The Paragraph Four Report®
Court of Appeals Opinions by Case Name
Court of Appeals Cases Numbered 18-XXXX to 20-XXXX

Opinions from the Court of Appeals for the Federal Circuit can be found in several places in ParagraphFour.com. Each Opinion issued for a particular product can be found under the product name, and you can also see how each individual Appellate Judge ruled in their various Opinions under the "Paragraph IV Appellate Judge" Section. In addition, you can find Opinions categorized by Issue. This Section merely categorizes the Opinions by Case Name. All of these sections are redundant which means that you can find Opinions from your perspective: by product, by Judge, by Issue, or by Case Name. So each Opinion can be found in four sections of the database. You do not need to check various sections to make sure you are not missing anything. So, for example, if you recall an Appellate Opinion that Glaxo was involved in but you can't remember the product or judge it involved, you can find it here.

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

<u>Adapt Pharma v. Teva </u> 20-2106, February 10, 2022. The Court of Appeals issued its Opinion in a case involving Narcan®(naloxone) Nasal Spray. In the lower court, the New Jersey District Court had found that claims in all four patents were obvious. The Court concluded that the plethora of prior art and medical practice strongly suggested and taught the creation of a nasal spray formulation to treat opioid overdose which these patents covered. In a 2-1 Opinion, the Court of Appeals concluded that the New Jersey District Court did not commit any clear error in arriving at its finding that the claims in the patents were obvious. However, the majority of the Court of Appeals called this a "close case" but deferred to the fact-finding of the New Jersey District which considered evidence presented in a two week trial. Absent clear error, the majority found no real reason to reverse its decision. Judge Newman offered the dissenting Opinion. Judge Newman noted that the invention embodied in the claims was unique, met an unmet medical need (particularly where many others had failed), and the combination of the formulation was not specifically indicated in the prior art. As such, she concluded that the claims were not obvious.
 Court of Appeals Opinion

<u>Amarin v. Hikma, </u> 20-1723, September 3, 2020. The Nevada District Court had concluded that the ANDAs of Hikma and Dr. Reddy's induced infringement of the six patents disputed in the bench trial. However, considering the prior art, Judge Du found that all of the claims in the patents were obvious. The primary piece of prior art was the PDR citation for Lovaza®(omega-3-acid ethyl esters), the first-to-market "fish oil" product to reduce triglycerides which citation covered many of the limitations of the claims, and when combined with another reference, led to the icosapent composition using only a certain ethyl ester rather than a combination of the ethyl ester with another. Essentially, it was obvious to try this composition that had an expected outcomes for its intended patients. One day after oral argument, the Court of Appeals affirmed this decision without opinion.

<u/>Amgen v. Amneal, </u> 18-2414, January 7, 2020. On January 7, 2020, the Court of Appeals for the Federal Circuit issued its Opinion in the Sensipar®(cinacalcet) case involving the question of whether the excipients used in three ANDA formulations infringed the 9,375,405 patent. The Delaware District Court had found that the Amneal and Piramal formulations did not infringe while the Zydus formulation infringed most of the key claims of the patent. The Court of Appeals started by reconstructing certain claims and concluding that the District Court construed the possible infringing excipients too narrowly. With this new construction, the Court of Appeals concluded that the Amneal formulation likely infringed the patent claims and remanded the case back to Delaware for the Court to sort it out. However, as for Piramal, the Court of Appeals affirmed its non-infringement on the grounds that the prosecution history of the patent by Amgen (modifying several claims) prevented it from asserting infringement under the doctrine of equivalents. This ruling was a pure analysis of competing legal doctrines and thus left Piramal with its

original ruling of non-infringement. Finally, the Court of Appeals turned to the Zydus formulation and affirmed its infringement. Zydus relied on the testimony of an expert which, in agreeing with the Delaware District Court, made inconsistent statements which undermined its argument that its excipient was non-infringing. This ruling does not necessarily end the case as the infringement ruling was separated from the invalidity issues and another appeal is pending.
 Court of Appeals Opinion (18-2414)

<u>Belcher v. Hospira</u> 20-1799, September 1, 2021. The Court of Appeals issued its Opinion in the case involving epinephrine. The original District Court Opinion had been sealed. However, the District Court had concluded that Hospira did not infringe the 9,283,197 patent and that it was also invalid and unenforceable due to inequitable conduct at the USPTO, a rarely seen defense in PIV cases. The appeal centered around the unenforceability issue. The Court of Appeals recounted that the claimed invention (of a pH range) was known to some degree by the Chief Science Officer of Belcher, the primary person prosecuting the patent with the USPTO. The Officer failed to reveal three key pieces of information which indicated that pH range was known and thus obvious and went on to deceive the USPTO by claiming the pH range was a “critical” and “unexpected” innovation. The Court of Appeals affirmed this finding, concluding that the deceptive intent was inferred from the statements and withheld information.
 Court of Appeals Opinion

<u>Biogen v. Banner Life Sciences</u> 20-1373, April 21, 2020. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving the 505(b)(2) NDA of Banner Life Sciences for Tecfidera®(dimethyl fumarate). The Delaware District Court ruled that the Banner Life product did not infringe the 7,619,001 patent. The patent was set to expire on April 1, 2018 but was granted a Patent Term Extension to June 20, 2020. In affirming the Delaware District Court, the Court of Appeals agreed that the 505(b)(2) monomethyl fumarate product did not infringe the patent because the patent term extension only included the dimethyl form.
 Court of Appeals Opinion (20-1373)

<u>Biogen v. Mylan</u> 20-1933, November 30, 2021. The Court of Appeals issued two Opinions involving Tecfidera®(dimethyl fumarate). In the first appeal, the Court considered the decision of the West Virginia District Court which found that the 8,399,514 patent was invalid due to lack of written description. The Court of Appeals, in a 2-1 decision, agreed, finding that the specifications were too vague to allow someone skilled in the art to know the correct dosing for the product. It also agreed with the West Virginia District Court that the inventor were not in possession of a method of administering a therapeutically effective dose before the priority date. In addition to the PIV case, Mylan filed a petition for Inter Partes Review over the same patent claims. In that proceeding, the Patent Board concluded that the claims were patentable, overcoming the argument that these were obvious. This decision led to a second, companion appeal. The Court of Appeals affirmed the finding of patentability though it did not consider the merits of the appeal. The affirming of the invalidity finding essentially rendered the second appeal moot.
<a href="https://paragraphfour.com/wp-content/uploads/2017/07/cafc20-1933.pdf"> Court of Appeals Opinion (20-1933) Court of Appeals Opinion (20-1673) (from IPR)

<u>Boehringer Ingelheim v. Mylan Pharmaceuticals </u> 19-1172, March 16, 2020. the Court of Appeals issued its Opinion in this case involving Tradjenta®(linagliptin) and linagliptin combination products. The case involved three patents. The District Court in New Jersey, after a bench trial, concluded that two of them (8,673,927 and 9,173,859) were invalid as obvious and for double patenting. The Court of Appeals agreed with the District Court in these findings, affirming that the claims which covered the use of linagliptin were essentially the same as earlier patents and were nonetheless obvious given prior art. However, it disagreed with an earlier order of the New Jersey District Court. During the course of the litigation, the Judge Sheridan granted a dismissal of the 8,853,156 patent, finding that the ANDA filers did

not infringe several of the patent claims. Judge Sheridan based his decision on the idea that the claims (which covered administering the drug to certain patient populations) reflected an “abstract idea” or “natural phenomena” and thus not a patentable matter. The Court of Appeals disagreed. It concluded that the claims were indeed directed at patentable subject matter although it acknowledged the fine line between claims that reflect laws of nature and something that is patentable. So, it reversed the New Jersey District Court. However, it sent the case back (“remanded”) to the District Court to consider whether this patent is invalid for other reasons such as obviousness.
 Court of Appeals Opinion

<u>Bristol-Myers Squibb v. Sigmapharm</u> 20-2229, September 3, 2021. The Court simply affirmed the Delaware District Court’s Opinion, its claims construction, and conclusions. Before bench trial, most ANDA filers settled, and three of them (Sigmapharm, Sunshine Lake, and Unichem) completed the trial phase which involved two patents (6,967,208 and 9,326,945) and arguments over infringement and invalidity. The patents covered the chemical structure and its crystalline form of a certain size. All three ANDA filers attempted to manufacture the product so that it would reduce crystal formation and structure to avoid infringing the patents. After analyzing a battery of characteristic testing by experts, the District Court concluded that ANDA filer Sigmapharm infringed the ‘208 patent, finding that its product contains apixaban and its crystalline form. Moreover, the Court concluded that all three ANDA filers (Sigmapharm, Sunshine Lake, and Unichem) infringed the ‘945 patent by finding that all products contain apixaban in its crystalline form in an infringing particle size (smaller than 89 microns). After this conclusion, Judge Stark made quick work of the invalidity arguments, concluding that claims in the ‘208 patent were not invalid for improper dependency, lack of enablement, or lack of written description. The Court likewise found the ‘945 patent valid, rejecting invalidity arguments that claims lacked enablement, written description, or were obvious.
 Court of Appeals Opinion

<u>BTG International v. Amneal et al </u> 19-1147, May 14, 2019. The Court of Appeals issued its Opinion in this case involving Zytiga®(abiraterone) case, affirming both the New Jersey District Court and Patent Trial and Appeal Board in finding the patent obvious. The appeal consolidated three Inter Partes Review decisions as well as a decision from the New Jersey District Court. In all of these proceedings, the Patent Trial and Appeal Board and District Court concluded that the claims of the 8,822,438 patent were obvious. The claims covered the use of abiraterone in combination with an anti-cancer agent or steroid for the treatment of prostate cancer. In consider the prior art, both tribunals found that prior art taught the combination and that a person skilled in the art would have been motivated to combine the products with an expectation of success in treating prostate cancer. As such, the claims were obvious, and the Court of Appeals agreed. After concluding the Board had properly constructed the claims, it quickly concluded that the claims were obvious considering the prior art.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion</doHTML>

<u>Eagle Pharmaceuticals v. Slayback </u>, 19-1924, May 8, 2020. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Belrapzo®(bendamustine). In the lower proceeding, the Delaware District Court applied the “disclosure-dedication doctrine.” In short, the 505(b)(2) filer Slayback had used the solvent ethanol in its formulation which the patents disclosed as a useable solvent but did not claim it as part of the invention. As such, ethanol was publicly disclosed, and Slayback could not infringe the patents under the disclosure-dedication doctrine which also barred patent holder Eagle Pharmaceuticals from arguing infringement under the doctrine of equivalents. The Court of Appeals agreed with the District Court and found no error in the Court’s judgment nor did it find any error in the Court’s ruling on this case in a summary proceeding before a full trial.
 Court of Appeals Opinion

<u>Eli Lilly v. Hospira</u> 18-2126, August 9, 2019. The Court of Appeals for the Federal Circuit issued its Opinion in an appeal stemming from two PIV cases involving Hospira and Dr. Reddy's over Alimta®(pemetrexed). The prior Indiana Southern District court had found that the two ANDA's infringed the 7,772,209 patent under the doctrine of equivalents. The claims of the patent covered administering pemetrexed with folic acid and vitamin B-12 as a method to enhance the pemetrexed. While the two ANDA filer's formulations were technically different, the Court had concluded that the result of the formulations was essentially the same. The Court of Appeals agreed, finding that the two products infringed the '209 patent through the doctrine of equivalents, finding that the differences in the formulations were not significant and that the result was essentially the same as infringing the patent claims.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Eli Lilly v. Apotex</u> 20-1328, December 21, 2020. The Court of Appeals affirmed a finding of infringement in a PIV case involving the 7,772,209 patent. This case marks the fourth time the Court of Appeals has found this patent to be either infringed or valid. This PIV case involved a 505(b)(2) NDA filing from Apotex which product used a different salt form of pemetrexed (dipotassium rather than disodium). Apotex made a technical legal argument concerning the claims Eli Lilly had amended. In short, Eli Lilly had amended the use claims to administering pemetrexed disodium (rather than an antifolate). The Indiana Southern District rejected the argument of Apotex in a summary judgment, concluding that Eli Lilly's amending its claims did not prohibit it from claiming infringement of its product by a product with a different salt form under the doctrine of equivalents and that the Apotex product indeed infringed under that doctrine. The Court of Appeals reviewed the record and history of the patent prosecution and agreed with the District Court, finding that the amendment did not prevent Eli Lilly from raising and prevailing on the doctrine of equivalents argument
 Court of Appeals Opinion (20-1328)

<u>Endo Pharmaceuticals v. Actavis Laboratories</u>, 18-1054, May 3, 2019. On May 3, 2019, the Court of Appeals issued its Opinion in this case involving a later-litigated patent 8,771,779 that covers Opana ER®(oxymorphone). The Delaware District Court had found, among other things, that the patent was not obvious which was considered on appeal. The patent covers the process of preparing highly pure morphinan-6-one compound and it specifications. While there was a combination of prior art that may have suggested this preparation, the Court of Appeals agreed with the District Court that a person skilled in the art would not have a reasonable expectation of success by doing so. However, this was a close decision and was split 2-1 with the dissent arguing that the standard of "expectation of success" as applied was too high and that FDA required the impurity content at a level that make up the claims in the patent.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Galderma v. Amneal </u>, 19-1021, March 25, 2020. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving two sets of patents covering Oracea®(doxycycline). In the Delaware District Court, the Court had found that Amneal infringed both sets of patents under the doctrine of equivalents. In considering the first set of patents which covered the immediate and delayed release elements of the formulation, the Court of Appeals affirmed this finding, concluding that the District Court correctly concluded that the Amneal product infringed these patents. However, the Court of Appeals reversed the District Court over the second set of patents which contained method of use claims, finding

that there was really no direct evidence of infringement. Note that the second set of patents expires before the first set of patents. There is one lingering PIV case involving this ANDA over a later-listed patent which trial is scheduled later this year.
 Court of Appeals Opinion (19-1021)

<u>Galderma v. Teva</u>, 19-2396, January 29, 2019. The Court of Appeals issued its Opinion in this Case involving Soolantra®(ivermectin) Cream. In the lower Delaware District Court, the Court found that three patents were invalid as being anticipated. In short, Judge Andrews found that a prior patent covering the application of ivermectin to reduce inflammatory lesions caused by rosacea anticipated the later three patents which had similar claims including efficacy benchmarks. In reversing, the Court of Appeals concluded that the claims of the one patent were too narrow top anticipate the claims in the later patent. As such, it reversed the District Court. However, the District Court, in ruling on the anticipation defense, did not reach other defenses ANDA filer Teva raised. So, the Court of Appeals remanded the case back to Delaware for the District Court to consider the obviousness and lack of written description defenses.
 Court of Appeals Opinion (19-2396)

<u>Horizon v. Dr. Reddy's et al </u>, 19-1607, January 6, 2021. The Court of Appeals for the Federal Circuit issued an Opinion in a later-filed PIV case involving Vimovo®(naproxen and esomeprazole). This case involved two patents (9,220,698 and 9,393,208). The patents included claims using the word "target" such that the use of certain dosing units targets a certain range pharmacokinetic profile and activity. The New Jersey District Court issued a summary judgment in favor of the ANDA filers, stating that "target" means to "set as a goal" which is indefinite as a specification. The Court of Appeals, finding nothing wrong with this rationale, concluded that "target" is an indefinite term, rendering the claims invalid and affirming the New Jersey District Court.
 Court of Appeals Opinion (19-1607)

<u>Hospira Inc. v. Fresenius Kabi </u>, 19-1329. January 9, 2020. The Court of Appeals for the Federal Circuit issued its Opinion over the validity of Claim 6 of the 8,648,106 patent of Precedex®(dexmedetomidine). The lower court in Illinois Northern District Court had found that the claim, covering the concentration of a ready-to-use premixed formulation of the injectable product to be obvious given the prior art. The Illinois Court had concluded that the prior art noted the loss in concentration of the preparation in the glass container and that the starting concentration of the newly finished product was obvious to meet the concentration limit after five months of storage. The Court of Appeals agreed. It concluded that the record in the Illinois District Court was ample to support the conclusion of obviousness. Note that the Delaware District Court had drawn the opposite conclusion in a prior case which was affirmed by the Court of Appeal for the Federal Circuit. However, these cases relied on different evidence and records in their respective proceedings.

<u>IBSA Institut v. Teva Pharmaceuticals</u> 19-2400, July 31, 2020. The Court of Appeals issued its Opinion in a PIV case involving Tirosint®(levothyroxine) which hinged on the meaning of the term "semiliquid" soft gelatin capsule. When construing the term "semiliquid," the Delaware District Court concluded that the term was vague and indefinite. The Court of Appeals agreed. First, it concluded that the patent nor its context offered any clear definition of what a semiliquid gelatin capsule was comprised of. Second, it noted that the two expert witness for both parties agreed that the term was not a commonly used or known term of art. As such, the claims containing this term were invalid for indefiniteness.

<u>Ino Therapuetics v. Praxair Distribution </u> 18-1019, August 27, 2019. The Court of Appeals issued its Opinion in this case involving 10 patents covering the inhalation product INOmax®(nitric oxide). Five of the patents claimed the process of identifying patients that would be inappropriate for therapy. In the Delaware District Court, Judge Sleet had concluded that these patents simply restated a natural

phenomena and were thus not patentable. The Court of Appeals, in a 2-1 decision, agreed, finding that the claims simply restated that certain patients would be harmed by the treatment due to their physiological condition; hence, the claims restated a natural phenomena which simply selected out these patients. However, the Court of Appeals did note that the Delaware Court erred by applying the "ineligible for patenting" ruling to all of the patents' claims though some were not asserted in the trial. The Court of Appeals remanded to have the clerk reissue a corrected judgment to correct the "clerical error." The Court of Appeals also affirmed the finding that ANDA filer Praxair did not use the same delivery system, thus not infringing the other five patents covering the verification system of the INOmax product.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Nalproprion Pharmaceuticals v. Actavis Laboratories</u>, 18-1221, August 15, 2019. The Court of Appeals issued its Opinion in this case involving Contrave®(naltrexone and bupropion), a product for weight management. The Delaware District Court had concluded that three patents were valid. On appeal, the Court of Appeals concluded that the 8,916,195 was indeed valid. The claims covered the dissolution profile of the product, and the Court of Appeals agreed that the description covered in the claims was adequate. However, it disagreed with the Delaware District Court and reversed the court on the other two patents (7,375,111 and 7,462,626), finding their claims invalid as being obvious. The claims covered the use of the two compounds in weight loss and management. While the Delaware District Court felt the prior art (which disclosed both useful in weight loss) did not render the claims obvious, the Court of Appeals simply took a different point of view finding the prior art and knowledge about the compounds made it an obvious thing to try them in combination. The Court of Appeals finding is a bit academic as the '195 patent expires after the other two patents. There was a dissenting Opinion filed in this case which felt the majority misapplied the law concerning the written description rules and would have found all three patents invalid.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Novartis Pharmaceuticals Corporation v. HEC Pharma </u> 20-1070, January 4, 2022. The Court of Appeals issued its Opinion in a case involving a later-filed patent (9,187,405) over Gilenya®(fingolimod) Capsules. The case originally came before the Delaware District Court. Although Novartis settled with 15 ANDA filers, one filer – HEC Pharma - proceeded to trial. Judge Jordan considered the primary patent claim which is the treatment of multiple sclerosis with 0.5mg of fingolimod daily absent an immediately preceding loading dose and whether HEC Pharma infringed the claims through its label and the defenses of lack of written description and anticipation. Judge Jordan quickly reached the conclusion that the HEC product infringed the patent because its label was identical to the Gilenya label and the patent claims. Moreover, the content of the claim and label created no confusion among practitioners and thus did not lack adequate written description. Finally, the Court concluded the anticipation defense could not prevail: the cited prior art publication did not qualify as prior art due to its known public access date nor, even if it were prior art, did not anticipate the dosage regimen contained in the patent. As such, the Court concluded the patent was valid and infringed. In reviewing this decision, the Court of Appeals – in a 2-1 majority – found no "clear error" in Judge Jordan's analysis and affirmed, finding the patent was valid and infringed.
 Court of Appeals Opinion Court of Appeals Opinion (errata)

<u>Novartis Pharmaceuticals Corporation v. West-Ward Pharmaceuticals </u> 18-1434, May 13, 2019. The Court of Appeals for the Federal Circuit affirmed the decision of the Delaware District Court

Finding of Patent Validity in Afinitor®(everolimus) Case. In Delaware, Judge Andrews concluded that claims 1-3 of the 8,410,131 patent were not obvious. The claims covered the use of everolimus to treat advanced renal cell carcinoma. While the Court of Appeals concluded that Judge Andrews was incorrect in his analysis that the prior art would not have motivated someone to try everolimus in such a manner, the Court of Appeals nonetheless found that the claims were valid in light of further obviousness analysis. The Court agreed with the Delaware District Court that ultimately the prior art would not have given a person skilled in the art any expectation of success for everolimus for the treatment of advanced renal cell carcinoma. As such, the claims are valid.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Par v. Hospira </u> 20-1273, November 23, 2020. The Court of Appeals for the Federal Circuit issued its Opinion in a case involving Adrenalin®(epinephrine). In the Delaware District Court, Judge Bataillon found that the Hospira ANDA literally infringed two patents. The Court of Appeals considered whether the Delaware Court had made a "clear error" in finding infringement. The claims included the term "about" such as the composition comprises "…in the range of about 6 to 8 mg/mL of a tonicity regulating agent…." The District Court concluded that the Hospira product infringed the claim though its tonicity regulating agent was typically found in the amount of 9 mg/mL. The Court found that this was close enough to satisfy the term "about." Moreover, it concluded that the ANDA product's use of citric acid could serve as a claimed "transition metal complexing agent" though typically used as a chelating agent and the amounts fell below the prescribed ranges – the term "about" made the agent close enough. The Court of Appeals agreed, finding no clear error and infringement. Court of Appeals Opinion

<u>Persion Pharmaceuticals v. Alvogen Malta Operations </u>, 18-2361, December 27, 2019. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Zohydro ER®(hydrocodone) ER Capsules. The initial cases at the Delaware District Court involving Alvogen and others settled, but this case involved two later-issued patents (9,265,760 and 9,339,499). The patent claims covered the method of treating patients with mild or moderate hepatic impairment and included differing steps on dosing administration. There were two primary published studies used as prior art. While Judge William Bryson concluded that the Alvogen product label infringed the claims and that the prior art did not anticipate the claimed methods, he concluded that the studies rendered the claims obvious. Moreover, the Court agreed with Alvogen that the written description really did not reveal an invention. In short, the claims were too broad and general in nature, merely observations taken from the prior art studies. Upon consideration of Judge Bryson's opinion, the Court of Appeals found no clear error and agreed with his rationale regarding obviousness. The Court of Appeals did not consider the anticipation ruling.

<u>Sanofi-Aventis v. Mylan Pharmaceuticals </u>, 20-1871, December 29, 2021. The Court of Appeals issued three opinions and one order regarding Lantus®(insulin glargine recombinant). The multiple appeals arise from several proceedings – a PIV case filed against a 505(b)(2) NDA from Mylan and several Petitions for Inter Partes Review Mylan had filed during the course of the PIV litigation. The proceedings involved five patents which focused on the injection device used with this product. Both the USPTO Patent and Trial Board and the New Jersey District Court had concluded that the claims of these patents were obvious and thus either unpatentable and invalid. The Court of Appeals made short work of the Sanofi appeal, concluding that the Board correctly concluded that the claims were unpatentable as obvious. Having drawn these conclusions, the Court of Appeals then considered the appeal from the District Court redundant and thus moot.
 Court of Appeals Order (20-1871) <a

href="https://paragraphfour.com/wp-content/uploads/2014/02/cafc20-2066.pdf"> Court of Appeals Opinion (20-2066)
 Court of Appeals Opinion (20-2071)
 Court of Appeals Opinion (21-1262)

<u>Sebala v. Actavis</u> 18-1036, April 20, 2021. The Court of Appeals issued its Opinion in the Brisdelle®(paroxetine) Capsules case, dismissing the appeal of the brand company Sebela. In the original PIV case in New Jersey, the District Court found that two patents were invalid as obvious. Sebela did not challenge this finding. Instead, it asked the Court of Appeals to affirm this finding but to also order that any alternative rulings (invalidity for lack of written description or utility) would not have a preclusive effect on another patent (9,393,237) which is currently being litigated. In other words, it wanted to ensure that this decision would not prevent it from arguing its '237 patent was valid against the lack of written description or utility in pending litigation. The Court of Appeals dismissed this appeal. Upon closer inspection of the New Jersey District Court Opinion and Judgment, it concluded that the Court mentioned these two defenses (lack of written description and utility) but did not rule that the two patents were invalid because of them. The Court only relied on the obviousness defense in its finding and did not make an "alternative ruling." As such, there was nothing for the Court of the Appeals to undo from the District Court, and Sebela lacked standing to bring the appeal.
 Court of Appeals Opinion (18-1036)

<u>Saint Regus Mohawk Tribe v. Mylan</u> 18-1638, July 20, 2018. The Court of Appeals issued its Opinion from an IPR proceeding involving Restasis®(cyclosporine) Ophthalmic Solution. As mentioned in a couple of Quarterly Notes, after several petitions for Inter Partes Review were filed, Allergan transferred its patent rights to the St. Regis Mohawk Tribe which then asked that the proceeding be terminated on the grounds that the Tribe, as the owner of the patents, enjoyed "sovereign immunity" where a private party such as Mylan could not bring an IPR proceedings against it. In affirming the IPR Board, the Court of Appeals denied the motion to terminate. After considering prior rulings regarding the sovereign immunity of Indian Tribes in certain situations, the Court of Appeals concluded that the IPR proceeding is more like an enforcement action by a federal agency, rather than simply a civil suit from a private party. As such, the Tribe was not immune from an IPR action which can thus proceed.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Sanofi v. Dr. Reddy's </u> 18-1804, August 14, 2019. The Court of Appeals for the Federal Circuit issued an interesting Opinion regarding two patents covering Jevtana®(cabazitaxel). This PIV case ran parallel to an Inter Partes Review proceeding and involved two patents – 5,847,170 (expires in September 2021) and 8,927,592 (expires April 2031). The '170 patent covered the chemical structure of the compound which substituted certain methoxy groups for hydroxyl groups in a similar compound docetaxel. Before the New Jersey District Court issued its ruling, the Patent Trial and Appeal Board concluded several of the claims of the '592 patent were unpatentable. Patent holder Sanofi did not appeal part of this decision, and the New Jersey District Court later concluded that six of these claims were invalid, the same claims Sanofi did not contest in the appeal of the IPR decision. The New Jersey Court also concluded that the '170 patent was not invalid for being obvious. In this appeal, Sanofi argued that the District Court decision over the six patent claims of the '592 patent was improper because there was no "case or controversy" regarding them – the patent holder had accepted the decision of the IPR decision (presumably to amend them at a

later date and get the patent reissued). The Court of Appeals agreed, concluding that the New Jersey should not have ruled that the six claims of the ‘592 patent were invalid and thus vacated this part of the decision. However, it did affirm the finding that the ‘170 patent was valid, overcoming obviousness.
<doHTML>
<img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Sanofi v. Mylan </u> 19-1368, November 19 2019. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Lantus®(insulin glargine) Case. Mylan had challenged two patents (7,476,652 and 7,713,930) which covered the product’s formulation through an Inter Partes Review proceeding at the USPTO. The claims essentially covered the modification of insulin by the use of a surfactant to improve its stability. In finding these claims obvious, the Patent Trial and Appeal Board considered the several pieces of prior art, including the Lantus label, and concluded that they both taught the improved formulation and motivated someone skilled in the art to use the surfactant to increase stability. Moreover, it rejected the Eli Lilly argument that the product’s sales indicated that the formulation was not expected to bring such commercial success because patents blocked the introduction of similar competitors or formulations. As such, the claims are unpatentable as obvious. In a 2-1 decision, the Court of Appeals agreed, finding that there was ample evidence the Board relied on to arrive at the obviousness decision and that it did not a reversible error when considering the secondary considerations of commercial success.
 Court of Appeals Opinion (cafc 19-1368) Court of Appeals (errata) (cafc 19-1368)
<u>UCB v. Actavis et al </u>, 18-1397, June 24, 2019. The Court of Appeals for the Federal Circuit issued its Opinion in this case involving Neupro®(rotigotine). In the lower court decision, the Delaware District Court had concluded that 6,884,434 patent was infringed and valid, overcoming obviousness and anticipation defenses, but then also found that the claims of the non-Orange Book polymorph patent 8,232,414 at issue were invalid due to the fact that the claims covered were put into practice before the priority date (the date of filing for the patent) and even though the claims were otherwise valid. The Court of Appeals dissected all of the claims, legal arguments, and appellate arguments and found that the Delaware District Court drew the correct conclusions. Finding no “clear error,” the Court of Appeals affirmed the findings, upholding the ‘434 patent and its infringement while invalidating the ‘414 patent. The ‘434 patent expires in March 2021.
<doHTML> <img src="html/mime_types/pdf.gif"> Appellate Opinion
</doHTML>

<u>Takeda v. Torrent</u> 20-1552, February 16, 2021. On February 16, 2021, the Court of Appeals for the Federal Circuit issued its Opinion in this case involving several alogliptin products. The New Jersey District Court had concluded that changes made to create the chemical structure of aloglipitin were not obvious – although the changes to prior compounds could be considered minor, there was nothing to motivate someone skilled in the art to synthesize and create alogliptin. The ANDA filers appealed, challenging several of the facts the New Jersey Court had found. The Court of Appeals made quick work of the appeal, concluding that even a few factual disputes or differences would not change the conclusion that a skilled artisan would not have been motivated to tweak the prior art with any expectation of success. As such, the Court of Appeals upheld the 7,807,689 patent as valid. The patent expires in 2028, and the affected brand products are Nesina®(alogliptin) Tablets, Kazano®(alogliptin and metformin) Tablets, and Oseni®(alogliptin and pioglitazone) Tablets.
 Court of Appeals Opinion

<u>UCB Inc. v Actavis et al </u> On April 12, 2023, the Court of Appeals issued its Opinion over the Delaware District Court's decision over the 10,130,589 patent in a case involving Neupro®(rotigotine) Extended-release Transdermal Film. This was the second trip to the Court of Appeals for the parties. This case involved a later-issued patent, and the District Court found this patent to be invalid due to anticipation and obviousness. On appeal, the case centered around the claims of the new patent which covered a range of rotigotine to a stabilizing agent. This range overlapped with the ranges set out in prior patents, and from that, Actavis (and Mylan) established its case for obviousness. At trial, patent holder UCB tried to overcome this finding by demonstrating that the prior patents taught away from the new claims or that the commercial success shows non-obviousness. The Delaware Court disagreed, finding the overlapping claims established obviousness and the contrary evidence was not enough to overcome it. On appeal, the Court of Appeals methodically went through the evidence and arguments and concluded that Delaware Court did not commit any errors in reaching its conclusion of invalidity due to obviousness.
 Court of Appeals Opinion (21-1924)

<u>Valeant v. Mylan</u> 18-2097, April 8, 2020. On April 8, 2020, the Court of Appeals for the Federal Circuit issued its Opinion in this case involving Relistor®(methylnaltrexone). The New Jersey District Court had entered a *summary judgment* in favor of patent holder Valeant. The Court concluded, before a complete trial took place, that claim 8 of the 8,552,025 patent was valid and not obvious. The Court of Appeals disagreed, reversing this decision and remanding it for further consideration. In essence, the claim covered the preparation of methylnaltrexone solution at a certain pH level (which level reduces degradation and thus enhances stability.) The core argument was that the New Jersey District Court rejected ANDA filer Mylan's citation of prior art references as they did not specifically deal with methylnaltrexone. The Court of Appeals disagreed, concluding that the prior art covered compounds that are structurally and functionally similar; thus, the Court reasoned, someone skilled in the art would have known that formulating to a certain pH might yield similar beneficial results. The ruling does not end the case. This ruling states that Mylan established a *prima facie* defense that Valeant can rebut at trial. Moreover, there are other patents in dispute that are in the litigation process.
  Court of Appeals Opinion

<u>Valeant v. Mylan</u> November 5, 2020. The Court of Appeals answered the question regarding venue in a Hatch-Waxman case which involved Jublia®(efinaconazole). The New Jersey District Court dismissed Mylan from a PIV case. The Court of Appeals agreed as to two of the Mylan entities because they were not incorporated nor had a principal place of business in New Jersey. As such, there was improper venue. The Court of Appeals held that for venue purposes, the act of infringement occurs only in districts where actions related to the submission of an ANDA occur, not all locations of the generic drug will end up being distributed. The Court of Appeals held the third foreign entity of Mylan may have been properly sued in New Jersey.