

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)
)
 Plaintiff,)
)
 v.) Civ. No. 98-197-SLR
)
 BOSTON SCIENTIFIC CORPORATION)
 and SCIMED LIFE SYSTEMS, INC.,)
)
 Defendants.)

Steven J. Balick, Esq., and John G. Day, Esq., of Ashby & Geddes, Wilmington, Delaware, and Gregory L. Diskant, Esq., Eugene M. Gelernter, Esq., Scott B. Howard, Esq., and Irena Royzman, Esq., of Patterson Belknap Webb & Tyler, LLP, New York, New York. Counsel for Plaintiff.

Josy Ingersoll, Esq., and Karen E. Keller, Esq., of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware, and George E. Badenoch, Esq., Albert J. Breneisen, Esq., Mark A. Chapman, Esq., William M. Merone, Esq., and Huiya Wu, Esq., of Kenyon & Kenyon LLP, New York, New York. Counsel for Defendants.

MEMORANDUM OPINION

Dated: August 10, 2009
Wilmington, Delaware


ROBINSON District Judge

I. INTRODUCTION

By decision dated March 28, 2002, I concluded, *inter alia*, that the nondisclosure of material prior art (Hillstead's U.S. Patent No. 4,856,516, hereafter, "Hillstead") during prosecution of U.S. Patent No. 5,643,312 ("the '312 patent") constituted inequitable conduct that also tainted the prosecution of U.S. Patent No. 5,879,370 ("the '370 patent"), thus making both unenforceable. (D.I. 255) By decision dated June 29, 2006, the Federal Circuit remanded the case for additional findings of fact regarding the deceptive intent of the '312 patentee and how the earlier inequitable conduct affected the later prosecution. (D.I. 319 at 8-9) Having conducted a review of the record in light of the parties' submissions¹ and consistent with the Federal Circuit's further guidance, I have concluded that my prior decision was not supported by clear and convincing evidence; i.e., defendants have not proven, by clear and convincing evidence, that the '312 and '370 patents are unenforceable by reason of inequitable conduct.

II. SUPPLEMENTAL FINDINGS OF FACT

1. The application for the '312 patent, entitled "Stent Having a Multiplicity of Closed Circular Structures," was filed on February 24, 1994 by Dr. Robert Fischell and his sons.

2. For the first two years after the application for the '312 patent was filed, Dr. Fischell prosecuted the application *pro se*. (D.I. 255 at 77; PX 5003)

¹I note in this regard, with deep regret, that this matter ended up buried among the multitude of matters (and the tens of thousands of pages of motions, briefs and appendices) filed by the parties associated with just the various stent cases on my docket, not to mention the papers filed in the dozens of other patent cases on my docket. My sincere apologies to the Federal Circuit and to the parties.

3. Starting in 1995, Morton Rosenberg, Esquire, represented Dr. Fischell in connection with foreign counterparts to the '312 application, but not in connection with the U.S. application for the '312 patent. (D.I. 1055 at 955)²

4. The European counterpart to the '312 application (hereafter, "the European application") had the same title as the '312 application and included three independent claims. None of the independent claims mentioned undulating longitudinal structures. (DX 11413) Dependent claim 8 of the European application, like claim 8 of the '312 application, included an added requirement of "longitudinals . . . of an undulating shape."

5. In June 1995, Mr. Rosenberg received a Search Report from the European Patent Office for the European application ("the Search Report"). (DX 10004) The Search Report listed one "X" reference (Sgro), four "Y" references (Wallstent [MedInvent], Inoue, Hillstead [Cordis] and Didcott) and one "A" reference (Cotenceau). (*Id.*) "X" references are "particularly relevant if taken alone;" "Y" references are "particularly relevant if combined with another document of the same category;" "A" references provide "technological background." (*Id.*)

6. Mr. Rosenberg testified that it was his practice for European prosecutions to "carefully" review any "X" references, but "just scan Y references . . . to see if anything jumps out . . . as to a problem area" because, in his experience, "you generally get rejected on the X references," while "Y references . . . are not particularly . . . relevant

²D.I. 1054 contains the testimony of Dr. Fischell from a February 2001 hearing. D.I. 1055 contains the testimony of Mr. Rosenberg from that same hearing. Both of these transcripts have been entered as part of the docket in Civ. No. 97-550-SLR.

during the [European] prosecution.” (D.I. 1055 at 984)

7. By letter dated July 17, 1995, Mr. Rosenberg sent a copy of the Search Report (and the references it cited) to Dr. Fischell. The letter stated:

Please note that the only reference which is stated as being particularly relevant to Claim 1 is European Patent Application #566807 whose inventor is Jean-Claude Sgro.

We have made a Patentee Search to determine whether we have any corresponding patent [to Sgro] in the United States but have come up negatively. It may pay us to make a translation [of Sgro] from the French to determine if this is relevant.

(DX 11021)

8. Dr. Fischell testified that, while he could not rule out the possibility that he glanced at the “Y” references after receiving the Search Report from Mr. Rosenberg, he had “no recollection of having seen [Hillstead]” prior to the issuance of the ‘312 patent in 1997. (D.I. 1054 at 852) Nothing in the July 1995 letter, nor in any other correspondence between Dr. Fischell and Mr. Rosenberg,³ calls attention to Hillstead.

9. In February 1996, Mr. Rosenberg was substituted as attorney for the ‘312 application. (PX 5003, Tab 25) The Search Report was never made part of his ‘312 application file. (D.I. 1055 at 989)

10. On June 20, 1996, in connection with prosecuting the ‘312 application, Mr. Rosenberg filed with the Patent and Trademark Office (“PTO”) an information disclosure statement (“IDS”) citing five references - Sgro, Wall, Sigwart, Palmaz and

³During discovery in this case, Dr. Fischell waived the attorney-client privilege for all communications with his attorney concerning the Hillstead reference. None of these communications include any discussion of Hillstead prior to the issuance of the ‘312 patent, either by Dr. Fischell or his attorney, Mr. Rosenberg.

Lam - none of which were among the “Y” references cited in the Search Report. (PX 5003, Tab 30) In preparing the IDS, Mr. Rosenberg did not review the Search Report or his European application file containing it. (D.I. 1055 at 989)

11. Also on June 20, 1996, application claim 28 was added, which claim required that the undulating longitudinals’ curved sections be joined to “straight sections” that run “generally parallel” to the stent’s longitudinal axis. (PX 5003, Tab 29) According to the papers submitted to the PTO, this claim language was added to distinguish Lam,⁴ which did not provide for such. (PX 5003, Tab 30; D.I. 1054 at 921; D.I. 1055 at 992-994)

12. In July 1996, the European Patent Office rejected claim 1 of the European counterpart to the ‘312 application based on Sgro. It did not mention any of the four “Y” references listed in the Search Report, noting instead that the “additional features of dependent claims 8 and 9 are not disclosed in their present form in any of the documents cited in the [Search Report].” (PX 5116)

13. The ‘312 patent issued on July 1, 1997. (PX 5000)

14. In the spring of 1998, after plaintiff had acquired the rights to the ‘312 patent and the application for the ‘370 patent, Dr. Fischell met with counsel representing plaintiff. During this meeting, Dr. Fischell was shown a copy of Hillstead. Dr. Fischell testified that this meeting was the first time he specifically recalled seeing Hillstead. (D.I. 1054 at 849-53)

⁴Lam actually discloses circumferential, as opposed to longitudinal, structures. (PX 5044) Nevertheless, at the time, Dr. Fischell and Mr. Mortenberg believed otherwise. (D.I. 1054 at 920; D.I. 1055 at 992)

15. In May 1998, an IDS was filed with the PTO in connection with the '370 application. The IDS cited 41 U.S. patents, seven foreign patent documents and thirteen articles. The cited references included the four "Y" references and one "A" reference from the Search Report. (PX 5002, Tab 16) On June 1, 1998, another IDS was filed, citing seven additional references. (*Id.*, Tab 23) Although Hillstead was among the prior art references identified in the IDS, it was not called out as a reference of particular interest.

16. On August 1, 1998, the examiner initialed each of the references on PTO Form 1449A, to indicate that he had considered each of the cited references. (*Id.*, Tab 18) The examiner did not comment on Hillstead.

17. During prosecution of the '370 patent, the patentees did not argue that undulating longitudinal structures did not exist in the prior art.

18. The '370 patent issued on March 9, 1999, with Hillstead among the "References Cited." (PX 5001)

III. STANDARD OF REVIEW

There can be no doubt that the Federal Circuit proceeds with great caution when it comes to declaring a patent unenforceable due to inequitable conduct. Indeed, the Court has reinforced of late the elevated evidentiary burden that must be met in order to successfully prove inequitable conduct. In the first instance,

the accused infringer must present "evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]."

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir.

2008) (hereafter referred to as *Star Scientific*). After reiterating the familiar “clear and convincing” evidentiary burden borne by the accused infringer regarding both materiality and intent to deceive, the Federal Circuit in *Star Scientific* further explained that,

even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty to inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. . . .

[Indeed,]just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith. As a result, court must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

Id. at 1366.

With respect to the deceptive intent prong,

“clear and convincing evidence must prove that an applicant had the **specific intent** to . . . mislead [] or deceiv[e] the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant **made a deliberate decision** to withhold a **known** reference.

Id. (citations omitted)(emphasis in original). In judging evidence of deceptive intent, the Federal Circuit recognizes that “direct evidence of deceptive intent is rarely available;” therefore, “such intent can be inferred from indirect and circumstantial evidence.” *Id.*

But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent

requirement. . . . Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the **single most reasonable inference** able to be drawn from the evidence to meet the clear and convincing standard.

Id. (citations omitted) (emphasis added).

IV. ANALYSIS

Because the Federal Circuit affirmed the conclusion “that a reasonable examiner would have considered Hillstead important in deciding whether to allow the ‘312 patent” (D.I. 319 at 5), I focus on whether the record contains clear and convincing evidence of a specific intent to deceive. In this regard, the Federal Circuit in this case instructed that,

[a]lthough as a general rule a party has no affirmative duty to search for relevant prior art, . . . “one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that material information or prior art.” [citations omitted] Thus, no duty to inquire arises unless the applicant or the prosecuting attorney “is on notice of the likelihood that specific, relevant, material information exists and should be disclosed.” [citation omitted] In such a case, the applicant or prosecuting attorney is not free to choose “not to investigate the facts necessary to determine the materiality of the [reference] in an effort to avoid complying with their duty to disclose.” [citation omitted]

(D.I. 319 at 6)

The first question that springs from a review of the instant record is whether it supports, by clear and convincing evidence, the conclusion that the experienced prosecutors at bar had a duty to inquire based on the notice provided in the Search Report, which specifically characterized Hillstead as relevant prior art, albeit not the most relevant. The answer, in my mind, remains “yes.” Given that “undulations” were a critical feature of the ‘312 application, and given that Hillstead’s undulating longitudinal

structures are plainly visible on the front page of that patent, even a “scan” by Mr. Rosenberg should have put him on notice that Hillstead merited the specific attention of Dr. Fischell.⁵

Of course, this conclusion does not end the inquiry. “[T]he fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct.” *Star Scientific*, 537 F.3d at 1366. As stated above, to be guilty of inequitable conduct in a case involving nondisclosure, defendants must prove, by clear and convincing evidence, that Dr. Fischell and/or Mr. Rosenberg “made a deliberate decision to withhold a known material reference.” *Id.* In the specific context of this case, there must be evidence that either or both of them “purposefully neglected their responsibility of candor to the PTO by ‘putting their heads in the sand’ regarding prior art.” (D.I. 319 at 7)

Upon further reflection, the evidence of record that tends to support a finding of deceptive intent is not clear and convincing. For the most part, defendants rest their case on the argument that Dr. Fischell was not credible in his explanation of why Hillstead was not disclosed to the PTO during prosecution of the ‘312 patent. (See, e.g., D.I. 324 at 8-12) Although such evidence is persuasive to a point, the inferences that can be drawn from the record evidence as a whole are inconclusive. To put the point another way, the evidence cited in support of finding inequitable conduct⁶ is not

⁵Especially in light of the interest being generated by stent research during this period of time.

⁶For example, notice of Hillstead’s materiality through the Search Report and inconsistent explanations for its nondisclosure.

clearly more compelling than the evidence cited in support of not finding inequitable conduct.⁷ As explained by the Federal Circuit in *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, “[w]henver evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.” 528 F.3d 1365, 1376 (Fed. Cir. 2008). I find that the inferences argued by plaintiff are supported by evidence of record and are as reasonable as those inferences argued by defendants. Therefore, although neither Dr. Fischell nor Mr. Rosenberg prosecuted the ‘312 application with the professional care and vigor one might expect from them,⁸ I believe it would be clear error for me to imbue their conduct with deceptive intent on this record.

Even had I concluded otherwise, defendants have failed to prove, by clear and convincing evidence, that the nondisclosure of Hillstead during the ‘312 prosecution carried over and affected the later ‘370 patent prosecution in ways that were “immediate” and “necessary” to the issuance of the ‘370 patent. More specifically, Hillstead was identified as relevant prior art in connection with the ‘370 patent; its relevance is apparent from viewing the front page illustration of undulations; the

⁷For example, no written communications between Dr. Fischell and Mr. Rosenberg specifically identifying or discussing Hillstead; their attempt to distinguish, rather than conceal, references disclosing stents with undulating longitudinals.

⁸Plaintiff describes Dr. Fischell as a “prolific inventor” who has been honored as such. Mr. Rosenberg is described as an experienced patent law practitioner who had represented Dr. Fischell on patent matters since 1989. (D.I. 326 at 4) Despite their combined expertise, it is apparent that Dr. Fischell relied on the advice of Mr. Rosenberg vis a vis the Search Report, even though it was Dr. Fischell, and not Mr. Rosenberg, who was responsible to the PTO for the ‘312 patent prosecution at the time.

examiner noted that he, in fact, did review Hillstead; the examiner did not comment on Hillstead in allowing the '370 patent.

V. CONCLUSION

For the reasons stated above, I conclude that defendants have failed to prove, by clear and convincing evidence, that either the '312 or the '370 patents are unenforceable by reason of inequitable conduct. An appropriate order shall issue.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

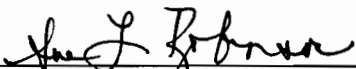
CORDIS CORPORATION,)
)
 Plaintiff,)
)
 v.) Civ. No. 98-197-SLR
)
 BOSTON SCIENTIFIC CORPORATION)
 and SCIMED LIFE SYSTEMS, INC.,)
)
 Defendants.)

ORDER

At Wilmington this 10th day of August, 2009, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that U.S. Patent Nos. 5,643,312 and 5,879,370 are not unenforceable by reason of inequitable conduct.

IT IS FURTHER ORDERED that the Clerk of Court shall enter judgment in favor of plaintiff and against defendants on this issue.



United States District Judge