal) represents the first cases concerning the BPCIA and the relevant manufacturers. The California District Court dismissed the case for lack of jurisdiction on two grounds: lack of an Article III "case or controversy" and under the process set out in the BPCIA. In affirming the dismissal, the Court of Appeals did not consider the BPCIA, concluding that there was no "case or controversy." Article III of the U.S. Constitution enables federal courts to have jurisdiction (ie, the authority rule) over actual "cases and controversies." The controversy must be "real and immediate." Given the facts, and particularly that Sandoz is still in Phase III of development, the Court of Appeals concluded that there was not a real or immediate controversy. After all, it reasoned, the product could fail in Phase III and there was no application pending for FDA to consider. As such, it agreed to dismiss this case and also pointed out that it did not want to create any hard rules regarding jurisdiction in the biosimilar area or BPCIA. However, given the facts presented, the Court of Appeals concluded the case was not yet a true controversy to be decided.

Sanofi-Aventis v. Glenmark Pharmaceuticals 12-1489, April 21, 2014. The Court of Appeals for the Federal Circuit issued its Opinion, affirming a finding of patent validity as well as $16M in damages a jury awarded Sanofi-Aventis because of the at-risk launch of Glenmark. Glenmark raised the obviousness defense on appeal arguing that really any combination of an ACE Inhibitor with a Calcium Channel Blocker would have been obvious to try. The Court of Appeals disagreed and concluded that a "double ring" product like trandolapril was not obvious along with the fact that nothing in the prior art suggested the combination of these two particular molecules. The unexpected benefit of once a day dosing also weighed in favor of a non-obviousness finding.

Senju v. Apotex, 13-1027, March 31, 2014. In this product's second appeal, the Court of Appeals issued its decision on March 31, 2014 in the Zymar®(gatifloxacin) Case. In the original case, Apotex prevailed, showing that the patent (6,333,045) was invalid due to obviousness. While Senju appealed that decision, it brought a second action against Apotex after it had the patent amended and reexamined, and the Delaware District Court dismissed the second case. In affirming the dismissal, the Court of Appeals concluded that the reexamination of the patent did not give Senju a second opportunity to file a PIV case for patent infringement. While the patent was different in a sense, the claims of the reexamined patent were narrower than the first, and the Court of Appeals concluded that this second case was appropriately dismissed on the doctrine of "claim preclusion" (formerly known as "res judicata".) In short, the law does not allow a second case over the same subject matter, and as such, the '045 patent is still invalid. There was a dissenting Opinion filed in this appeal with the judge commenting that the narrower claim in the reexamined patent does not mean that the owner of the patent had narrower rights under the patent and that it could possibly continue with its second case.

Senju v. Lupin, 13-1630, March 20, 2015. The Court of Appeals for the Federal Circuit issued its Opinion in the Zymaxid®(gatifloxacin) Case case involving the 6,333,045 patent, a patent which had been subject to prior judicial decisions and trips to the Court of Appeals. The Delaware District Court had concluded that the several claims of the patent, in spite of being qualified and limited on a re-issue, were obvious. The Court of Appeals, in a 2-1 decision, agreed that the several prior art reference rendered the use of gatifloxacin with disodium edatate as obvious. The dissenting opinion focused on Senju's legal argument that the unexpected results of the use were not properly considered.

Shire v. Amneal et al , 14-1736, September 24, 2015. The Court of Appeals issued its Opinion in the Vyvanse®(lisdexamfetamine) case. The case involved five ANDA filers and four patents that covered derivatives of amphetamine. The New Jersey District Court had granted summary judgment, finding that the four patents were valid overcoming the obviousness defense. The Court of Appeals agreed, concluding that there really was no evidence that the prior art disclosed the active ingredient L-lysine-d-amphatimine or would have motivated Shire to develop it or its salts. Moreover, the Court of Appeals affirmed a secondary finding that the five ANDA filers waited too long to raise the on-sale bar. However, the Court of Appeals reversed the New Jersey Court in regards to the API supplier Johnson Matthey. The Court of

Appeals concluded that supplying the active pharmaceutical agreement fell within the safe harbor provisions and thus did not induce infringement.

Shire v. Watson, 13-1409, March 28, 2014. The Court of Appeals reversed the Florida Southern District Court involving Lialda®(mesalamine) Delayed Release Tablets. After trial, the District Court had concluded that Watson had infringed the sole Orange Book patent and also that the patent was valid, overcoming the lack of enablement and written description defenses. In reviewing the claims construction, the Court of Appeals concluded that the District Court had construed the terms "inner lipophilic matrix" and "outer hydrophilic matrix" too broadly. With a narrower claims construction, the Court of Appeals remanded (that is, sent the case back) to the Florida Southern District Court for a determination as to whether the Watson formulation infringes the patent given the narrower definition.

Sunovian v. Dey Pharma, 11-1507, April 16, 2012 The Court of Appeals affirmed non-infringement. In this case, after Sunovian brought a PIV case against Dey case over two patents, Dey filed a declaratory action over the last-to-expire patent 6,451,289 which also received a PIV certification. While Sunovian offered a covenant not to sue, Dey refused. The parties entered a consent judgment on non-infringement allowing Sunovian to appeal on grounds that the Court in Delaware lacked jurisdiction. In rejecting this argument, the Court of Appeals noted that the Medicare Modernization Act of 2003 contemplated declaratory actions particularly where there was a first filer that had settled and thus "parked" exclusivity (which was the situation here). The Court concluded that the District Court had jurisdiction over the case to enter judgment, and that Sunovian's offer to not sue on the patent was not enough to remove jurisdiction. The Opinion is somewhat academic in the sense that the underlying case between these parties was found in favor of Sunovian in February, and the District Court is considering post-trial motions.

Sunovian v. Teva Pharmaceuticals , 13-1335, September 26, 2013. The Court of Appeals for the Federal Circuit issued its Opinion, reversing the New Jersey District Court and concluding that the Dr. Reddy's ANDA product infringes the last-to-expire patent. This case involved several ANDA filers which cases have resolved. Eszopiclone is the (s)-enantiomer of zoplicone which patent claimed it to be "essentially free of the levorotatory isomer" which the Court construed as less than 0.25% of the isomer. While Dr. Reddy's certified to the Court that it would manufacture a product containing the range of 0.3-0.6% of the isomer, its application allowed for a standard of 0.0-0.6% (not more than 0.6%). Notwithstanding the certification, the Court of Appeals concluded as a matter of law that the ANDA specification controlled and would create literal infringement. The 6,444,673 patent expires in 2014; all of the Orange Book patents have already expired.

Takeda Pharmaceutical Company v. Zydus Phamaceuticals 13-1406, February 20, 2014. The Court of Appeals for the Federal Circuit issued its Opinion in the Prevacid®(lansoprazole) Solutab ODT case. The case had been appealed from New Jersey District Court where the Court concluded that the 6,328,994 patent was infringed and valid. On appeal, the Court of Appeals disagreed with the claims construction of the district court, concluding that the granule size covered by the patent was 400 micrometers or less rather than the construction of 400 micrometers, +/- 10%. Given this construction, and the Zydus formulation of granules averaging 412 micrometers, the Court of Appeals reversed and concluded that the Zydus formulation did not infringe the patent. However, the Court of Appeals did affirm the finding of validity, overcoming defenses of indefiniteness, lack of written description, and lack of enablement.

Teva Pharmaceuticals v. Sandoz Inc, 12-1567, July 26, 2013. On July 26, 2013, the Court of Appeals affirmed and reversed. In the District Court of New York, the Court had concluded that all patents were infringed and valid. The Court of Appeals considered 9 patents, some of which are non-Orange Book, process patents. The Court concluded that the Sandoz and Mylan formulations infringed the patents and that the patents were not invalid due to obviousness or lack of enablement. However, it further split the claims into two Groups. Group II claims were those found in four of the patents while Group I claims covered the other five patents (one of which expires in 2015). When analyzing the issue of indefiniteness, the Court of Appeals considered the

term "molecular weight." It concluded that the Group II claims were reasonably clear regarding the term molecular weight. However, the Group I claims, the Court construed the term as ambiguous because molecular weight can mean different measurements. So, it reversed, finding the Group I claims invalid due to indefiniteness and remanded. The Court remanded to the District Court to determine the length of the injunction.

Teva Pharmaceuticals v. Sandoz Inc, 12-1567 on remand, June 18, 2015. On June 18, 2015, the Court of Appeals for the Federal Circuit issued its remand Opinion in this case involving the 20mg/mL strength of Copaxone. In an earlier decision, the Court of Appeals had concluded that the last-to-expire process patent (5,800,808) was invalid for indefiniteness. Teva appealed this decision to the US Supreme Court which last year remanded the case back to the Court of Appeals to consider the issue of indefiniteness again, in light of a different legal standard of review, providing more deference to the original trial court in New York. On reconsideration, the Court of Appeals, in a 2-1 decision, once again concluded that the term "molecular weight" in Claim 1 of the patent was indefinite. In applying a new standard for indefiniteness articulated by the Supreme Court in a different case, the Court of Appeals concluded that the term did not inform one skilled in the art with "reasonable certainty" as to the scope of the invention. As the dissenting opinion points out, the majority opinion also discounted the argument that determining the meaning of "molecular weight" was a question of fact and did not provide any deference to the New York Court.

Warner Chilcott v. Lupin, 12-1262, October 22, 2014. The Court of Appeals for the Federal Circuit issued its three page Opinion, affirming the decision of the New Jersey District Court. In January of 2014, after a bench trial, the New Jersey District Court concluded that the only patent in dispute (7,704,984) was valid, overcoming the sole defense of invalidity. The Court of Appeals simply agreed with the rationale of the New Jersey Court, concluding that while there was prior art covering various combinations of estrogen and progestin, there were many possible combinations yet none of them led to the combination and regimen outlined in the patent. As infringement was stipulated, the patent remains valid and expires in 2029.

Warner Chilcott v. Teva, 14-1439, November 18, 2014, November 18, 2014, The Court of Appeals for the Federal Circuit issued its Opinion on the Actonel®(risedronate) Once-a-Month formulation. In the Delaware District Court, the Court had granted summary judgment to four ANDA filers (Teva, Sun, Apotex, and Mylan), concluding that the two patents at issue (7,192,938 and 7,718,634) were invalid due to obviousness. In affirming, the Court of Appeals agreed that the method of use covered by the patents – the once-monthly dosing of 150mg – were obvious given the literature and prior studies that taught that the dosing would likely be beneficial for the treatment of osteoporosis. This Opinion also noted a similar finding of invalidity for the '634 patent in the Boniva®(ibandronate) appeal.