

United States Court of Appeals for the Federal Circuit

02-1516

MCNEIL-PPC, INC.,

Plaintiff-Appellant,

v.

L. PERRIGO COMPANY and PERRIGO COMPANY,

Defendants-Appellees.

Harry J. Roper, Roper & Quigg, of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were Raymond N. Nimrod and Steven R. Trybus.

James A. Mitchell, Price, Heneveld, Cooper, DeWitt & Litton, of Grand Rapids, Michigan, argued for defendants-appellees. With him on the brief were Steven L. Underwood and Richena Y. Brown.

Appealed from: United States District Court for the Eastern District of Pennsylvania

Judge Berle M. Schiller

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DECIDED: August 1, 2003

Before MICHEL, Circuit Judge, ARCHER, Senior Circuit Judge, and LOURIE, Circuit Judge.
LOURIE, Circuit Judge.

McNeil-PPC, Inc. (“McNeil”) appeals from the decision of the United States District Court for the Eastern District of Pennsylvania holding certain claims of four of McNeil’s patents invalid and awarding attorney fees to L. Perrigo Company and Perrigo Company (collectively “Perrigo”). McNeil-PPC, Inc. v. L. Perrigo Co., 207 F. Supp. 2d 356 (E.D. Pa. 2002). Because the district court correctly determined that the asserted claims of McNeil’s patents are invalid, but clearly erred in finding this to be an exceptional case within the meaning of 35 U.S.C. § 285 and awarding attorney fees to Perrigo, we affirm-in-part and reverse-in-part.

BACKGROUND

In the late 1980s, facing the then-imminent January 30, 1990 expiration of U.S. Patent 3,714,159 covering the best-selling antidiarrheal product Imodium[®] A-D, McNeil sought patentable improvements that would allow it to extend its position as market leader. Id. at 358-60. Dr. Jeffrey Garwin, McNeil's assistant director of clinical research for gastrointestinal products, proposed at the time to pair loperamide, the active antidiarrheal ingredient in Imodium[®] A-D, with the antigas drug simethicone, in order to treat both diarrhea and the flatulence that often accompanies it. Id. at 359-60. Following Garwin's proposal, McNeil scientists evaluated a combination containing 2 mg loperamide and 125 mg simethicone, and allegedly found that the combination produced a synergistic effect. McNeil was granted two patents relating to that research: U.S. Patent 5,248,505, entitled "Method for Treating Gastrointestinal Distress," claiming methods of using compositions containing combinations of antidiarrheal compounds and simethicone to treat "a human suffering from an intestinal disorder"; and U.S. Patent 5,612,054, entitled "Pharmaceutical Compositions for Treating Gastrointestinal Distress," claiming the antidiarrheal/simethicone compositions themselves. Collectively, the two patents are referred to as "the Garwin patents." Id. at 360.

Further research with chewable tablets containing a combination of loperamide and simethicone led to the discovery that the simethicone in those tablets apparently "surrounded" the loperamide over time, decreasing its bioavailability, and thereby reducing the tablets' shelf-life. Id. at 359, 366. McNeil researchers Charles Stevens, Michael Hoy, and Edward Roche then found that the decrease in bioavailability could be avoided by using a polymeric barrier to separate the simethicone from the loperamide. Id. at 367-68. Subsequently, McNeil obtained U.S. Patents 5,716,641 and 5,679,376 (both entitled "Simethicone Containing Pharmaceutical Compositions," and collectively referred to as "the Stevens patents"), covering that method and the resulting tablets, respectively. Id. at 366-67.

McNeil has sold loperamide/simethicone combination tablets having the impermeable barrier of the '376 and '641 patents as Imodium[®] Advanced since 1997, pursuant to an approved New Drug Application (“NDA”).

Perrigo filed an Abbreviated New Drug Application (“ANDA”) at the United States Food and Drug Administration (“FDA”) in 2000 under 21 U.S.C. § 355(j), seeking approval to market a generic version of Imodium[®] Advanced. Id. at 359. Along with the bioavailability/bioequivalency test data that it was required to include in its ANDA, Perrigo filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (i.e., a “paragraph IV certification”), declaring that the Garwin patents are invalid; that the Stevens patents are invalid; and that Perrigo’s proposed manufacture, use, and sale of its loperamide/simethicone combination product would not infringe the Stevens patents. As required under 21 U.S.C. § 355(j)(2)(B), Perrigo also gave notice of its ANDA filing to McNeil as the patent owner and NDA holder, providing a detailed statement of the factual and legal bases for Perrigo’s opinion that the Garwin and Stevens patents are invalid and that the Stevens patents would not be infringed if its product were to be approved for marketing. Id.

On March 7, 2001, McNeil filed suit against Perrigo under 35 U.S.C. § 271(e)(2)(A), alleging that Perrigo’s submission of its ANDA was an act of infringement of numerous claims of the Garwin and Stevens patents. Id. McNeil later amended its complaint twice, ultimately asserting infringement of only claims 14 and 16 of the '505 patent, claim 15 of the '054 patent, claims 1 and 2 of the '376 patent, and claims 1-3 of the '641 patent under § 271(e)(2)(A). Id. The asserted claims of the '505 patent read as follows:

14. [A method for treating a human suffering from an intestinal disorder characterized by the symptoms of diarrhea and flatulence or gas comprising administering to said human in a combined pharmaceutical composition, an effective amount of an antidiarrheal compound selected from the group consisting of loperamide, bismuth subsalicylate, diphenoxylate, polycarbophil, their pharmaceutically acceptable salts and mixtures thereof; and an

antiflatulent effective amount of simethicone,] wherein the amount of simethicone administered is 125 mg per dosage unit and the amount of loperamide administered is 2 mg per dosage unit.¹

16. A method for treating a human suffering from an intestinal disorder characterized by diarrhea and flatulence and or gas comprising administering to said human in a combined pharmaceutical composition, 4 mg of loperamide and an antiflatulent effective amount of simethicone; thereafter administering to said human in a combined pharmaceutical composition, 2 mg of loperamide and an antiflatulent effective amount of simethicone until the diarrhea is controlled.

The asserted claim of the '054 patent reads as follows:

15. [A composition for treating a human suffering from an intestinal disorder characterized by the symptoms of diarrhea and flatulence or gas comprising: an effective amount of an antidiarrheal compound selected from the group consisting of loperamide, bismuth subsalicylate, diphenoxylate, polycarbophil, their pharmaceutically acceptable salts and mixtures thereof; and an antiflatulent effective amount of simethicone,] comprising 125 mg of simethicone and 2 mg of loperamide.²

The asserted claims of the '641 patent read as follows:

1. A method of enhancing the dissolution profile of a pharmaceutical from a solid dosage form comprising the pharmaceutical and simethicone, comprising: providing the pharmaceutical in a first portion of said dosage form, said pharmaceutical is selected from the group consisting of diphenoxylate, loperamide and loperamide-N-oxide, pharmaceutically acceptable salts thereof, and combinations thereof; providing the simethicone in a second portion of said dosage form; and separating said first and second portions with a pharmaceutically acceptable polymeric barrier which is impermeable to simethicone and the pharmaceutical.

2. The method of claim 1 wherein the pharmaceutical is selected from the group consisting of loperamide, loperamide-N-oxide, pharmaceutically acceptable salts thereof and combinations thereof.

3. The method of claim 1 wherein the pharmaceutical comprises loperamide HCl.

The asserted claims of the '376 patent read as follows:

1. A solid oral dosage form for the treatment of gastrointestinal distress comprising a therapeutically effective amount of a pharmaceutical for the

¹ Claim 14 of the '505 patent depends from claim 2, which in turn depends from claim 1, and the relevant portions of those independent claims are shown in brackets above.

² Claim 15 of the '054 patent depends from claim 2, which in turn depends from claim 1; the relevant portions of those independent claims are shown in brackets above.

treatment of gastric disorders selected from the group consisting of diphenoxylate, loperamide, loperamide-N-oxide, pharmaceutically acceptable salts thereof, and combinations thereof; and a therapeutically effective amount of simethicone wherein the oral dosage form has a first portion containing the pharmaceutical and a second portion containing simethicone and the first and second portions are separated by a pharmaceutically acceptable polymeric barrier, which is impermeable to simethicone and the pharmaceutical.

2. The solid oral dosage form of claim 1 wherein the pharmaceutical comprises loperamide HCl.

Following a bench trial, the district court concluded that the asserted claims of the Garwin patents were obvious over three prior art references: an Australian pharmaceutical reference publication entitled "Mims Annual 1980, Section 1e Antidiarrheals," which discloses a product called Diareze that combines the antidiarrheal compound attapulgite with simethicone "to help relieve the pain and discomfort of gaseous distention"; French Patent Application 2,565,107, which discloses the use of simethicone and activated charcoal, also a known antidiarrheal; and U.S. Patent 4,980,175 (the "Chavkin patent"), which discloses combinations of various substances, including the antidiarrheal polycarbophil and simethicone. Id. at 362. The court found that one of skill in the art at the time of the inventions would have known that flatulence commonly accompanies diarrhea, and concluded that it would have been obvious to replace attapulgite, activated charcoal, or polycarbophil in the prior art references with loperamide, which was, after all, the active ingredient in the best-selling antidiarrheal drug, to treat both diarrhea and gas. Id. at 364. The court discounted the value of McNeil's objective evidence, including evidence of unexpected results, commercial success, and copying by others, and held the asserted claims invalid. Id. at 371-72.

The district court then concluded that the product for which Perrigo was seeking FDA approval would not infringe the Stevens patents, because that product directly juxtaposes loperamide and simethicone layers without any impermeable polymeric barrier between them. Id. at 367-68, 372-73. The court held that the asserted claims of the Stevens patents

were, in any event, also invalid for obviousness over the Garwin patent applications, which taught making tablets having separate loperamide and simethicone layers, in view of the prior art U.S. Patent 4,198,390 (the “Rider patent”), which taught the use of an impermeable polymeric barrier to prevent migration and deactivation of simethicone in simethicone-containing antacid tablets. Id. at 368-69, 373.

Finally, the district court awarded attorney fees to Perrigo, stating that McNeil’s conduct during prosecution of the patents in suit was “careless, irresponsible, and, at the very least, tantamount to studied and deceptive ignorance.” Id. at 374. According to the court, “McNeil’s repeated erroneous representations, failure to disclose relevant prior art, and overall persistence in prosecuting exceedingly obvious ‘inventions’ make this case exceptional.” Id. The court accused McNeil of having engaged in “a scheme for extending the life of a drug about to go off patent . . . without the slightest regard for the intent and purposes of the patent laws,” and found that “McNeil’s sole motive was to compromise [those] statutes and constitutional protections for the sake of profits.” Id.

The district court concluded its opinion with a discussion of the constitutional basis for the patent system and what it perceived to be a deviation from the original purposes of that system by business-driven decisions. According to the court:

The patent laws “promote the Progress of Science and useful Arts” by rewarding innovation with a temporary right to exclusivity. U.S. Const., art. I, § 8, cl. 8. . . . Long ago, in Hotchkiss v. Greenwood, 52 U.S. 248, 11 How. 248, 267, 13 L. Ed. 683 (1851), the Supreme Court established that the sine qua non of patentability is invention, and as stated in 35 U.S.C. § 100(a), the legal definition of invention is synonymous with discovery. . . . Over time, patent law has developed its own, new language, and has even come to require special qualifications for lawyers appearing before the PTO. These developments tend to obscure the fundamental notions of invention and discovery.

Acting within this often esoteric area of the law, patent lawyers are called upon to play the roles of chemists, engineers, physicians, and physicists – now, they are also asked to be magicians. That is, patent lawyers are asked to defend – with smoke and incantations when necessary – business-driven decisions having nothing to do with inventing or discovering anything. Consistent with schemes to prolong the legally[] protected period of exclusivity, companies hire highly talented attorneys to perform acts of legal legerdemain in

order to make modest developments look and feel like inventions, when in reality the purported discovery is nothing more than a creation of an advertising and marketing department. In-house counsel should be cautioned that complicity in patent prosecution for unsanctioned legal purposes may give rise in the future to review of that behavior by the appropriate attorney disciplinary machinery. Advancing a client's economic interests is not a license to forget one's ethical responsibilities.

It is not lost on this Court that by developing ("not inventing") a combination drug, the law automatically permitted McNeil a three-year period of exclusivity However, by concocting multiple patent applications and litigating their validity, this period of exclusivity has been extended by two years and, with an appeal, will extend even further, effectively doubling the initial period of exclusivity. The business-driven decision that it is worth the investment to "invent an invention" will continue unabated unless a vigorous PTO or a Court sees this transparent attempt to subvert the patent laws for what it is. The patent laws are not the private sandbox of pharmaceutical companies. Regrettably, I am constrained by law to award only counsel fees for Plaintiff's behavior, although I am not unmindful of the fact that while this patent litigation continues, competition in the marketplace is foreclosed and the public is forced to pay higher prices.

Id. at 374-75.

McNeil now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

McNeil appeals the district court's holding that the asserted claims of the Garwin and Stevens patents are invalid for obviousness. McNeil also appeals the court's award of attorney fees to Perrigo.

A. Obviousness

Obviousness is a legal conclusion based on the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1 (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. Id. at 17-18. When reviewing a district court's decision, we review a district court's underlying findings of fact for clear error, while we rule de novo on the ultimate issue of obviousness. Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1355 (Fed. Cir. 1999).

On appeal, McNeil argues that the district court erred by holding the asserted claims of the Garwin patents invalid for obviousness. In particular, McNeil contends that the prior art failed to provide any disclosure of or motivation to make the claimed combination. According to McNeil, the court committed several legal errors in its obviousness analysis. First, McNeil alleges, the court defined the problem to be solved in terms of its solution. According to McNeil, the problem was not how to “make a combination that treats diarrhea and gas,” but how to treat diarrhea and gas. Second, McNeil argues, the court employed an improper “obviousness of substitution approach,” and judged the invention on the subjective motives of the inventor and his employer, rather than on its merits. Third, with respect to the references cited by the district court, McNeil argues that the Mims reference and the French patent were both before the PTO during prosecution of the Garwin patent application³ and that the Chavkin patent, the only prior art cited by the court that was not before the PTO, merely describes “liquid carriers for administration of . . . compositions.” Although the Chavkin patent mentions both polycarbophil (termed a “bio-adhesive agent” in the reference) and simethicone, McNeil contends that it does not suggest using both in a single composition. According to McNeil, the court’s conclusion that it would have been obvious to combine loperamide with simethicone because diarrhea is often accompanied by flatulence totally disregards evidence that (1) simethicone was not generally believed to be an antifatulent; and (2) flatulence and diarrhea were never separately treated before the invention because loperamide itself relieves flatulence by treating the underlying diarrhea. McNeil argues that the court’s finding that simethicone was a known antifatulent is clearly erroneous, because simethicone was known to be an “antigas” agent only because it stimulates burping and belching, and thereby helps relieve stomach, i.e., gastric, gas. However, flatulence is caused

³ Perrigo points out that McNeil actually cited to the PTO a 1989 Mims reference, not the 1980 Mims reference referred to by the district court. It appears, however, that the relevant portions of the disclosures of those two references are the same.

by intestinal gas, McNeil contends, and stimulating the passing of that gas would exacerbate flatulence. Lastly, McNeil asserts that the court also failed to give proper weight to undisputed objective evidence of nonobviousness, including unexpected results and copying, discounting that evidence without any good reason.

Perrigo responds that the district court's decision is supported by clear and convincing evidence of obviousness. Moreover, according to Perrigo, McNeil does not challenge as clearly erroneous any of the court's factual findings other than those relating to secondary considerations, but instead attempts to propose on appeal numerous new findings of fact that either are not supported by the record or else are plainly contrary to the court's findings. Perrigo also points out that Stephen M. Collins, The Irritable Bowel Syndrome, 138 Can. Med. Ass'n J. 309 (1988), an article referenced in Garwin's laboratory notebook but not cited to the PTO, teaches treatment of irritable bowel syndrome with both loperamide and simethicone.

We agree with Perrigo that the district court's decision was supported by clear and convincing evidence. The court found, in particular, that the concurrence of diarrhea and flatulence had been noted in more than twenty prior art articles and publications, McNeil, 207 F. Supp. at 361; that a 2-4 mg dose of loperamide was known to be a commercially successful and effective antidiarrheal, and simethicone was a well-known antiflatulent sold in more than twenty-five different products (some including a 125 mg dose), by the time of Garwin's alleged invention, id. at 362; and that combinations of several other well-known antidiarrheals with simethicone had been described in the prior art, even if they had not been commercialized, id. Thus, the district court found that all of the limitations in the asserted claims of the Garwin patents were known and that there was motivation to combine those elements as of Garwin's asserted invention date. We see no error in the court's determination.

We also agree with Perrigo that the district court properly discounted the probative value of McNeil's asserted evidence of secondary indicia of nonobviousness. The court found that McNeil had launched a massive marketing and advertising campaign in connection with the launch of the Imodium[®] Advanced product, obscuring any nexus that might have existed between the merits of the product and its commercial success. Id. at 364-65. The court also found that the article cited by McNeil as demonstrating that simethicone did not reduce intestinal gas was based on the results of a study involving only nine participants and thus did not rise to the level of statistical significance. Id. at 362 n.13. Finally, the court found that the results of clinical studies adduced by McNeil were inconsistent, not shown to be reproducible, and did not include comparative data vis-à-vis placebos or other antidiarrheal/antiflatulent combinations necessary to demonstrate unexpected or synergistic effects. On the basis of the district court's findings, which reflect clear and convincing evidence of obviousness, we affirm the court's decision holding claims 14 and 16 of the '505 patent and claim 15 of the '054 patent invalid.

McNeil next argues that the district court erred by holding the asserted claims of the Stevens patents invalid for obviousness. According to McNeil, the Rider patent described using an impermeable polymeric barrier to prevent inactivation of simethicone by antacids, not to prevent coating of loperamide by simethicone. In concluding that Stevens's invention would have been obvious, McNeil contends, the court failed to consider that neither the Garwin patents nor the Rider patent identified the problem solved by Stevens, i.e., the short shelf life of loperamide in combination tablets with simethicone. McNeil cites In re Zurko, 111 F.3d 887 (Fed. Cir. 1997), and In re Sponnoble, 405 F.2d 578 (CCPA 1969), for the proposition that an invention may be patentable even if "the remedy may be obvious once the source of the problem is identified." According to McNeil, the prior art failed to identify the problem, and the claims of the Stevens patents must therefore have been nonobvious.

Perrigo responds by arguing that the court's unchallenged factual findings supports the conclusion of obviousness.

We agree with Perrigo that the evidence clearly and convincingly supports the district court's conclusion. The district court found that the Garwin patents taught both the combination of loperamide and simethicone, and the separation of those two ingredients into different layers of a tablet. The court also found that the Rider patent taught that simethicone could be kept separated from other active ingredients in combination products using an impermeable polymeric barrier. McNeil does not challenge those factual findings. Although, as McNeil points out, the Rider patent did not disclose the specific interaction of simethicone with loperamide, we see no error in the district court's finding that the Rider patent provided motivation to include an impermeable polymeric barrier to prevent simethicone migration from one layer to an adjacent pharmaceutical-containing layer. McNeil's arguments to the contrary are unconvincing. On the basis of those findings, and in view of the lack of any significant objective evidence of nonobviousness, we affirm the court's conclusion that claims 1-3 of the '641 patent and claims 1 and 2 of the '376 patent are invalid for obviousness.

B. Attorney Fees

McNeil argues that the district court abused its discretion by awarding attorney fees to Perrigo. Paraphrasing this court's precedent, McNeil argues that an award of attorney fees under § 285 to an accused infringer may be based on only two grounds: (1) inequitable conduct in the PTO, and (2) bad faith litigation. Neither of those applies in this case, according to McNeil, and there is no other legally cognizable basis to grant attorney fees to an accused, but prevailing, infringer. McNeil also alleges that the district court erroneously buttressed its award of attorney fees by finding that McNeil had benefited by invoking the Hatch-Waxman Act's stay provisions codified at 21 U.S.C. § 355(j)(5)(B)(i). According to McNeil, it is undisputed that McNeil did not and has not invoked the stay provisions of that

Act. Notwithstanding the fundamental premise of the patent laws that the profit motive provides a critical incentive to invent, McNeil argues, the court characterized McNeil's legitimate business decisions as an attempt to "subvert the patent laws" and criticized McNeil's inventions as part of "a scheme." McNeil also alleges that the court's "unwarranted attack" on McNeil has encouraged a host of misplaced antitrust actions filed against McNeil.

Perrigo responds by arguing that McNeil's attorneys made false representations during the seven years of prosecution of the Garwin patents, including assertions that Garwin had discovered the concurrence of diarrhea and flatulence, that Garwin was the first to combine an antidiarrheal with simethicone, that simethicone was believed to be ineffective at treating flatulence, and that the combination of loperamide and simethicone displayed synergistic effects; and failed to disclose the Chavkin patent, the Collins article, and the 1980 Mims reference. The court's finding that McNeil aggressively prosecuted the Garwin patent applications in "studied and deceptive ignorance" is well supported, according to Perrigo, and is not clearly erroneous. McNeil's claim of infringement of the Stevens patents, made without McNeil's having conducted even the most rudimentary examination of Perrigo's product, by itself justifies the award of attorney fees, Perrigo contends. Finally, Perrigo's attorney, during oral argument in this appeal, suggested that attorney fees are warranted in this case on the ground of "aggressive carelessness" on the part of McNeil during patent prosecution, and that we should accordingly affirm the district court's award of fees to Perrigo.

The court in exceptional cases may award reasonable attorney fees to a prevailing party. 35 U.S.C. § 285 (2000). "Among the types of conduct which can form a basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Evidence of such conduct must be supported by clear and convincing evidence. Id. "In the case of

awards to prevailing accused infringers . . . ‘exceptional cases’ are normally those of bad faith litigation or those involving fraud or inequitable conduct by the patentee in procuring the patent.” Cambridge Prods. Ltd. v. Penn Nutrients Inc., 962 F.2d 1048, 1050-51 (Fed. Cir. 1992). In Revlon, Inc. v. Carson Products Co., 803 F.2d 676 (Fed. Cir. 1986), this court found clear error, requiring reversal, in a district court’s finding a case to be “exceptional” within the meaning of 35 U.S.C. § 285 in the absence of inequitable conduct during prosecution of the patent or misconduct during litigation. Id. at 679. The court held that, where the existence of bad faith during proceedings before the PTO fails to rise to the level of inequitable conduct, no gross injustice is prevented by ordering payment of attorney fees, and that proper application of the law dictates that the award of attorney fees be reversed. Id. Although “the trial judge may exercise his discretion to award attorney fees and costs because of inequitable conduct during prosecution of the patent or misconduct during litigation . . . [, a]ttorney fees are not to be routinely assessed against a losing party in litigation in order to avoid penalizing a party ‘for merely defending or prosecuting a lawsuit.’” Id. (quoting Fleischmann Distilling Corp. v. Maier Brewing Co., 386 U.S. 714, 718 (1967)).

We have not previously held any party liable for attorney fees for either vigorously prosecuting its patent application or enforcing a presumptively valid patent, even where that patent was later invalidated, in the absence of clear and convincing evidence of inequitable conduct or misconduct during litigation. We decline Perrigo’s invitation to do so on these facts. The district court did not find that McNeil’s conduct during litigation was egregious or that its patent prosecution rose to the level of inequitable conduct, and we find no other basis for finding this to be an “exceptional” case. A patent owner has the “right to exclude others from making, using, and selling the invention and to enforce those rights until [its patents are] held invalid [or expire].” Concrete Unlimited Inc. v. Cementcraft, Inc., 776 F.2d 1537, 1539 (Fed. Cir. 1985). That right is not unlimited; bad faith litigation, where a patentee initiates

litigation on a patent he knows is invalid or is not infringed, is conduct offensive to public policy, Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 875-76 (Fed. Cir. 1985), and can provide a basis for granting attorney fees.

Given the existence of patents issued by the PTO with a presumption of validity, the present lawsuit was not found to have been brought in bad faith. It is noteworthy in that regard that Perrigo did not challenge McNeil's claims of infringement of the Garwin patents, and that, although Perrigo calls McNeil's claim of infringement of the Stevens patents "outrageous," the record reflects that McNeil's experts advanced a plausible theory of infringement of those claims as well. The district court specifically found that "Perrigo's product does contain polymeric materials," McNeil, 207 F. Supp. 2d at 367 n.25, but ultimately concluded that that product would not infringe because it does not contain an impermeable barrier as required by the asserted claims. The district court found that the parties "essentially agree[d]" that the question whether Perrigo's ANDA product would infringe the Stevens patents "turns solely on whether the Perrigo's [sic] ANDA product employs an impermeable polymeric barrier," which in turn appears to have turned merely on the court's construction of that term. *Id.* at 368. Moreover, although the claims at issue have now been held to be invalid, they had not been held to be invalid at the time that they were asserted against Perrigo. The present fact of their invalidity cannot be used to bootstrap the argument that they were asserted in bad faith, absent clear and convincing evidence that McNeil had reason to believe that the claims were invalid or not infringed.

The district court was notably disturbed that McNeil set out as an objective developing products that extended the life of their basic patent on loperamide. Its concern was with McNeil's objective to obtain additional patent protection on an invention whose patent was about to expire, more than with its conduct in doing so. Short of inequitable conduct or litigation misconduct, neither of which was found here, however, McNeil was entitled to file

patent applications on what it considered to be patentable inventions (in fact, the PTO did grant those patents). While it may be considered more socially desirable for companies to seek truly novel inventions for maladies not yet treatable, the patent laws set the standards of novelty, non-obviousness, and utility as the requirements for patentability, without making value judgments concerning the motives for making and attempting to patent new inventions of lesser medical value. Thus, as no inequitable conduct, or litigation or other misconduct, was found, the exceptional case finding of the district court cannot stand. Accordingly, we reverse the district court's grant of attorney fees to Perrigo.

CONCLUSION

The district court did not err in holding the asserted claims of McNeil's '505, '054, '376, and '641 patents invalid, but clearly erred in finding this to be an exceptional case under 35 U.S.C. § 285 and awarding attorney fees to Perrigo. The court's decision is therefore

AFFIRMED-IN-PART and REVERSED-IN-PART.

COSTS

Each party to bear its own costs.