The Paragraph Four Report®
Court of Appeals Opinions by Case Name
Court of Appeals Cases Numbered 07-XXXX to 10-XXXX

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

Abraxis Bioscience v. Navinta LLC, 09-1539, November 9, 2010. The Court of Appeals vacated the judgment of the District Court in New Jersey. While the District Court concluded that the patent covering Naropin®(ropivacaine) was infringed and valid, the Court of Appeals vacated the judgment on entirely different grounds without reaching the substance of the case. The Court of Appeals concluded that Abraxis did not have standing to bring the Complaint. The facts revealed that Abraxis had purchased the product and patent from AstraZeneca. However, there was a break in the chain of title to the patents among the several Astra entities. In short, when the case was filed, Abraxis did not legally own the patents though it finally received title to the patents several months later. As such, the Court of Appeals concluded that Abraxis did not have standing to bring the case in the first place, and that the District Court in New Jersey should dismiss it on remand back to that court.

Adams Respiratory v. Perrigo Company, 10-1246, August 5, 2010. The Court of Appeals for the Federal Circuit vacated and remanded this case back to Michigan for further proceedings. Back in March, the District Court granted summary judgment to Perrigo, concluding that Perrigo's ANDA product did not infringe the 6,372,252 patent. In considering the appeal, the Court of Appeals agreed with Adams Respiratory that the District Court had construed the term "equivalent" improperly. In short, the original construction of the claim had the effect of making Adams prove infringement beyond what the law requires. So, the Court of Appeals reconstructed the claim. In addition, the Court of Appeals noted that Adams provided enough evidence to establish infringement but that the District Court in Michigan will need to reconsider the case with the reconstructed claim.

ALZA vs. ANDRX, 09-1350, April 26, 2010 The Court of Appeals made short order of affirming the finding of the 6,919,373 patent was invalid due to lack of enablement. Claim 1 of the patent described a method of treating ADHD with methylphenidate in a formulation with "an ascending release rate over an extended period of time." While the product Concerta® used an osmotic formulation, the patent specification also mentioned usage in non-osmotic formulation without providing enough information that would enable someone skilled in the art to develop a non-osmotic formulation without undue experimentation.

AstraZeneca vs. Aurobindo, 10-1460, December 14, 2012. On December 14, 2012, the Court of Appeals for the Federal Circuit issued its opinion in the Crestor case. Back in June of 2010, Judge Farnan in the Delaware District Court issued his last opinion in a PIV case before retiring from the bench. He had concluded that the reissued RE37,314 patent was valid (overcoming defenses of obviousness and an

improper reissue), enforceability (overcoming a defense of inequitable conduct), and infringement (only as to Apotex as other defendants stipulated to infringement.) In affirming the decision, the Court of Appeals agreed with the District Court on all points. However, there was a sticking point with the reissue defense, a defense not usually raised in a Paragraph IV case. Two appellate judges concluded that the reissue was proper because the fact that the original patent overlapped with prior art references was a permissible error to correct where there was no showing of a deliberate attempt to deceive the patent office. However, in a dissenting opinion, one judge commented that the error in the original patent should be narrowly interpreted to being an accident or mistake, rather than a patent prosecution strategy which was arguably employed in this case.

AstraZeneca vs. Teva Pharmaceuticals, 08-1480, September 25, 2009. On September 25, 2009, the Court of Appeals for the Federal Circuit affirmed a summary judgment, concluding that there was no inequitable conduct in the patent prosecution for Seroquel. The Court of Appeals concluded that AstraZeneca's statements at issue before the USPTO regarding prior art were not material and there was really little evidence presented that suggested AZ had an intent to deceive the USPTO. The USPTO had asked AZ to present data on the most similar compound which it did. While there may have been other relevant data on other similar compounds, AZ's failure to do present these data did not amount to inequitable conduct. The patent at issue (4,879,288) expires in 2011 with pediatric exclusivity expiring in March 2012.

Bayer Schering v. Barr Laboratories, 08-1282, August 5, 2009. Court of Appeals affirms finding of patent invalidity due to obviousness in Yasmin(r)(drospirenone) case. The compound was poorly water soluble and did not hold up well in acid. The patent in question used a micronization which would have been obvious to try as a formulator would. However, the enteric coating, which was also an obvious formulation to try, did nothing better than a normal pill which led to the invention. The Court of Appeals concluded that both of these formulations would have been obvious to try thus leaving the patent invalid.

Boehringer Ingelheim v. Barr and Mylan, 09-1032, January 25, 2010. On January 25, 2010, the Court of Appeals reversed and remanded this case back to Delaware. After a bench trial, the District Court had concluded that the 4,886,812 patent was invalid due to obviousness-type double patenting. In so doing, the District Court did not allow Boehringer Ingelheim's Section 121 "safe harbor" defense. In short, during the application process, BI submitted two additional divisional patent applications, springing from the original patent application. The three applications led to two patents, the second of which was the '812 and was held invalid due to obviousness. In reversing, the Court of Appeals concluded that the safe harbor defense was applicable to this situation as it was designed to prevent the rejection of a subsequent divisional application (when the PTO requires restriction or division of the first application as it did here) based upon the first application. As such, it reversed and sent the case back to Delaware for additional consideration.

In re brimonidine Litigation, 10-1102, May 19, 2011. On May 19, 2011 the Court of Appeals for the Federal Circuit issued a mixed opinion in this case including a concurring/dissenting opinion by one of the judges. The Delaware District Court had concluded that all of the five patents involved in this case were valid. One ANDA applicant Apotex had stipulated to infringement while the other applicant Exela did not. The product was a follow on product that included the use of a solubility enhancer and a preservative which improved the new product as it had a lower dosage strength but higher pH level which made it more patient friendly. On appeal, Apotex argued that the patents were indeed invalid due to obviousness. The Court of Appeals agreed with Apotex in part, reversing the decision on the primary patent (5,424,078) and finding it invalid as one skilled in the art would have created a similar solution. While Apotex argued that the additional related patents were merely a combination of ideas involving the first Alphagen product and another Allergan product Refresh Tears®, the Court disagreed, concluding that the use of the preservative and solubility enhancer was not obvious, so it affirmed the finding of validity for those patents. As for

Exela, the Court of Appeals reversed the district court's finding of infringement of the 6,641,834 patent. The patent covers formulations of over 7.0pH, and the Exela application called for its product to be about 6.7pH. The district court had concluded that Exela would likely manufacture a product with a pH higher than 7.0. In reversing, the Court of Appeals concluded that the ANDA called for a product of 6.7pH which would have to be assumed for legal analysis and thus found the Exela formulation to be non-infringing.

Cancer Research Technologies v. Barr Laboratories, 10-1204, November 9, 2010. The Court of Appeals reversed the District Court's finding that the patent for Temodar®(temozolomide) was unenforceable. The Delaware District Court had concluded that the 5,260,291 patent was unenforceable due to prosecution laches (a failure to actively move its patent application through the USPTO process) and inequitable conduct on the grounds of intentionally withholding material information from the USPTO. In reversing, the Court of Appeals noted that while the patent prosecution took a long time, there was no evidence showing that anyone was adversely affected (or prejudiced) during the prosecution of the patent nor did Cancer Research benefit. As such, there was no prosecution laches. Also, the Court of Appeals simply disagreed that there was no intent to deceive the USPTO when the inventor did not disclose certain data from the USPTO and thus there was no inequitable conduct.

Daiichi Sankyo v. Mylan, 09-1511, September 9, 2010. The Court of Appeals for the Federal Circuit affirmed the validity of the 5,616,599 patent. In doing so, it agreed with the District Court in New Jersey that the patent was not invalid due to obviousness. The ANDA filer Mylan (Matrix) had argued that the patent covering the chemical compound was obvious, considering that it was chosen as a lead compound and modified from the DuPont patent disclosing losartan. The Court of Appeals disagreed, concluding that it would not been obvious to one skilled in the art to create a compound from a first generation ARB such as the ones mentioned in the losartan patent and that there had been some unexpected results from the structural modifications. This decision affects three olmesartan products: Benicar®, Benicar HCT®, and Azor®.

Duramed Pharma v. Paddock Labs, 10-1419, July 21, 2011. The Court of Appeals for the Federal Circuit affirmed the finding of non-infringement. The District Court in New York had granted summary judgment to Paddock over the 5,908,638 patent. In his Opinion, Judge Sand concluded that the Paddock ANDA did not infringe the sole patent in dispute on the grounds of prosecution history estoppel. The Court of Appeals agreed, noting that the USPTO issued the Duramed patent on the condition that the claim involving the formulation's moisture barrier coating be limited to a coating "comprising ethylcellulose." The Paddock formulation did not use ethylcellulose, and Duramed proceeded on a doctrine of equivalents claim for infringement. However, both courts agreed that the Paddock formulation was non-infringing on the grounds of prosecution history estoppel. Because the USPTO required Duramed to narrow its claim to include ethylcellulose, it was restricted to that particular formulation and the equivalents doctrine could not be applied.

Duramed Pharma v. Watson Labs, 10-1331, March 25, 2011. The Court of Appeals for the Federal Circuit reversed and remanded a case back to the Nevada District Court over Seasonique®(levonorgestrel and ethinyl estradiol) Tablets. The Nevada Court had granted Duramed summary judgment, finding that Watson did not establish that the 7,320,969 patent was invalid for obviousness. (Basically, the patent covered a contraceptive dosing regimen.) In reversing, the Court of Appeals concluded that the Nevada Court should have looked at the several prior art references Watson cited (articles and a patent) as a whole, rather than in isolation. In so deciding, the Court of Appeals also gave an opinion that Watson had likely established that the patent was invalid for obviousness and that Duramed would likely need to rebut this back in Nevada.

Eisai v. Dr. Reddy's Laboratory and Teva, 07-1397, July 21, 2008. On July 21, 2008, the Court of Appeals for the Federal Circuit affirmed the district court's ruling that found the 5,045,552 patent infringed, valid, and enforceable. Both Teva and Dr. Reddy's had stipulated to infringement; however, they had raised the argument that the patent was invalid due to obviousness and

unenforceable due to inequitable conduct. In agreeing with the district court, the Court of Appeals concluded that the prior art established by previous proton pump inhibitors omeprazole and lansoprazole did not render the '552 patent obvious as the chemical structures were a bit dissimilar and it was also unclear as to which patent would be considered the lead compound. The ANDA filers also did not provide enough evidence to establish that Eisai's interactions with the Patent and Trademark Office were sufficient to merit a defense of inequitable conduct.

Eli Lilly v. Actavis, et al, 10-1500, July 29, 2011. On July 29, 2011, the Court of Appeals for the Federal Circuit ruled in favor of Eli Lilly over the sole Strattera patent. Previously, the District Court in New Jersey concluded that the 5,658,590 patent which disclosed the use of the product for ADHD was valid on obviousness and enablement grounds. However, it concluded that the patent was invalid for lack of utility. While the Court of Appeals affirmed the validity findings of the New Jersey District Court, it reversed the ruling that the patent was invalid due to lack of utility. The Court of Appeals reasoned that while no studies had proven the product useful for ADHD, there was no reason for one skilled in the art to question the objective truth about the use of the product for ADHD. As such, the Court of Appeals concluded that the patent is indeed valid and infringed.

Eli Lilly v. Sun Pharmaceuticals, 10-1105, July 28, 2010. The Court of Appeals for the Federal Circuit issued its opinion, concluding that the 5,464,826 patent was invalid due to obviousness-type double patenting. The Appellate Court agreed with the District Court in Michigan that the prior patent (4,808,614) disclosed both gemcitabine and its use for the treatment of cancer and that the later '826 patent restated the use of the product for cancer. As the Court summarized, "In light of the earlier '614 patent's description of gemcitabine's use in treating cancer, the asserted claims of the later '826 patent, which recite a method of using gemcitabine to treat cancer, are not patentably distinct from the '614 patent's claim to gemcitabine. The asserted claims of the later '826 patent simply claim the anticancer use disclosed in the specification of the '614 patent as a method of use claim." (page 15).

Eli Lilly v. Teva Pharmaceuticals, 10-1005, September 1, 2010. The Court of Appeals affirmed a bench trial decision regarding six patents covering Evista. The Court agreed with the Indiana District Court that four of the six patents in the dispute which the Court labeled the Bone Loss Patents and the Low Dose Patent were valid and that Teva was unable to establish that these patents were invalid due to obviousness. In short, the Court of Appeals concluded that one skilled in the art would not refer to prior art and conclude that raloxifine could be used to treat postmenopausal osteoporosis. However, the Court also agreed with the District Court in invalidating two patents which the Court labeled as the Particle Size Patents. Noting that the patents were insufficient in describing how to achieve a certain particle size, the Court concluded that these two patents were invalid for lack of written description under the requirement of Section 112.

Forest Laboratories vs. IVAX, 07-1059, September 5, 2007. Court of Appeals affirmed a ruling of patent validity for the RE34,712 patent that covers Lexapro®(escitalopram). The Court of Appeals did not believe that the Court in Delaware made any errors in concluding that the patent was valid. The prior publication cited in the defense did not render the patent obvious or anticipated. In addition, the reissue patent did not broaden its scope. However, the court did narrow the district court's injunction to include only those products covered by the ANDA and not "any product."

Janssen vs. Apotex, 08-1062, September 4, 2008. The Court of Appeals for the Federal Circuit affirmed the dismissal of Apotex's Declaratory Action. In short, Teva was first to file on this product which has three patents listed in the Orange Book. The compound patent (4,804,663) was upheld as infringed, valid, and enforceable in the tablet case, meaning that Teva could gain approval and launch before the expiration of the other two patents set to expire in a few years. Jannsen did not bring any litigation to defend those two patents. Along the course of events,

Apotex had filed an ANDA and had stipulated to infringing the '663 patent, and Janssen had agreed not to sue Apotex on the other two patents. Apotex filed a declaratory action to see if it could get a judgment on the other two patents. The District Court in New Jersey dismissed this action, and the Court of Appeals, considering these facts, agreed that there was no "case or controversy" creating jurisdiction to hear the case. The idea here is that regardless of outcome, Teva would still be entitled to first to file exclusivity and a case declaring these patents invalid would not change that outcome or harm Apotex.

Janssen vs. Teva Pharmaceuticals, 08-1594, September 25, 2009. On September 25, 2009, the Court of Appeals for the Federal Circuit affirmed the Delaware District Court's finding of patent invalidity due to lack of enablement in the reminyl®(galantamine) case. In short, a specification in a patent must provide enough information so that one skilled in the relevant art can either make (or carry out in the case of a process) the invention without "undue experimentation." Along with enablement, the invention must also show utility – that it is useful for some purpose. Here, the Court of Appeals agreed with the District Court that the specification in the 4,663,318 patent merely stated a theoretical benefit and thus was invalid due to lack of enablement as it failed to show utility. As the specification stated, "Drugs that can normalize these abnormalities would have a reasonable expectation of efficacy in Alzheimer's disease."

King Pharmaceuticals vs. Eon Labs, 09-01437, August 2, 2010. The Court of Appeals affirmed a grant of summary judgment of invalidity of two patents for Skelaxin®(metaxalone). In so deciding, the Court agreed with the District Court of New York Eastern that the claims of the 6,407,128 and 6,683,102 were either anticipated or obvious given the prior art. In short, the claims involved the taking of metaxalone with food which had been disclosed in prior articles. However, the Court of Appeals vacated the judgment against Elan Pharmaceuticals. Elan had sold the product and patent rights to King, and the Court of Appeals concluded that the district court did not have jurisdiction over it.

Merck vs. Apotex, 08-133, August 21, 2008. Court of Appeals affirmed a judgment of dismissal. Related to the case immediately below, after the Court concluded the 4,797,413 valid and infringed, Apotex tried to bring the two other patents ('443 and '735) into the controversy after Merck had disclaimed them. At this point, Hi-Tech had the 180 day exclusivity, and Apotex felt that if it could get a judgment on the '443 and '735 patents, then that may trigger the Hi-Tech exclusivity forfeiture if Hi-Tech did not market within 75 days after the judgment. Basically, as the '413 patent expires in October 2008, the Court of Appeals felt this was moot as there would not be enough time to get a judgment at the district court and dismissed the case

Mitsubishi Chemical Co v. Barr Laboratories, 10-1432, August 2, 2011. The Court of Appeals for the Federal Circuit issued its opinion, affirming the judgment of the New York Southern District Court. In so doing, it concluded that the 5,214,052 patent covering Argatroban®(argatroban) Injection was infringed and valid. The patent included methods of dissolving argatroban by adding a saccharide and ethanol. Barr had argued that the claims were anticipated by a prior scientific article and also rendered obvious by other prior art references. In rejecting these arguments, the Court of Appeals accepted the translation of the Japanese article that the District Court had used and noted that the article, or the other prior art references, did not anticipate the dissolution method covered by the Mitsubishi patent or render it obvious to one skilled in the art.

Ortho-McNeil vs. Lupin Ltd, 09-1362, May 10, 2010. The Court of Appeals affirmed the ruling of summary judgment for Ortho-MCNeil, preserving the patent term extension for patent 5,053,407. In affirming the extension, the Court noted that Levaquin®(levofloxacin) was a "drug

product" and was entitled to patent term extension by statute. The Court noted that though the product was an enantiomer of ofloxacin, it was still a "drug product" under the statute.

Pfizer vs. Teva, 07-1271, March 7, 2008. This is an appeal from a trial bench ruling that three patents '823, '165, and '068 were infringed, valid, and enforceable. The Court of Appeals disagreed with one of the patents and concluded that the '068 patent was invalid due to obviousness double type patenting. Using the '165 patent as prior art, the Court concluded that the claims in the two patents were not patentably distinct. However, the Court of Appeals did agree that the other two patents were valid. In so doing, it agreed that the "best mode" requirement was met. The idea of the "best mode" is that the invention must reflect the best mode of achieving the purpose of the invention. As the Court put it, "The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention. The test for compliance with best mode is comprised of two steps: first, whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention; and second, whether the inventor's disclosure was adequate to enable one of ordinary skill in the art to practice the best mode of the invention." (page 18) The Court agreed with Pfizer that the inventions reflected the best mode as the preference Pfizer had towards COX-2 inhibition was disclosed, not concealed, and did not affect the claims of the patents.

Procter & Gamble vs. Teva, 08-1404, May 13, 2009. The Court of Appeals affirmed a finding of patent validity over Actonel(r)(risedronate). Teva had argued that the patent was invalid due to obviousness from a prior patent. The prior patent identified several polyphosphonate molecules that could be used in the treatment of osteoporosis. Teva had argued that one of the molecules listed in that patent had structural similarities to risedronate, the subject of the second patent that was in dispute, which would render the patent invalid. The Court of Appeals agreed with the trial court that the prior patent would not motivated someone trained in the art to modify the molecular structure to create risedronate. In fact, the potency and toxicity profile was an unexpected result, rebutting the defenses of obviousness.

Purdue Pharma v Par Pharmaceuticals, 09-1553, June 4, 2010. The Court of Appeals affirmed a finding of patent invalidity due to obviousness in the Ultram ER®(tramadol) case. The Court of Appeals agreed that the 6,254,887 and 7,074,430 patents were obvious in light of the prior art. However, the Court also agreed with the district court that there was no intent to deceive the Patent and Trademark Office leaving the conclusion that the patents were not unenforceable due to inequitable conduct.

Sanofi-Aventis v Apotex, 07-1438, December 12, 2008. Court of Appeals affirmed the District Court's ruling that the 4,847,265 patent was valid. Apotex raised issues of obviousness and anticipation. While it is reasonably well known that separating an enantiomer creates isomers that can have different biological properties, there were no facts in this case that would support the claim that it would have been obvious to do so in order to create a beneficial biologically active isomer.

Sanofi-Aventis v. Sandoz, 09-1427, September 10, 2009. On September 10, 2009, the Court of Appeals issued its opinion in this case involving Eloxatin®(oxaliplatin). The District Court in New Jersey had granted summary judgment when it construed the generic products did not infringe the 5,338,874 patent as the relevant Claim 1 was a "product by process" claim limiting the patent to oxaliplatin resolved by means of high performance liquid chromatography. As such, the defendants did not infringe as their manufacturing process was different. However, the Court of Appeals concluded that absent language restricting the claim, such a claim needs to be read more broadly. The Court of Appeals concluded that "Claim 1 of the '874 patent is not limited to

optically pure oxaliplatin produced by HPLC; this is a composition claim, not a product-by-process claim."

Santarus v. Par, 10-1360, September 4, 2012. On September 4, 2012, the Court of Appeals issued its Opinion in this Case which covered both the capsule and powder formulations of Zegerid®(omeprazole and sodium bicarbonate). The case involved several patents covering the use of the omeprazole with a buffering agent instead of being enteric coated. Several patents stemmed from the first. The Court of Appeals affirmed the finding of no inequitable conduct. However, it reversed the finding that the 7,399,772 patent was invalid for lack of written description which in turn affected a priority date between patents. After further consideration of the obviousness defenses, the Court of Appeals affirmed the finding that many of the claims of many of the patents were invalid. However, it reversed a finding of invalidity of the same '772 patent. The import of this is that all of the patents have the same expiration date being in July 2016.

Schwarz v. Paddock Laboratories, 07-1074, October 12, 2007. Court of Appeals affirmed a summary judgment of non infringement of Univasc®(moexipril). The Appellate Court agreed that the during the original patent prosecution, the patent was amended (after an obvious objection) to narrow the claims from "metal containing stabilizer" and "alkaline earth metal salt" to a more narrow term of "an alkali or alkaline earth metal carbonate." Though the Paddock product used an alkali equivalent, Schwarz was barred from arguing infringement by the doctrine of equivalents under the theory of "amendment based prosecution history estoppel" because it had amended its application and now cannot argue that a broader equivalent is infringing.

Syntex v. Apotex (Acular LS), 08-1021, July 9, 2008. In the second go-around at the Court of Appeals, the Court affirmed the summary judgment ruling in favor of Syntex (Roche Palo Alto). In doing so, it agreed that the Apotex ANDA for Acular LS and for Acular were essentially the same and that the 5,110,493 patent was valid and infringed. Apotex had attempted to show non-infringement under the "reverse doctrine of equivalents" by showing that the principle of the invention was sufficiently different than the '493 patent though it literally infringed the patent. The Court of Appeals agreed that Apotex failed to show that the principle of its formulation and ANDA was different and thus could not get past its infringement under the reverse doctrine of equivalents. In addition, its other defenses were precluded under the doctrine of claim preclusion as many of the issues involving the '493 patent had been litigated before under the other Apotex ANDA.

Teva Pharmaceuticals v. Eisai Inc, 09-1593, October 6, 2010. This case stems from a declaratory action filed by Teva on Aricept®(donepezil). Ranbaxy was first to file but did not certify against the molecule patent. Eisai did not file suit. Teva did certify against the molecule patent, and Eisai filed a PIV case against Teva. Teva subsequently filed a declaratory action on the remaining four Orange Book patents that were not placed at issue in the PIV case between them. The District Court in New Jersey dismissed the case for lack of controversy over the remaining four Orange Book patents that were not part of a PIV case Eisai filed against Teva.. The Court of Appeals reversed, holding that Teva, as a second PIV filer, had an injury in fact creating an Article III controversy as if it were to prevail in the declaratory action, it would act as a trigger event to Ranbaxy's exclusivity.

Tyco Healthcare v. Mutual Pharmaceutical Company, 10-1513, June 22, 2011.
The Court of Appeals for the Federal Circuit issued its opinion, affirming a summary. The District Court in New Jersey had granted summary judgment to Mutual because it concluded that the patent was invalid due to obviousness. The patent covered a lower dose of the product (7.5mg), but the British National Formulary had recommended the usage of the product for treatment of insomnia in elderly patients in a low dose (5-15mg) several years before the patent

application. The Court of Appeals agreed that this recommendation rendered the patent obvious to someone skilled in the art, noting that such a prior art reference created a presumption of obviousness which Tyco could not overcome.

Unigene Laboratories v. Apotex Inc, 10-1006, August 25, 2011. On August 25, 2011, the Court of Appeals for the Federal Circuit issued its Opinion in the Fortical®(salmon-calcitonin) Nasal Spray Case and affirmed summary judgment in favor of Unigene. In the District Court of New York Southern, the Court granted summary judgment, finding that the patent at issue (RE40,812E) which covered the nasal spray formulation was not obvious in light of the prior art patent which covered the oral solid formulation. Salmon calcitonin is polypeptide which is unstable and poorly absorbed. Because of these technical issues, the nasal spray formulation was sufficiently different than the oral solid formulation, and the prior art patent would not render the nasal spray formulation obvious to anyone skilled in the art.