The Paragraph Four Report®
Court of Appeals Opinions by Case Name
Court of Appeals Cases Numbered 15-XXXX to 17-XXXX

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

Acorda Therapeutics v. Roxane Laboratories, 17-2078, September 10, 2018. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Ampyra®(dalfampridine). In the prior Delaware District Court case, Judge Stark concluded that four patents were invalid as obvious – the prior art were several studies involving the compound which the majority of the Court of Appeals discussed at length. In agreeing with the Delaware District Court, the Court of Appeals concluded that the dosing regimen contained in the claims of the four patents would have been obvious to try considering the prior study designs. However, it conceded that the NDA holder Acorda had many failures with this product in development and that the product had a great deal of commercial success which is evidence that the dosing regimen may not have been so obvious at the time of invention. However, the 2-judge majority of the Court of Appeals noted that the broad claims of the primary product patent would have blocked others from trying to develop this product to improve the walking ability of a patient with multiple sclerosis which yielded the claims in the disputed patents. The majority concluded that, if the prior patent blocked product development by others (or otherwise risk infringement), that suggests that Acorda was aware of the potential success of the product in spite of their failures in development. As such, the Court of Appeals concluded the balance of information leads to the finding of obviousness. However, Judge Newman dissented, placing more weight on the fact that Acorda had years of product development failure, Judge Newman concluded that the dosing regimen was not obvious and that the earlier blocking patent was not sufficient reason to overcome the numerous failures in development suggesting the regimen was indeed not obvious.

Allergan Inc v. Sandoz, 16-1085, March 17, 2017. The Court of Appeals issued its Opinion from a long-line of PIV cases and appeals which began in 2010. This appeal arose from cases filed in 2014 over patents issued after the original cases began. Essentially, the issue before the Court of Appeals was that, given the similar nature of the claims in these later-issued patents from the original patents, whether the court had already litigated these claims to the point that they should not be considered again. The North Carolina District Court had concluded that the claims of these later patents had essentially been considered before and should not be tried again, a concept known as "collateral estoppel." Thus the North Carolina court had dismissed the cases and concluded these claims were likewise invalid, given all of the prior court rulings. For the most part, the Court of Appeals agreed. In first noting the lengthy court proceedings over this product, the Court of Appeals concluded that Allergan had already had a chance to litigate these claims before and thus was "collaterally estopped" from bringing these cases over what was substantively the same claims. However, as far as Sandoz was concerned, it noted that certain claims of the 8,926,953 patent were not properly before the court, and reversed on those grounds. As it concluded, "We affirm the District Court's judgments with respect to Akorn, Inc., Hi-Tech Pharmacal Co., Inc., Apotex Inc., Apotex Corp., and claims 8, 23, and 26 of the '953 patent as applied to Sandoz, Inc. We reverse the District Court's judgment for Sandoz, Inc. with respect to claims 1−7, 9−22, and 24−25 of the '953 patent." In theory, this

decision should end the litigation for Akorn, Hi-Tech, and Apotex but the Sandoz case may end up going back to the North Carolina District Court unless the parties could settle.

Allergan Inc v. Sandoz, 17-1499, December 22, 2017. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Combigan®(brimonidine and timolol) Ophthalmic Solution which genesis began in 2009 with several decisions and trips to the Court of Appeals. In its latest iteration, the Texas Eastern District Court considered three patents (all of which expire in April 2022) and ruled that the ANDA filer Sandoz had infringed Claims 1-8 of one of the patents (8,748,425) but had not infringed the other two. The Texas Court had further concluded that these patents were valid. The Court of Appeals affirmed that the three patents were valid, agreeing that the prior art did not teach the combination. However, it reversed the finding that Sandoz infringed the '425 patent. Noting that the ruling was "literal infringement," the Court of Appeals cited the fact that the claims covered 0.5% timolol. However, both the brand and the Sandoz ANDA contain 0.68% timolol. Thus, the Court of Appeals concluded that the Sandoz ANDA does not literally infringe the claims and affirmed that it likewise did not infringe the other two patents.

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. Apotex, 17-1010, November 13, 2017. On November 13, 2017, the Court of Appeals for the Federal Court issued its Opinion involving the Abbreviated Biologics License Applications of Apotex under the BPCIA. After a trial, the Florida Southern District Court concluded that the Apotex aBLA product did not infringe the 8,952,138 patent. The patent essentially covered a method of properly folding non-mammalian proteins (such as bacteria) so that the proteins would not, in effect, clump into limited-solubility aggregates. The District Court found that the concentration of the buffer Apotex used did not infringe the limitations set by the '138 patent. The Court of Appeals agreed finding non-infringement and further rejected the arguments of Amgen involving claim construction. The aBLA applications include both Neulasta and Neupogen®(filgrastim).

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.

Atalis Pharmatech v. Apotex Inc, 17-1344. January 4, 2018. The Court of Appeals for the Federal Circuit issued its Opinion. The Delaware District Court had concluded that Apotex had infringed two patents covering the formulation of the extended-release product of Amrix®(cyclobenzaprine). In reversing, the Court of Appeals concluded that the Delaware Court had improperly constructed the key claims. The Court of Appeals agreed with Apotex's claim construction and concluded that the term "extended release

coating" as a "continuous outer film applied onto the surface of the active-containing core" which enables extended release of the active ingredient. As such, the Court of Appeals returned the case back to Delaware with the new claim construction for further consideration.

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.

Bayer v. Watson, 16-2169, November 1, 2017. The Court of Appeals for the Federal Circuit issued an Opinion in this Case. The Delaware District Court had found the three Orange Book patents valid. However, ANDA filer Watson appealed the decision over the 8,613,950 patent, claiming that the ODT formulation of sorbitol and mannitol was obvious. While the Delaware District Court had found the claims obvious, the Court of Appeals disagreed. In finding two claims of the '950 patent obvious, the Court of Appeals focused on the fact that the prior art would have motivated the development of an ODT formulation for the class of drugs and noted the possibility of developing such a formulation. The Court of Appeals also noted that the Delaware District Court did not mention these prior art sources which the Court of Appeals considered very relevant to the obviousness defense. Moreover, the Court emphasized that while the prior art may have preferred a delayed-release formulation, the prior art nevertheless pointed to the possibility of developing an immediate release formulation which was how the product formulated. As such, it concluded that there would be indeed a high degree of motivation to develop an ODT formulation, to use the two components covered in the claims, and to create an immediate release formulation.

Braintree Laboratories v. Breckenridge Pharmaceutical 16-1731, May 5, 2017. The Court of Appeals issued its Opinion in this case involving Suprep Bowel Prep Kit, reversing and remanding the case back to the District Court of New York for an entry of judgment of patent infringement. About a year ago, the New York District Court had granted summary judgment to Cypress (Breckenridge), concluding that the formulation did not infringe the sole Orange Book patent. The Court of Appeals disagreed, finding that the Breckenridge product infringes the patent. The Court of Appeals concluded that the Breckenridge product label serves to instruct on how to clean the colon using its product which infringes the patent in fundamental terms.

Cubist v. Hospira, 15-1197, November 12, 2015. On November 12, 2015, the Court of Appeals affirmed the decision of the Delaware District Court. The Delaware Court had concluded that the first-to-expire patent, a reissued patent, was valid and that the remaining four patents were invalid due to obviousness. The issues on appeal regarding the reissued patent are not commonly seen in PIV appeals. The Court of Appeals agreed that the "certificate of correction" present in the reissued patent (expiring in June 2016) was not enough to invalidate it as the corrected chemical diagram was minor and did not change the scope of the patent. Also, the reissued patent did not expand its claims or scope in its reissue and thus did not "recapture" what was surrendered during the application process. So, the Court of Appeals affirmed the validity of this patent and the invalidity of the later-to-expire patents as they were obvious given the prior art.

Cumberland Pharmaceuticals v. Mylan, 16-1155. On January 26, 2017, the Court of Appeals for the Federal Circuit issued its Opinion in this case, affirming the decision of the District Court in Chicago. The patent covered the product free a chelating agent, and in the district court case, the court concluded that the prior art actually taught away from the removal of the chelating agent (edetate disodium) as it was considered necessary for stability and thus concluded the patent valid and not obvious. Moreover, the district court concluded that the conversations the product sponsor had with FDA did not mean that FDA conceived of the idea of removing the chelating agent. When considering the record on appeal, the Court of

Appeals simply concluded that the record and evidence supported the district court decision and thus affirmed the patent's validity.

Depomed v. Purdue, 15-2029, March 24, 2016. The Court of Appeals affirmed the decision of the Patent Trial and Appeal Board of the USPTO stemming from three Inter Partes Reviews filed by Purdue. The IPR's concerned two Orange Book patents (6,340,475 and 6,635,280) which are listed for three branded products Glumetza®(metformin), Janumet XR®(metformin and sitagliptin), and Gralise®(gabapentin). While the PIV cases involving these products settled, Depomed sued Purdue for patent infringement over these two formulation patents (claiming Purdue's product OxyContin®(oxycodone) infringed the patents.) In turn, Purdue filed three IPR's over these patents. Back in July, the USPTO Board found that the prior art references would not have motivated anyone to create the formulation covered by the patents nor would have suggested success in trying. As such, the Board found that patents valid. In affirming this decision, the Court of Appeals simply agreed with the Board's rationale that the prior art would not motivate anyone skilled in the art to piece together the prior art and attempt the formulated mixture.

Dr. Falk Pharma v. Generico LLC et al 17-2636, June 12, 2019. The Court of Appeals issued its Opinion which stemmed from two decisions in a case involving Apriso®(mesalamine). First, the Court of Appeals affirmed the decision of the Patent Trial and Appeal Board in an Inter Partes Review proceeding which found two claims of the 8,865,688 patent unpatentable due to obviousness. The Court of Appeals agreed that the dosing regimen for the remission of ulcerative colitis covered by claims were obvious as the several pieces of prior art suggested the protocol and motivated one skilled in the art to combine the reference sources. Second, the Court of Appeals considered what was technically a second appeal from a decision regarding Mylan from a PIV case in West Virginia District Court. There, Judge Keeley concluded that the Mylan formulation did not infringe claim 1 of the same patent. After the Court of Appeals affirmed patent invalidity of claim 1, it then dismissed this appeal as moot.

Eli Lilly v. Perrigo, 16-2555, November 22, 2017. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Axiron®(testosterone). The Indiana District Court had issued a lengthy Opinion regarding three patents and four ANDA filers finding claims in two patents invalid but the third was valid yet not infringed by three of the ANDA filers. On appeal, Eli Lilly challenged the obviousness finding of the 8,435,944 and Amneal challenged the validity and infringement finding of the 8,807,861. In affirming the decision of the Indiana District Court, the Court of Appeals agreed with the Court's findings and analysis. It noted that there was ample evidence that the claim of the '944 patent was obvious given the prior art. Moreover, it also found that the '861 patent was neither anticipated nor obvious and that the Amneal applicator infringed the patent.

Eli Lilly v. Teva Parenteral Medicines, 15-2067, January 12, 2017. The Court of Appeals issued its Opinion upholding the sole patent at issue. The 7,772,209 patent was issued during the pendency of the first set of PIV cases over Alimta and covered the co-administration of folic acid and vitamin B12 to reduce the toxicity effects of pemetrexed. Over the course of two separate trials in Indiana, the District Court concluded that the four ANDA filers infringed the patent and that the patent was valid. In considering several issues, the Court of Appeals agreed, finding that the ANDA filer labels and the drug's administration with folic acid and B12 would infringe the '209 patent. In addition, the Court of Appeals agreed that the patent was valid: the term "vitamin B12" was not indefinite; the use of folic acid and vitamin B12 to offset toxicity of pemetrexed was not obvious given the prior art; and the claims of the '209 patent were not obvious variants of claims in a prior Eli Lilly patent to amount to double-patenting.

Endo Pharmaceuticals v. Actavis Laboratories, 16-1146, October 14, 2016. The Court of Appeals affirmed the decision of the District Court in Texas (Eastern). This case involved two patents that covered a gel formulation that had effective penetration enhancers for testosterone through the skin without being irritating. The District Court concluded that the patents were not invalid because the prior art patents did not anticipate the gel formulation at issue or render them obvious. Analyzing the prior art, the Court of Appeals affirmed patent validity.

Endo Pharmaceuticals v. Custopharm, 17-1719 July 13, 2018. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving the two Orange Book patents listed for Aveed®(testerone) Injection. The product is comprised of a mixture of active ingredient testosterone undecanoate dissolved in mixture of castor oil and a co-solvent benzyl benzoate. In the Delaware trial, ANDA Custopharm had pointed to three prior art articles which discussed small-scale clinical studies using an injectable of testosterone undecanoate in castor oil as rendering the current Aveed formulation as obvious to try. Judge Robinson disagreed, concluding that the articles were not enough to render the patents invalid due to obviousness because the articles never discussed any co-solvent, dosing strength or regimen. In affirming this conclusion, the Court of Appeals simply found that Judge Robinson committed no reversible error in her analysis.

Endo Pharmaceuticals v. Teva Pharmaceuticals, 15-2021. On May 16, 2018, the Court of Appeals for the Federal Circuit issued its Opinion in a case involving Opana ER®(oxymorphone). In the prior case in the New York Southern District Court, Judge Griesa concluded that two patents, covering many formulation components, were valid and all but two claims infringed. The Court then enjoined (that is, prevented) the ANDA filers from marketing their products until those patents expire in February 2023. The Court of Appeals agreed, concluding that the claims of the patents were not obvious given the prior art as well as being properly described as written and not indefinite. Moreover, the Court of Appeals agreed with the District Court, placing a heavy weighting on the expert testimony, that the ANDA filers infringed all but two of the claims. The Court finally concluded the injunction was proper.

Endo Pharmaceuticals v. Teva Pharmaceuticals, 17-1240. On March 29, 2019 the Court of Appeals for the Federal Circuit issued its Opinion in a case involving Opana ER®(oxymorphone).
The case stemmed from a secondary case filing on a patent issued after the first set of PIV cases. The claims of patent 8,808,737 covered the method of using a lower dose of oxymorphone to safely and effectively treat patients that are renal impaired. While the Delaware District Court concluded that the claims were invalid as reciting unpatentable "laws of nature" (that is, the use was simply reflecting a natural phenomena and thus not patentable subject matter), the Court of Appeals disagreed. Using a two-part test, the Court of Appeals concluded that the use of a lower dose was a permissible method of use which recited specific dosage strengths to a specific set of patients. This, the Court of Appeals concluded, was an inventive step of patentable subject matter and thus held the claims valid.

Forest Laboratories v. Sigmapharm et al 17-2369. On March 14, 2019, the Court of Appeals for the Federal Circuit issued its Opinion in this case, involving Saphris®(asenapine) Sublingual Tablets, vacating and remanding it back to the Delaware District Court. The original PIV case had a mixed decision over several claims of the 5,763,476 patent which covered elements of the sublingual formulation. First, the District Court found the claims to be valid, overcoming obviousness, and second, while it concluded that several of the ANDA filers infringed claims, two others did not infringe three claims. In vacating this ruling, the Court of Appeals agreed with most of the analysis of the District Court on the obviousness question but nonetheless sent the case back on the question of whether lack of compliance motivated the development of the sublingual formulation which was not a fact specifically considered by the District Court. If so, it might indicate the formulation was obvious. Moreover, it then considered the infringement issue and how claim 4 was constructed. In vacating the non-infringement decision, the Court of Appeals noted that the district court erroneously construed the term "excitation" as limited to "excitation disorders." The Court of Appeals noted that "excitation" is really a broader symptom, not disorder, and the District Court needs to reconsider the infringement issue based on this construction.

Forest Laboratories v. Teva Pharmaceuticals, 16-2550, December 11, 2017. The Court of Appeals for the Federal Circuit issued its Opinion in a case that hinged on claims construction of Namenda XR®(memantine) patents. The appeal involved five patents that all included a similar claim regarding the concentration of the extended-release form as compared to an immediate-release dosage form. However, the claim (or others) did not specify exactly how to compare the two dosage forms. In his construction, Judge Stark in the Delaware District Court construed this to mean a comparison measured in human pharmacokinetic studies. Given this construction, Judge Stark concluded the patents invalid as indefinite as not specifying key measurements for the comparison. The Court of Appeals agreed, finding that the

Delaware Court's construction was reasonable and other alternatives were not preferred or viable. As such, the claims were indeed indefinite.

Genzyme Corp v. Dr. Reddy's Laboratories, 16-2206, December 18, 2017. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Mozobil®(plerixafor) Injection. In the trial proceeding, the sole issue was one claim (19) in one patent (7,897,590) and one defense being obviousness. The claim involved using granulocyte-colony stimulating factor (G-CSF) in combination with plerixafor for certain transplant procedures. The ANDA filers had argued that the combination of G-CSF and plerixafor was obvious given the prior art of clinical study findings and another patent. In rejecting the defense, Judge Sleet concluded that the use of plerixafor (used for HIV treatment at the time) and G-CSF to mobilize stem cells before transplant was not taught in any way by the two primary prior art sources and that the expected success of such a combination was low. In affirming this decision, the Court of Appeals agreed with Judge Sleet's analysis of the facts, concluding that the prior art did not provide a reasonable expectation of success in combining G-CSF with plerixafor. As such, the Court of Appeals found the patent valid.

Grunethal GMBH v. Alkem Laboratories, 17-1153, March 28, 2019. The Court of Appeals for the Federal Circuit issued its Opinion from an appeal arising from a mixed decision of the New Jersey District Court in the Nucynta ER®(tapentadol) cases. The New Jersey Court had concluded that the 7,994,364 patent was valid and overcame the defense of obviousness. The Court of Appeals concluded that the New Jersey Court's rationale for not finding obviousness of the patent was reasonable given the fact that the '364 patent covered polymorph Form A while the prior art only recognized the B Form and that the use claims were likewise not obvious. Moreover, it found that the District Court did not err in concluding that two ANDA filers (Actavis and Hikma) did not infringe a second patent (8,536,130) and that otherwise the patent was valid. As such, it affirmed the mixed ruling of the New Jersey District Court.

Helsinn Healthcare v. Teva Pharmaceuticals, 16-1284, May 1, 2017. The Court of Appeals for the Federal Circuit issued its Opinion which focused on the sole defense of the "on-sale bar" which requires an inventor to apply for its patent before it is offered for sale or within one year after making it available for sale. The New Jersey District Court had determined that Helsinn's Supply and Purchase Agreement of Aloxi®(palonosetron) Injection with a distributor did not constitute an "on-sale bar" even though the Agreement was made well before the critical date (one year before patent application) as it did not meet the "on-sale" criteria. In interpreting the statute and the amendments found in the America Invents Act, the Court of Appeals reversed, drawing the opposite conclusion. Even though the product was still in Phase III development, the Court of Appeals concluded that the invention was reduced to practice and ready for patenting before the critical date – well before one year it applied for the patent. Moreover, the Supply Agreement constituted a "sale" under the statute which the Court of Appeals found was not changed by the America Invents Act in circumstances like the one presented here. As such, it concluded that several claims of all four patents are invalid.

HZNP Medicines v. Actavis 17-2149, October 10, 2019. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Pennsaid®(diclofenac) Topical Solution which was decided in a piecemeal fashion in the New Jersey District Court. The District Court considered a dozen patents and had found, through claims construction and summary judgment, that most of them were invalid as including indefinite terms such as "Impurity A" and non-infringed by the Actavis formulation. However, one patent was left for trial (9,066,913), and the District Court concluded that this patent was valid and infringed, overcoming a claim that the patent was obvious. The Court of Appeals meticulously reviewed the District Court's analysis and found that there was no error.

IMPAX Laboratories v. Lannett Holdings 17-2020, June 28, 2018. The Court of Appeals issued its Opinion in this case involving two patents covering Zomig®(zolmitriptan). In the prior case, the Delaware District Court found that both patents were valid, overcoming several defenses. On appeal, ANDA filer Lannett focused the appeal on the sole issue of whether formulating zolmitriptan into a nasal spray was obvious. In affirming the Delaware District Court, the Court of Appeals summarily dismissed the arguments of Lannett. The Court of Appeals concluded that the cited prior art would not render the

formulation obvious and not motivate a formulation developer to develop zolmitriptan in nasal spray form. As such, the Court of Appeals did not find any error in the Delaware Court's rationale and affirmed the validity of both patents.

Intendis GMBH v. Glenmark Pharmaceuticals 15-1902, May 16, 2016. The Court of Appeals for the Federal Circuit issued its Opinion, affirming the finding of the Delaware District Court. By applying the doctrine of equivalents, the Court of Appeals concluded that the Glenmark formulation infringed the patent when it substituted two excipients that served the same function as skin penetration enhancers as the excipients covered by the patent. The Court of Appeals also agreed that the prior art did not render the patent obvious.

Medicines Company v. Mylan Pharmaceuticals, 15-1113. April 6, 2017. The Court of Appeals issued its Opinion in the case involving Mylan. The District Court in Illinois had concluded that the Mylan formulation had infringed one patent (7,582,727) but not the second (7,598,343). The injectable product is made by dissolving bivalirudin into a solution, adjusting the pH with a solvent, and then by removing the solvent. The infringement issue revolved around how the bivalirudin was mixed. First, the Court of Appeals concluded that the Illinois District Court should have construed the claims of both patents to be the same – requiring "efficient mixing" to achieve the end product. Second, the Court of Appeals found it somewhat difficult to define the term "efficient mixing" but settled on an example found in the specifications which called for using multiple mixing devices. As Mylan only used one mixing device in its process, it could not infringe the claims of the patents.

Merck v. Amneal, 17-1560. On February 9, 2018, the Court of Appeals for the Federal Circuit issued its Opinion in an appeal involving the ANDA from Amneal for Nasonex®(mometasone). In the Delaware District Court, Judge Robinson concluded that the Anmneal product was the anhydrous form of mometasone which did not infringe the patent covering the monohydrate. At the Court of Appeals, Merck claimed that the Amneal product would convert to the monohydrate and that the batches produced for trial examination were not reflective of the commercial product. The Court of Appeals disagreed. After reviewing the discovery procedures in the case, it concluded Judge Robinson committed no reversible errors in the court procedure or interpretation of expert testimony and data. As such, it affirmed that the Amneal ANDA product does not infringe the 6,127,353 patent.

Merck v. Hospira, 17-1115. On 10/26/17, the Court of Appeals issued its Opinion in a case involving a non-Orange Book process patent and the product Invanz®(ertapenem). The Delaware District Court had concluded that the Orange Book patent at issue (5,923,323) was valid but that the process patent (6.486,150) was obvious. The Delaware Court concluded that the process covered by the '150 patent was not only taught by the prior patent and other information but also that it merely reflected ordinary manufacturing steps. The parties only appealed the decision over the '150 patent presumably because the Orange Book '323 patent expires this November. In a split 2-1 decision, the Court of Appeals affirmed the Delaware District Court's decision over the '150 patent, agreeing that the claims were arguably common manufacturing steps that would have been taken given the knowledge of the prior art and thus rendering the claims invalid as obvious.

Merck v. Warner Chilcott, 16-2583, October 19, 2017. The Court of Appeals for the Federal Circuit issued its Opinion in this case, reversing the Delaware District Court. The Delaware District Court had concluded that two claims of the only Orange Book patent were invalid as obvious from the only prior art being an earlier patent application. Looking at the same set of facts, the Court of Appeals disagreed. In finding the claims not obvious, the Court of Appeals focused on the fact that the prior application called for a contraceptive ring with two-compartments which released the active ingredients in certain concentrations, ratios, and rates. Not only did the claims of the patent at issue (5,989,581) cover a one-compartment delivery ring, but also the prior art application warned of the difficulty in controlling release rates of the active ingredients in a one-compartment system. As such, the Court of Appeals concluded that the prior

art would not have made it obvious to change the design of the ring from a two-compartment system to one with only one compartment.

Merck & CIE v. Watson, 15-2063 May 13, 2016. The Court of Appeals issued its Opinion in a case that covers two products Beyaz® and Safyral® and reversed the decision of the Delaware District Court. In the Delaware case, the District Court concluded that the 6,441,168 patent was valid, overcoming several defenses. The Court of Appeals focused on one of these defenses – the on-sale bar which invalidates a patent if it were found that the invention covered by the patent was offered for sale (or placed into commerce) more than one year before the patent was applied for. Looking at the same facts as the District Court, the Court of Appeals drew the opposite conclusion. The Court of Appeals concluded that Merck and Weider Nutrition were in discussions about the sale of the crystalline calcium salt of a tetrahydrofolic acid (MTHF) which is what the patent claim covers. Along the way, Weider offered to buy two kg's of MTHF, and Merck sent a fax to Weider listing the price and delivery terms. Although the sale was never completed, the Court of Appeals concluded that the Merck fax was a firm offer of sale, made about 18 months (more than one year) before Merck applied for the patent. As such, the Court of Appeals concluded that the claim was invalid under the on-sale bar.

Millenium v. Sandoz, 15-2066, July 17, 2017. On July 17, 2017, the Court of Appeals for the Federal Circuit issued its Opinion, reversing the judgment of the Delaware District Court. The Delaware District Court had concluded that the sole patent in dispute 6,713,446 was obvious – the Court figured that lyophilizing bortezomib and adding a bulking agent mannitol led to the obvious natural result of creating a stable formulation of a bortezomib-mannitol ester. In reversing, the Court of Appeals disagreed. At first, the Court of Appeals pointed to the facts that the inventors of bortezomib had been trying to stabilize the liquid form of bortezomib without success before moving to the lyophilizing process, and the results in the mannitol ester of bortezomib yielded unexpected properties. Moreover, the Court of Appeals noted that there was no specific prior art, including prior patents, that taught the lyophilization of bortezomib in the presence of mannitol would yield the chemical reaction, compound, or its stability and other properties that followed, and at the very least, the prior art would never have motivated someone to try. As such, the Court of Appeals concluded that the totality of circumstances, including its commercial success, rendered the patent non-obvious and valid. [doHTML]

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.

Novartis Pharmaceuticals Corporation v. Noven Pharmaceuticals 16-1678, April 4, 2017. On April 4, 2017, the Court of Appeals for the Federal Circuit issued its Opinion from an appeal from a decision of the Patent Trial and Appeal Board of the USPTO. The case involved two patents (6,316,023 and 6,335,031) which had been the subject of PIV cases and decisions since 2011. While prior court decisions from Delaware and the Court of Appeals for the Federal Circuit had concluded that the patents were valid, the Patent Trial and Appeal Board had concluded that different prior art presented to it rendered several patent claims unpatentable. The Court of Appeals agreed. First noting that the Patent Trial and Appeal Board was not necessarily bound by the prior court decisions, the Court of Appeals agreed that the evidence before it considered new evidence and citation to different prior art. Considering this publication, the Court of Appeals likewise found the claims invalid for being obvious.

Novartis Pharmaceuticals Corporation v. Breckenridge Pharmaceuticals 17-2173, December 7, 2018. The Court of Appeals for the Federal Circuit issued an Opinion in a rather unique case involving the 5,655,722 patent which covers two brand products Afinitor®(everolimus) and Zortress®(everolimus). This case is unique as the facts unfolded in to create an usual circumstance. When Novartis applied for the '722 patent, the law allowed for a patent term of [i]17 years after the patent issued[/i] (plus any patent term extension). Two years later, it applied for a second similar patent (6,440,990), but by that time, the law changed to allow for a patent term of [i]20 years after the "earliest effective filing" date of the patent application.[/i] This change in law created a bit of an anomaly: the first patent ('772) expired after the second patent ('990) though the first had been applied for two years before it. Under this odd fact pattern, the Delaware District Court, applying the rationale of a prior Court of Appeals case, concluded that the second '990 patent could act as a reference for a double-patenting defense – which essentially invalidates a second patent issued if a prior patent (or reference) is too similar, the idea being to prevent patent owners from getting additional patents issued which are alike to the original, thus extending the patent term. As such, the Delaware District Court concluded that the '772 patent was obvious for double-patenting. The Court of Appeals disagreed and reversed. After differentiating this case from the prior Court of Appeals decision which the Delaware Court relied on, the Court of Appeals concluded that the second patent application could not be a reference for the first patent. It also noted the fairness of reaching this outcome – Novartis did not benefit or extend the life of the first patent by filing the second. As such, the Court of Appeals ruled that the '990 patent could not serve as a reference for the '772 patent for purposes of double-patenting, and while not explicitly declaring the '772 valid, the implication, of course, is that it is valid under the double-patenting defense.

Novartis Pharmaceuticals Corporation v. Ezra Ventures, 17-2284, December 7, 2018. The Court of Appeals issued an Opinion which considered an issue involving a double-patenting defense and how it is affected by a patent term extension and a change in the patent law in the mid-1990's. This case arose from a unique circumstance. Novartis had applied for and received issuance of a patent (5,604,229) which received a [i]17 year patent term after its approval.[/i] Per the Hatch-Waxman Act, Novartis had two patents eligible for "patent term extension" which gives a patent additional patent term (up to five years) to make up for the market time lost for the patent during the FDA review time of the underlying drug product application (as the patents are applied for and granted long before FDA approves the drug). The USPTO granted the patent term extension, and the Delaware District Court found this to be a valid patent term extension, a ruling which disposed of the underlying PIV case. In Delaware and on appeal, the ANDA filer Ezra Ventures argued that the patent term extension was wrongfully granted and was tantamount to double-patenting. Ezra argued that the USPTO granted the Novartis application to a very similar patent (6,004,565) which Novartis had applied for some four years after the first '229 patent. However, as the law changed for patent terms, this second '565 patent was granted a [i]20 year term after its application was filed.[/i] As it turned out, the patent term of the first patent – the one with the patent term extension – lasted until February 18, 2019, nearly a year and a half after the second '565 patent expired. So, Ezra argued, the extension had the effect of "double-patenting" by unfairly extending the life of the first patent, well beyond the patent term of a very similar second patent. The Court of Appeals disagreed. In affirming the Delaware District Court, the Court of Appeals concluded that the Hatch-Waxman Act allowed Novartis to choose which patent it wanted the patent term extension applied to, lawfully did so, and the USPTO granted the extension as the patent met the appropriate criteria. Moreover, the original '229 patent was not otherwise found to be invalid and the '565 patent could not act as a prior reference. As such, the second patent, and the change in the patent law, could not act to terminate or reduce the life of the patent term extension. As such, the '229 patent will expire early next year.

Novartis Pharmaceuticals Corporation v. Torrent Pharmaceuticals 16-1352, April 12, 2017. On April 12, 2017, the Court of Appeals for the Federal Circuit issued its Opinion from a Final Decision of the USPTO Patent and Trial Board. Back in September, the PTAB issued its decision in two consolidated Inter Partes Review proceedings. Both IPR's challenged all of the claims of the 8,324,283 patent. The patent claims primarily cover the combination of fingolimod with a sugar alcohol (mannitol), and the Board made the straightforward conclusion that two prior art sources disclosed this combination rendering it obvious. Moreover, the Board did not believe that amending the claims would render them patentable. The

Court of Appeals affirmed the finding and also rejected some procedural issues Novartis raised on appeal. As a side note, Torrent filed one of the IPR's before the first PIV certification was filed.

Nuvo Pharmaceuticals v. Dr. Reddy's Laboratories 17-2473, May 15, 2019. Th Court of Appeals issued its Opinion in this case involving Vimovo®(esomeprazole and naproxen). The original PIV case in New Jersey involved two patents (6,926,907 and 8,557,285) which covered the formulation for the PPI/NSAID combination. The release challenge of the combination was solved in its formulation which included a coating surrounding the NSAID component and the PPI having portions with and without an enteric coating. While the New Jersey District Court found the claims covering the formulation valid overcoming several defenses, the Court of Appeals disagreed. In considering the "written description" requirement, the Court of Appeals reversed, finding the claims were not adequately described. In short, "written description" requires that the claims be sufficiently described so that a person skilled in the art can understand what the inventor is claiming as the invention and be able to put the invention into practice. Here, the claims were too vague by stating the PPI and NSAID components are to be "in an amount to be effective…." Without more, the Court of Appeals concluded, the claims were insufficient to describe the invention. In essence, the invention was more of a theory or idea than something that could either be put into practice or was so inherent in the wording that the invention could be understood. As such, the Court of Appeals concluded that the claims, and patents, were invalid due to lack of written description.

Orexo AB v. Actavis, 17-1333, September 10, 2018. The Court of Appeals issued its Opinion in this case involving Zubsolv®(buprenorphine and naloxone), reversing the decision of the Delaware District Court. In its original Opinion, the Delaware District Court found one patent (the first-to-expire) 8,454,996 valid and infringed, but for the second patent (8,940,330, expiring in 2032), the Delaware Court concluded that it re-stated already known data, rending it invalid due to obviousness. On appeal, the appellate court considered only the validity of the '330 patent. In reversing the Delaware Court, the Court of Appeals reconsidered the information and found that patent was not obvious. In essence, while it agreed that the data did express the ingredients that led to the claims, none of the data (or prior art) suggested the combination of the two primary components nor did the prior art suggest that the combination of ingredients would achieve an enhanced therapeutic effect. So, it concluded that one skilled in the art would not have been motivated to put the two components together, and hence the patent was not obvious.

Sanofi v. Watson 16-2722, November 9, 2017. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Multaq®(dronedarone) Tablets and its two patents. The Delaware District Court had found that the labels of ANDA filers Watson and Sandoz would induce infringement of the 8,410,167 patent and further ruled that patent valid, overcoming obviousness. It also found infringement of the 8,318,800 patent. In affirming the conclusion of the District Court, the Court of Appeals agreed that the product labels would induce infringement of the claims of the '167 patent (basically covering the method of decreasing hospitalization for certain patient with atrial fibrillation), and that the patent was not obvious as a person skilled in the art would not have had a reasonable expectation that dronedarone would be effective in reducing hospitalizations for the patient population. Moreover, the Court of Appeals agreed with the more expansive construction of the claims of the '800 patent and that the ruling of infringement was appropriate.

Shire v. Watson Laboratories et al 16-1785, February 10, 2017. This particular case arose out of the Florida Southern District Court and its finding that the Watson ANDA infringed two claims of the 6,773,720 patent. In reversing, the Court of Appeals noted that the first claim had "Markush" limitations (that is, the claim listed certain alternative elements as part of the claimed invention.) When analyzing the Watson ANDA, it concluded that its use of magnesium stearate in its formulation matrix was not part of the Markush group. As such, the Court of Appeals concluded that the Watson ANDA does not infringe.

Spectrum v. Sandoz, 15-1407, October 2, 2015. The Court of Appeals for the Federal Circuit issued its Opinion in the case involving Fusilev®(levoleucovorin), the ANDA of Sandoz, and the product's sole Orange Book patent. In the proceedings in Nevada District Court, the Court concluded that two claims of the 6,500,829 patent were invalid as obvious because it was well known since the 1980's that leucovorin existed as a mixture of isomers – one desirable for biologic activity (6S) and the other "undesirable" isomer

(6R) – and that the (6S) isomer could be isolated and purified. The plethora of literature and prior patents rendered the first two claims obvious. In addition, it concluded that the dosage strengths offered by Sandoz could not infringe several claims in the patent and thus also found the Sandoz product to be non-infringing. In its Opinion, the Court of Appeals reviewed the District Court findings and concluded that the conclusions were free of error. As such, it affirmed the findings of invalidity and non-infringement.

Sunovian v. Emcure et al, 17-1798, April 16, 2018. The Court of Appeals for the Federal Circuit issued its Opinion in a case involving Latuda®(lurasidone). The case completely hinged on claims construction. The parties had stipulated to a judgment based on the claims construction in the New Jersey District Court. After the Markman Hearing, Judge Chesler construed certain claim 14 of the 5,532,372 patent in broader terms as covering "lurasidone, lurasidone's enantiomer, as well as mixtures of these enantiomers." From that, the parties stipulated to infringement and patent validity, and the Court of Appeals affirmed. Using the plain language of the claims and prior claims construction cases involving enantiomers, the Court of Appeals concluded that the New Jersey District Court appropriately construed the claims in broader terms and were thus valid and infringed.

Supernus Pharmaceuticals v. TWi Pharmaceuticals 17-2513, September 6, 2018. In affirming the New Jersey District Court decision over Oxtellar XR(r)(oxcarbazepine), the Court of Appeals likewise found three patents valid and infringed by ANDA filer TWi. While the claims of the three patents covered the components of an extended-release formulation (here, a homogenous matrix comprised of oxcarbazepine, a matrix forming polymer, an agent to enhance solubility, and a release-promoting agent), TWi essentially appealed on the District Court's claims construction and interpretation as well as the fact that the District Court relied too heavily on its prior decision over the same patents involving a different ANDA filer. The Court of Appeals rejected these arguments, finding that the prior decision in no way precluded the arguments TWi raised in its case and also agreed with its claims construction. Given the claims, the Court of Appeals made short order of finding the TWi product infringing and also that the claims were valid over the arguments that they were indefinite or lacked a proper written description.

Teva v. Sandoz, 17-1575, October 12, 2018. On October 12, 2018, the Court of Appeals for the Federal Circuit issued two Opinions in companion cases over Copaxone®(glatiramer) 40mg/mL. One appeal stemmed from a trial decision of the Delaware District Court finding claims in four patents obvious while the other appeal came from the USPTO Patent Trial and Appeal Board in an Inter Partes Review proceeding likewise finding claims of three of the patents obvious. On appeal, the Court of Appeals affirmed these findings. The four patents essentially covered the dosing administration of 40mg/mL three times a week which was an improved dosing regimen over its predecessor 20mg/mL product which required daily dosing. Considering the prior art, the Court of Appeals concluded that both tribunals arrived at the correct conclusion that the prior art would have motivated someone skilled in the art to try a less-frequent dosing regimen rendering these "Low Frequency Glatiramer Acetate Therapy" patents invalid as obvious.

Tris Pharma Inc. v. Actavis Laboratories, 17-2557, November 20, 2018. On November 20, 2018, the Court of Appeals for the Federal Circuit issued its Opinion in case involving Quillivant XR®(methylphenidate). In the PIV case, the Delaware District Court had found that the claims of the five patents were invalid as obvious. The Court had concluded that the prior art, history of the product's development, and other extended-release methyphenidate products rendered the formulation claims of the Quillivant XR patents as obvious. In short, Judge Sleet concluded that the combination of the prior art would have motivated a developer to develop an extended-release formulation with the stability and release profile found in the claims. However, the Court of Appeals found the District Court Opinion and rationale lacking. The Court of Appeals sent the case back to Delaware ("remanded") in order for the District Court to find more facts and apply the facts to the obviousness legal analysis. As the Court of Appeals stated, "…the district court's opinion merely recites the parties' arguments but fails to explain or identify which arguments it credits or rejects." (page 12) As such, the Court of Appeals concluded that the record on appeal did not provide enough information for it to rule on the merits of the appellate case.

UCB v. Accord, et al, 16-2610, May 23, 2018. On the Court of Appeals for the Federal Circuit issued its Opinion in this case involving Vimpat®(lacosamide). In the lower court proceeding, the Delaware District Court had concluded that the sole remaining Orange Book patent was valid, overcoming several defenses the 11 ANDA filers had made at trial. In a split 2-1 decision, the Court of Appeals concluded that Judge Stark had properly applied the legal standards to all of the defenses (obviousness, double-patenting, and anticipation) and properly analyzed the legal standard from "exhaustive fact findings." While the patent expires in 2022, there is currently on appeal a decision from the Patent Trial and Appeal Board which likewise found the patent valid.

Vanda Pharmaceuticals v. West-Ward Pharmaceuticals, 16-2701, April 13, 2018. The Court of Appeals for the Federal Circuit issued its Opinion, affirming the decision of the Delaware District Court. In considering the sole patent on appeal (6,586,610) in case involving Fanapt®(iloperidone), the Court of Appeals meticulously agreed with the rationale of the Delaware District Court that the West-Ward ANDA induced infringement and the patent was valid (overcoming a claim that it lacked sufficient written description.) However, one lingering issue regarded patent subject matter. West-Ward argued that the claims – which covered identifying poor metabolizers of genotype CYP2D6 and adjusting dosage accordingly – really covered a natural process and were not the proper subject of an invention. In a 2-1 split, the Court of Appeals disagreed, affirming the Delaware Court on this point as the majority concluded the claims did not cover a natural process, phenomena, or laws of nature as articulated in a legal standard set forth by the Supreme Court.

Warner Chilcott v. Teva, 15-1588, March 18, 2016. The Court of Appeals issued its Opinion, agreeing with the opinion and judgment of the New Jersey District Court. Atelvia(tm)(risedronate) Delayed-release Tablets was designed to negate the food effect of prior osteoporosis products where the calcium in food reduced product bioabsorption by combining risedronate and EDTA. The trial in New Jersey proceeded on single claims in two patents (7,645,459 and 7,645,460) and primarily one prior art source which was a patent application. In considering the prior art, Judge Hochberg concluded that while these claims were not anticipated, they were indeed obvious as the combination of 35mg of risedronate and EDTA was known and expected to mitigate the undesired food effect. As such, the Court invalidated the two claims as obvious, and the Court of Appeals agreed with the New Jersey court's rationale and conclusion.