

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

THERASENSE, INC.,

Plaintiff,

v.

BECTON, DICKINSON AND
COMPANY,

Defendant.

AND CONSOLIDATED CASES.

No. C 04-02123 WHA

Consolidated with

No. C 04-03327 WHA

No. C 04-03732 WHA

No. C 05-03117 WHA

**ORDER ON REMAND
REGARDING
INEQUITABLE CONDUCT**

INTRODUCTION

The court of appeals, sitting *en banc*, vacated a finding herein of inequitable conduct and remanded with instructions to redetermine specified questions under a new standard. Using the new standard, this order again comes to the same conclusion that the patent in suit was procured through inequitable conduct.

STATEMENT

Plaintiff Abbott Laboratories commenced patent infringement actions against various defendants. All were subsequently consolidated and a trial date was set for May 2008. In a trial

1 on Abbott's U.S. Patent No. 5,820,551, invalidity and unenforceability were tried first and tried to
2 the bench.¹

3 Before trial began, Abbott made a request to add Attorney Lawrence Pope, who stood
4 co-accused of the inequitable conduct, as a live trial witness. During his earlier deposition,
5 however, in an effort to prevent further examination and in aid of repeated instructions not to
6 answer, Abbott's counsel had on three separate occasions insisted that Attorney Pope would *not*
7 appear in person at trial. Based on Abbott's insistence that he would not appear live at trial,
8 Abbott's request to allow him to do exactly that was initially denied. The other side had relied on
9 the promise. During trial, however, Abbott renewed its motion to allow Attorney Pope to testify
10 in person at trial. Abbott was then asked to submit a sworn proffer. Faced with the gravity of the
11 accusation against Attorney Pope, the Court relented and allowed Abbott to call him over
12 defendants' strong objections.

13 After the bench trial, the findings of fact and conclusions of law held that patent
14 claims one through four were invalid due to obviousness, and that the entire patent was
15 unenforceable due to inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F.
16 Supp. 2d 1088, 1127 (N.D. Cal. 2008). On appeal, a three-judge panel, consisting of Judges
17 Daniel Friedman, Timothy Dyk, and Richard Linn, unanimously affirmed the finding of
18 obviousness, and affirmed, in a two-to-one split, the finding of inequitable conduct, Judge Linn
19 dissenting. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1311 (Fed. Cir. 2010).
20 A petition for rehearing *en banc* was granted. A six-judge majority in the *en banc* panel
21 remanded for a new assessment on inequitable conduct, this time applying new intent and
22 materiality standards. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir.
23 2011).

24 The majority opinion by Chief Judge Randall Rader increased the proof and findings
25 needed for both intent and materiality. It reaffirmed that clear and convincing evidence is
26 required to support a finding of specific intent to deceive the PTO. It reaffirmed that an accused
27

28 ¹ Therasense, Inc. and Medisense, Inc. are wholly-owned subsidiaries of Abbott Laboratories. For convenience, each is referred to as Abbott.

1 infringer cannot carry its burden simply because the patentee fails to prove a credible alternative
2 explanation. Overruling precedent, however, the court held that a weak showing of intent can no
3 longer be offset by a strong showing of materiality, and intent cannot be inferred solely from
4 materiality. Instead, to prove specific intent to deceive the PTO, the accused infringer must prove
5 by clear and convincing evidence that the applicant knew of the omitted reference, knew that it
6 was “but for” material, and made a deliberate decision to withhold it. *Id.* at 1290–92. Most
7 dramatic was the introduction of the “but for” test.

8 *Therasense* worked a seismic shift in the law of inequitable conduct. Prior case law had
9 employed a standard of materiality based on the PTO’s well-known Rule 56 duty of candor.
10 *Bruno Independent Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1352–53 (Fed.
11 Cir. 2005). Under Rule 56, among other things, a reference was material if it “refute[d] or [was]
12 inconsistent with any position the applicant took regarding patentability.” 37 C.F.R. 1.56 (2011).
13 *Therasense*, however, held that materiality would henceforth use a but-for definition, meaning
14 that submission of the withheld item would have led to a rejection. *Id.* at 1292.

15 Under the new standard, therefore, an applicant or attorney may knowingly and
16 deliberately withhold from the PTO any reference known to be inconsistent with a position taken
17 by him or her before the PTO so long as the withholder does not know that the reference itself
18 would lead to a rejection. It would not be enough to prove that the applicant or attorney expected
19 that the concealment would help win an allowance or expected that, if revealed to the examiner,
20 the reference would cause the examiner to merely question patentability. Rather, the applicant or
21 attorney must know — and it must be later proven that he or she knew — that the item, if
22 revealed, would lead to a rejection.

23 A four-judge dissenting opinion, by Judge William Bryson, made common cause with the
24 majority on two points: The standard for intent should be specific intent to deceive the PTO and
25 there should not be a sliding scale. *Id.* at 1302. The dissenting judges parted company with the
26 majority, however, over the change in materiality. They viewed the PTO’s traditional Rule 56 as
27 the best materiality standard. *First*, the PTO is in a better position to know what information its
28 own examiners would need to conduct effective and efficient examinations. *Second*, the new rule

1 for materiality will not adequately police the disclosure obligations of patent applicants, an
2 important public policy consideration, given that the PTO proceedings one-sided with no
3 adversary to present argument. *Id.* at 1303. The four dissenting judges stated that the new test
4 “does not merely reform the doctrine of inequitable conduct, but comes close to abolishing it
5 altogether.” *Id.* at 1304. In its amicus brief, the PTO agreed with the dissenting judges that the
6 materiality standard should be left undisturbed.

7 Judge Kathleen O’Malley, concurring-in-part and dissenting-in-part, disagreed with the
8 new but-for standard and would have affirmed the finding of materiality but agreed to remand on
9 the issue of intent to deceive. *Id.* at 1296–302. Senior Judge Friedman, who had affirmed the
10 finding of inequitable conduct as part of the earlier panel majority, was not part of the *en banc*
11 panel. Of the twelve circuit judges participating in the two appellate decisions, therefore, six
12 expressly favored the new and tougher materiality standard. Despite the closeness of the decision
13 and the importance of the question to our patent system and national economy, no petition for
14 certiorari was filed in the Supreme Court.

15 The remand instructions from the court of appeals were as follows:

16 On remand, the district court should determine whether
17 there is clear and convincing evidence demonstrating that
18 Sanghera or Pope knew of the EPO briefs, knew of their
materiality, and made the conscious decision not to disclose
them in order to deceive the PTO.

19 * * *

20 On remand, the district court should determine whether the
21 PTO would not have granted the patent but for Abbott’s
22 failure to disclose the EPO briefs. In particular, the district
23 court must determine whether the PTO would have found
Sanghera’s declaration and Pope’s accompanying
submission unpersuasive in overcoming the obviousness
rejection over the ’382 patent if Abbott had disclosed the
EPO briefs.

24 *Id.* at 1296.

25 On remand, there was extensive briefing, both before and after a long hearing and oral
26 argument. The parties rested their cases on the 2008 trial record.
27
28

FINDINGS ON REMAND ISSUES

This order now turns to the remand issues.

1. REMAND FINDING NO. 1: THE WITHHELD EPO BRIEFS WERE MATERIAL UNDER THE NEW BUT-FOR TEST.

The court of appeals instructed the district court to redetermine the issue of materiality using the new but-for standard. The 2008 order found that the EPO briefs were highly material and inconsistent with the main point being made by Abbott to the PTO examiner. The EPO briefs centered on the precise concern of the PTO examiner, who was ultimately misled by Abbott's submissions. 565 F. Supp. 2d at 1112. This order again makes the finding under the clear and convincing standard and further finds that the omission of the EPO briefs was but-for material, leading to the allowance of the '551 patent; that is, the examiner would not have finally allowed the '551 patent had the EPO briefs been submitted. The evidence is clear and convincing on this point, as follows.

A. The "Optionally, But Preferably" Sentence Was the Roadblock Against Allowance of the '551 Patent.

Blood-glucose test strips for diabetes management were already well known. Such strips employed electrochemical sensors on an electrode to measure the level of glucose in blood. As blood came in contact with the sensors, glucose in the blood reacted with an enzyme on the sensor to generate electrons. The electrons then passed via a chemical mediator to the active electrode, which then electrically signaled the glucose concentration. Since electrodes were already well-known, the point of contention over the '551 patent came down to membranes and specifically whether or not the '551 application revealed for the first time that a protective membrane around the active electrode was unnecessary for use in whole blood. Whole blood is normal blood drawn outside the body (as in a blood sample). Live blood is blood still inside the body. Both contain red blood cells.

The original application leading to the '551 patent was filed in 1984. For thirteen years, it saw multiple rejections over prior art U.S. Patent No. 4,545,382, another patent owned by Abbott. When Abbott acquired Medisense, Inc. and its then-pending '551 patent application in 1997, Abbott's in-house lawyer, Lawrence Pope, took over the prosecution. He advanced a new

1 argument for patentability: Whereas the '382 patent had *required* a protective membrane around
2 the active electrode, the pending '551 invention did not (TX 470 at AL28137–39). To make this
3 no-membrane argument to the PTO, however, Attorney Pope needed to show that the '382 patent
4 disclosure indeed had required a protective membrane. But as the PTO examiner pointed out to
5 Attorney Pope the '382 patent specification had already called out an *optional* protective
6 membrane. In point of fact, the '382 patent specification stated that, for the invention there
7 disclosed, a protective membrane was only optional, not required (col. 4 at 63–66) (emphasis
8 added):

9 *Optionally, but preferably* when being used on live blood, a
10 protective membrane surrounds both the enzyme and the
 mediator layers, permeable to water and glucose molecules.

11 The enzyme and mediator layers referenced were on the active electrode. The protective
12 membrane could optionally surround those layers but was not required in the '382 teaching.

13 To overcome this, Attorney Pope took the position that in 1983 skilled artisans all
14 assumed that a protective membrane was needed when testing whole blood and that the
15 “optionally, but preferably” sentence would have been understood to mean “required” when used
16 with whole blood. Again, this was supposedly because the conventional wisdom in 1983 was that
17 a protective membrane was necessary to protect a sensor when used in whole blood (TX 470 at
18 AL28138).

19 To accept this, the examiner required a qualified scientist’s declaration swearing that
20 “optionally, but preferably” would have been understood to mean “required” (TX 469 at
21 AL28129). This is where Dr. Gordon Sanghera came in. Dr. Sanghera, who was Abbott’s
22 research director for managing IP applications, provided a sworn declaration representing to the
23 examiner that “based on his historical knowledge” he was “confident” and “sure” that those
24 skilled in the art would have understood the phrase to mean that a protective membrane was
25 required when used with whole blood, given that this was the supposed conventional wisdom at
26 the time (TX 443 at TH0012275). Attorney Pope made the same representation and added that
27 there was “no teaching or suggestion” in the '382 patent to omit a protective membrane for use in
28 whole blood. To meet the question why that very sentence was not such a teaching, he said that

1 skilled artisans would have viewed the sentence as mere “patent phraseology” rather than as a
 2 “technical teaching” (TX 470 at AL28138–39). Put differently, the submissions represented that
 3 the accepted understanding at the time of the ’382 invention was that protective membranes were
 4 necessary when testing whole blood and that the sentence in question would not have been
 5 regarded as a teaching to the contrary.

6 **B. The Abbott EPO Briefs.**

7 Several years earlier, however, while prosecuting the European counterpart to the ’382
 8 patent, European Patent 0,078,636, Abbott itself had made contrary representations to the
 9 European Patent Office regarding the very same “optionally, but preferably” sentence. In order to
 10 distinguish a German prior art patent, which had required a different type of membrane, Abbott
 11 had seized upon the very same sentence at issue and urged that it was “unequivocally clear” that a
 12 protective membrane was indeed optional and not required, stating as follows (TX 315 at 8)
 13 (emphasis added):

14 In the application from which the [’382/’636 patent] was
 15 granted, a membrane never constituted a feature of the
 16 independent claim. In fact, a membrane did not appear but
 17 in original claim 13 (claim 10 as granted) and is defined as a
 “protective membrane permeable to water and glucose
 molecules.” Column 5, lines 30 to 34 of the [’636 patent]
 provides the following information:

18 “Optionally, but preferably when being used on live
 19 blood, a protective membrane surrounds both the
 20 enzyme and the mediator layers, permeable to water
 and glucose molecules.”

21 It is submitted that this disclosure is *unequivocally clear*.
 22 The *protective membrane is optional*, however, it is
 23 preferred when used on live blood in order to prevent the
 large constituents of the blood, in particular [red blood cells]
 from interfering with the electrode sensor.

24 In another EPO brief, Abbott again argued that point (TX 311 at AL54151–52) (emphasis added):

25 Contrary to the semipermeable membrane of [the German
 26 reference], *the protective membrane optionally utilized* with
 the glucose sensor of the patent [in] suit is not controlling
 the permeability of [glucose] Rather, in accordance
 with column 5, lines 30 to 33 of the [’636 patent]:

27 “Optionally, but preferably when being used on live
 28 blood, a protective membrane surrounds both the

1 enzyme and the mediator layers, permeable to water
2 and glucose molecules.”

3 At the EPO hearing, Abbott yet again argued to the EPO that either “you had a membrane that
4 was permeable to glucose, or you had no membrane at all” under the teachings of the ’382 patent
5 (Tr. 772–73).²

6 The EPO accepted Abbott’s arguments and held that the “optionally, but preferably”
7 sentence disclosed electrodes “with and without protective membranes” (TX 314 at 6–7)
8 (emphasis added):

9 Now Claim 1 is silent as to the presence or absence of a
10 membrane. However dependent Claim 9 is directed to the
11 feature that the sensor electrode has a protective membrane
12 permeable to water and glucose molecules, from which it
13 follows that Claim 1 is intended to embrace sensor
14 electrodes *with and without such protective membranes*.
15 Further in column 5, lines 30 to 33 it is stated that
16 optionally, but preferably when being used on live blood, a
17 protective membrane surrounds the enzyme and the
18 mediator layers, permeable to water and glucose molecules.

19 Abbott’s argument to the EPO had been clear: A protective membrane was preferable for use
20 with live blood and optional in all other cases including whole blood but in any case was never
21 required (*see, e.g.*, TX 311 at AL54151–54).

22 **C. Had the PTO Examiner Been Provided the EPO Briefs,
23 He Would Not Have Allowed the ’551 Patent To Issue.**

24 If the PTO examiner had read the EPO briefs, then he would *not* have allowed the ’551
25 patent to issue. Even without knowledge of Abbott’s EPO briefs, the PTO examiner had already
26 raised the ’382 sentence as a problem (TX 469; see Tr. 136). In his interview summary with
27 Attorney Pope, the PTO examiner wrote that the ’382 patent expressly taught that its sensor did
28 not require a membrane (specifically referring to the “optionally, but preferably” passage) but that
an affidavit from Abbott could overcome this teaching (TX 469) (emphasis added):

Applicant indicated that he would like to submit claims
specifically covering a compound specific electrode with the
filtering membrane absent. The Higgins, et al. (’382)
disclosure was discussed esp[ecially] the paragraph

² For all purposes relevant to this action, Abbott’s EP ’636 and US ’382 shared the same specification as each other. In both, the “optionally, but preferably” sentence and its immediate context were completely identical. This order refers to them as the ’382 patent.

1 spanning *columns 4 & 5* [the optionally but preferably
2 paragraph]. It was determined that since Higgins et al.
3 appear to require the membrane for use with whole blood
4 (see example 8) an affidavit or other evidentiary showing
5 that at the time of the invention such a membrane was
6 considered essential would overcome this *teaching*.

7 The EPO briefs would have reinforced the examiner's expressed concern on the meaning of the
8 "optionally, but preferably" teaching.

9 The PTO examiner was completely dependent on Attorney Pope and Dr. Sanghera to
10 accurately represent the information covered by their submissions. The examiner relied on their
11 submissions and allowed the '551 patent. The examiner was misled by and relied on the
12 representations, which would have been proven false by the EPO briefs.

13 Abbott now argues that the trial record is silent on how the examiner would have reacted
14 to the EPO briefs. In one sense, this is true, for trial courts cannot demand that PTO examiners
15 testify on this issue. PTO examiners cannot be compelled to testify about their "bases, reasons,
16 mental processes, analyses or conclusions" in reaching a decision on an application. *Green v.*
17 *Rich Iron Co., Inc.*, 944 F.2d 852, 854 (Fed. Cir. 1991). Even if examiners could so testify and
18 even if they could remember the specific case, the exercise would still involve hindsight opinion.
19 Surely this is not what *Therasense* required. Instead, the court of appeals surely meant that but-
20 for causation should be evaluated in the same traditional way known to the trial courts, that is, the
21 trier of fact must evaluate all of the trial evidence and make an estimate as to what would have
22 happened in the alternative scenario. Doing so here, it is manifest that the withheld EPO briefs
23 would have contradicted Abbott's declaration and submission. The EPO briefs would have
24 convinced the examiner that skilled artisans would have understood the sentence to teach optional
25 protective membranes. Had the EPO briefs been presented to him, the examiner would have seen
26 through Abbott's representations to him. In that event, the examiner would have persisted in the
27 13-year history of rejections. This is an inference but it has been shown by clear and
28 convincing evidence.

Abbott counters that even if the EPO briefs had been before the examiner, and if the
examiner had understood that the '382 patent had already described a membraneless sensor, he
would not have believed that such a possibility was achievable in 1983 and would still have

1 allowed the '551 patent. This is wholly unpersuasive. The 2008 order found this attack on the
 2 '382 disclosure unconvincing when invalidating claims one through four of the '551 patent. The
 3 reason was and remains simple. The plain language of the '382 disclosure was clear that the
 4 disclosure taught that a protective membrane was preferable for use with live blood and optional
 5 in all other cases including whole blood; it was never required in any case. For these very
 6 reasons, claims one through four of the '551 patent were found invalid as obvious both at the
 7 district court and by twelve judges on the Federal Circuit. *Therasense, Inc. v. Becton, Dickinson*
 8 *& Co.*, 649 F.3d 1276, 1296 (Fed. Cir. 2011). The examiner would have come to the same
 9 conclusion. In short, had the EPO briefs been before the examiner, he would have rejected the
 10 '551 patent application. This has been shown by clear and convincing evidence.³

11 2. REMAND ISSUE NO. 2 — KNOWLEDGE OF BUT-FOR MATERIALITY.

12 The court of appeals instructed the district court to “determine whether there is clear and
 13 convincing evidence demonstrating that Sanghera and Pope knew of the EPO briefs, knew of
 14 their materiality, and made the conscious decision not to disclose them in order to deceive the
 15 PTO.” 649 F.3d at 1296.

16 Two parts of this are straightforward. Both Dr. Sanghera and Attorney Pope knew of the
 17 EPO briefs. And, they made a conscious decision not to disclose them. The evidence on these
 18 points is overwhelming and need not be repeated here. Indeed, these points seem conceded by
 19 all.

20 Requiring more inspection is whether they knew of the materiality of the EPO briefs —
 21 measured under the new but-for standard — and whether their intent in withholding them was to
 22 deceive the PTO. With respect to knowledge of materiality, the key question is: Did they know
 23 that disclosure of the EPO briefs would lead to a rejection?

24 In evaluating this, a question of law arises: Do we presume that the disclosure of the EPO
 25 briefs would have been accompanied by a further, hypothetical submission setting forth Abbott's
 26 argument for distinguishing those EPO briefs? To this, the *en banc* majority opinion did not give
 27

28 ³ Although the *en banc* majority opinion stated that materiality need only be proven by a
 preponderance of the evidence, the opinion went on to require that knowledge of materiality be proven by clear
 and convincing evidence. It seems, therefore, that materiality must be proven by clear and convincing evidence
 anyway in order to satisfy the knowledge of materiality element. This is the standard used in this order.

1 a direct answer. The best reading of the opinion is that such further explanations are premature at
 2 this step. *First*, the remand instruction as to materiality focused on the question “whether the
 3 PTO would have found Sanghera’s declaration and Pope’s accompanying submission
 4 unpersuasive in overcoming the obviousness rejection over the ’382 patent if Abbott had
 5 disclosed the EPO briefs.” 649 F.3d at 1296. Notably, this remand instruction called out specific
 6 *actual* documents, namely the *actual* submissions and the *actual* suppressed items. It did not
 7 mention consideration of hypothetical memoranda. The further remand instruction as to
 8 knowledge of materiality directed the district court to determine whether the withholders “knew
 9 of their materiality,” again without adding in consideration of hypothetical memoranda. And, in
 10 its long analysis of materiality and knowledge of materiality, the *en banc* majority opinion
 11 nowhere stated that a withholder should receive the benefit of hypothetical arguments in making
 12 these determinations.

13 *Second*, the PTO had encountered this post-hoc problem and had expressly stated that
 14 materiality should be judged “before any consideration is given to evidence which may be
 15 submitted in an attempt to establish a contrary conclusion of patentability.” 37 C.F.R. 1.56
 16 (2011). The point of its caveat was to eliminate the apologies for nondisclosure suggesting that
 17 concealed art could have been explained away. The *en banc* majority noted this feature of Rule
 18 56 and used it to explain why it was important, in the court’s view, to harden the definition of
 19 materiality. But it did not disapprove of evaluating knowledge of materiality without regard to
 20 hypothetical efforts to distinguish the withheld item. *Id.* at 1294.

21 *Third*, if, at the “knowledge of materiality” stage in the *Therasense* framework, the
 22 applicant must be credited with reasons for why the withheld material should make no difference
 23 to the examiner, then such a rule would be in conflict with another *Therasense* rule that the
 24 applicant must not and may not be required to present any reasons for the withholding until *after*
 25 a “threshold” case has been proven. That is, *Therasense* insisted that the applicant must not be
 26 required to give an explanation at all for the withholding until after a threshold case has been
 27 established. One of the three elements needed for a threshold case was held expressly to be
 28 knowledge of materiality. *Id.* at 1290–91. In proving knowledge of materiality, is the accused

1 infringer, therefore, required to anticipate an explanation not yet due and to negate it even before
 2 it is in play? This conceptual snafu is avoided by holding that at the “knowledge of materiality”
 3 step, explanations that might have been (but were not) given to the examiner are premature.
 4 Instead, the explanations come into play only after the threshold case, including knowledge of
 5 materiality, has been established. The knowledge of materiality inquiry must focus, as the
 6 remand instructions call out, on the impact of the actual withheld item. (The explanation offered
 7 here by Abbott will be considered below as part of the intent analysis).

8 Applying the foregoing, this order finds, by clear and convincing evidence, that
 9 Dr. Sanghera and Attorney Pope knew that if they had included the actual EPO briefs along with
 10 their actual PTO submissions, the examiner would have rejected the claims. They knew that the
 11 very language they were characterizing as mere “patent phraseology” and not a teaching had been
 12 earlier argued by Abbott itself to the EPO to be an “unequivocally clear” teaching. They knew
 13 that the very same language had earlier been represented as teaching that a protective membrane
 14 was at most merely “preferred” when dealing with “live blood” and “optional” in all other cases,
 15 including whole blood. The evidence is clear and convincing that Dr. Sanghera and
 16 Attorney Pope knew the content of the EPO briefs and knew that the EPO briefs, standing alone,
 17 would so seriously undermine their submission that the examiner would have reverted
 18 to unpatentability.

19 **3. REMAND ISSUE NO. 3 — SPECIFIC INTENT TO DECEIVE.**

20 The next remand issue is whether Dr. Sanghera and Attorney Pope intended to deceive the
 21 PTO when they withheld the EPO briefs. In addressing this issue, it is again best to say how this
 22 district judge reads *Therasense* on some subordinate questions.

23 *First*, that an item is material and that the withholder “should have known of its
 24 materiality” are no longer sufficient to prove intent under *Therasense*. 649 F.3d at 1290. This
 25 holding overruled decisions as recent as one year before the 2008 findings herein. In *Cargill,*
 26 *Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366–67 (Fed Cir. 2007), for example, the Federal
 27 Circuit repeatedly used the phrase “should have known” to affirm a finding of inequitable
 28 conduct, as had earlier decisions in the same vein. The Federal Circuit has now outlawed this

1 phrase and mode of analysis. That someone “should have known” of an item’s materiality may
2 no longer be considered.

3 Instead, Part V of the *en banc* majority opinion, in canvassing the law of specific intent to
4 deceive, summarized the necessary elements as follows:

5 In other words, the accused infringer must prove by clear
6 and convincing evidence that the applicant knew of the
7 reference, knew that it was material, and made a deliberate
8 decision to withhold it.

9 *Id.* at 1290.

10 Thus, three elements together are enough to establish a threshold case of specific intent to
11 defraud: (i) actual knowledge of the withheld item, (ii) actual knowledge of its materiality (using
12 the but-for standard), and (iii) a deliberate decision to withhold it. The second element — actual
13 knowledge of materiality — is, of course, a harder-to-prove element than materiality itself.

14 In addition to the *Therasense* test quoted above, Abbott contends that the accused
15 infringer must separately and independently prove specific intent to deceive the PTO. This order,
16 however, reads Part V of the *en banc* majority opinion to hold that the three elements are indeed
17 sufficient to establish at least a threshold case of specific intent to deceive. Most of Part V dealt
18 with why gross negligence was insufficient and why materiality by itself was insufficient. Part V
19 therefore insisted on actual knowledge of materiality as a required element of the three-part test.
20 Nowhere in Part V was there a fourth stand-alone intent element. Instead, a threshold case of
21 specific intent to defraud can be inferred from the three elements stated above. This
22 understanding is supported by a subsequent Federal Circuit decision interpreting the same
23 sentence quoted above to hold that specific intent to deceive can be proven by finding those three
24 elements. *American Calcar, Inc. v. American Honda Motor Co., Inc.*, 651 F.3d 1318, 1335–36
(Fed. Cir. 2011).

25 Nonetheless, out of caution, this order proceeds on the assumption that even once the three
26 elements are proven, the district judge must still consider all the facts and circumstances shown at
27 trial and determine whether there was a specific intent to deceive the PTO. That is, while the
28 three elements establish at least a threshold case of inequitable conduct, the district judge should

1 consider whether, in combination and viewed in light of all the trial evidence, specific intent to
2 deceive is clear and convincing.

3 *Second*, what is the role of explanations or the absence thereof? *Therasense* stated that the
4 “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s]
5 a threshold level of intent to deceive by clear and convincing evidence” and added that “the
6 absence of a good faith explanation for withholding a material reference does not, but itself, prove
7 intent to deceive.” 649 F.3d at 1291. The “threshold level” referenced is the set of the three
8 elements above. Until those are proven, the patentee can remain silent and its silence may not be
9 used against it. If the threshold is met, however, then the silence of the patentee may be
10 considered as adverse evidence. Any explanation given may be considered, pro or con, on the
11 overall mix of trial evidence.

12 *Third*, the en banc majority described the role of circumstantial evidence as follows:

13 Because direct evidence of deceptive intent is rare, a district
14 court may infer intent from indirect and circumstantial
15 evidence. [citation omitted.] However, to meet the clear
16 and convincing evidence standard, the specific intent to
17 deceive must be “the single most reasonable inference able
18 to be drawn from the evidence.” *Star*, 537 F.3d at 1366.
19 Indeed, the evidence “must be sufficient to *require* a finding
20 of deceitful intent in the light of all the circumstances.”
21 *Kingsdown*, 863 F.2d at 873 (emphasis added). Hence,
when there are multiple reasonable inferences that may be
drawn, intent to deceive cannot be found. *See Scanner
Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365,
1376 (Fed. Cir. 2008) (“Whenever 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.”).

22 *Id.* at 1290–91 (emphasis in original). The second sentence in this block quote stated that specific
23 intent to deceive must be “the single most reasonable inference.” Where, however, two *equally*
24 reasonable inferences are possible, the more innocent one must be adopted, as stated in the
25 decision and parenthetical squib at page 1291 (col. one).

26 With the foregoing in mind, this order now addresses the remand issue of specific intent to
27 deceive the PTO. The three elements necessary for a “threshold showing” have been proven by
28 clear and convincing evidence.

1 *First*, Dr. Sanghera and Attorney Pope knew of the EPO briefs. This is conceded.
2 *Second*, as set forth in Remand Findings Nos. 1 and 2 above, they knew that the EPO briefs were
3 material (using the but-for standard). *Third*, they made a conscious decision to withhold. This is
4 conceded. The threshold case has been proven.

5 On the overall evidence, moreover, intent to deceive is the single most reasonable
6 inference. This Court has re-read its earlier decision, the trial record, and re-affirms all factual
7 findings, leaving out the “should have known” phrase with apologies, and emphasizing that
8 Dr. Sanghera and Attorney Pope actually knew of the materiality of the withheld EPO briefs.
9 Again, the single most reasonable inference is that Dr. Sanghera and Attorney Pope had the
10 specific intent to deceive the PTO by withholding the EPO briefs. This finding is based on clear
11 and convincing overall trial evidence whether or not Abbott’s explanations are taken into account.

12 Without repeating all of the prior findings, this order now lists the main facts and
13 circumstances leading this district judge to find that the single most reasonable inference is
14 specific intent to deceive the PTO. After thirteen years of rejections, Attorney Pope and
15 Dr. Sanghera realized that the “optionally, but preferably” sentence in Abbott’s own ’382 prior art
16 patent was the last roadblock to eking out an allowed claim. They knew the examiner had
17 permitted them to file a declaration swearing around the ’382 sentence and that the declaration
18 had to establish that skilled artisans would not have understood the sentence in its plain language
19 sense but would have construed it otherwise. They knew, however, that Abbott’s own EPO briefs
20 had earlier exalted the plain meaning of the very same sentence and had stated that the sentence
21 was “unequivocally clear.” They knew that the EPO briefs were in conflict with their own
22 submissions to the PTO wherein they had tried to explain the sentence away as not a “teaching”
23 but merely “patent phraseology.” They knew that they were telling the PTO that the ’382 patent
24 had required a protective membrane for use with whole blood, but they also knew that Abbott’s
25 EPO briefs had said the protective membrane was, at most, merely preferred for live blood and
26 optional otherwise. Despite a close friendship with the ’382 Inventor Allen Hill, Dr. Sanghera
27 did not ask him how his “optionally, but preferably” sentence would have been understood, an
28 obvious question for anyone who wished to be accurate (Tr. 740–42). Attorney Pope and

1 Dr. Sanghera were keen to win an allowance quickly in order to meet competition in the
 2 marketplace, as illustrated by the fact that the very day the '551 patent issued, Abbott asserted it
 3 in an infringement action against a competing home diabetic kit made by Lifescan, Inc. *Abbott*
 4 *Laboratories v. Lifescan, Inc., et al.*, 1:98-cv-12053-EFH (D. Mass. Oct. 13, 1998). The single
 5 most reasonable inference to be drawn is that Dr. Sanghera and Attorney Pope intended to
 6 deceive the PTO by consciously withholding the EPO briefs.⁴

7 In the face of this evidence, Abbott has offered its explanation for the conscious
 8 withholding of material items. In that respect, the remand instruction seemed to criticize the 2008
 9 order for using the absence of a good faith explanation against Abbott. *Id.* at 1296. This order
 10 now clarifies that intent to deceive has been proven with or without regard to any explanation.

11 At trial, Abbott chose affirmatively to introduce an explanation, going so far as to revoke
 12 its earlier promise and to insist that Attorney Pope be allowed to testify and to offer explanation
 13 beyond those in his deposition. This was allowed. This is not a case, therefore, where the
 14 patentee gave no explanation and its silence was held against it. Here, the patentee demanded to
 15 testify and the district court found (and finds again) that its story is not credible and the witness
 16 demeanor was not favorable.

17 The explanation given was that Dr. Sanghera and Attorney Pope thought that there was a
 18 distinction between a *protective* membrane and a *diffusion-limiting* membrane and that the EPO
 19 briefs had not really addressed the issue of whether a *protective* membrane was required and
 20 instead had really addressed only the issue of whether a *diffusion-limiting* membrane was required
 21 by the '382 invention. Without repeating the many steps in the argument, Abbott's main point
 22 boiled down to the proposition that they thought, at the time of the PTO submission, that the
 23 embarrassing words in the EPO briefs were mere dicta that could be explained away as
 24 unnecessary. As found in the 2008 order, this explanation is not credible. Before the EPO,
 25 Abbott made two points to distinguish the earlier prior art, one point of which has been the
 26

27
 28 ⁴ Inventor Hill explained at his deposition, which was entered into the trial record, that the "optionally,
 but preferably" sentence indeed disclosed membraneless sensor for use in whole blood (Hill Dep. at 74-75)
 (Dkt. No. 792 at Exh. C) (Joint Motion to Admit Certain Deposition Transcripts).

1 problem ever since. That Abbott might have succeeded before the EPO with only the other point
2 does not eliminate the fact that the critical point was indeed made and made indelibly.

3 The single most reasonable inference to be drawn from the trial record, including witness
4 demeanor, and particularly the witness demeanor of Dr. Sanghera and Attorney Pope, is that they
5 *did* believe that the omission was necessary to win an allowance and that they *did* deliberately
6 elect to withhold the EPO briefs — precisely because they knew the briefs could not be explained
7 away. This order finds the withholding was done with specific intent to deceive the PTO and
8 finds that the evidence in support of this finding, circumstantial though it may be, is clear and is
9 convincing. The explanation simply lacked sufficient coherence and consistency compared to the
10 rest of the record. There is not one shred of documentary evidence to corroborate their testimony
11 that at the time in question they actually believed or documented or discussed the supposed
12 reason for not submitting the EPO briefs. It surfaced for the first time in this litigation.

13
14 * * *

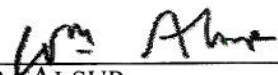
15
16 Although not specifically called out in the remand instructions, elsewhere in the
17 *Therasense* opinion was a requirement for district courts to weigh the equities to determine
18 whether the applicant's conduct before the PTO warrants rendering the entire patent
19 unenforceable. 649 F.3d at 1287. Here, the conduct of Attorney Pope and Dr. Sanghera warrants
20 the remedy of unenforceability. Abbott was willing to conceal important evidence to get the
21 patent and immediately use it to suppress the competition. There is no countervailing equity.
22 Unenforceability is the just result.

CONCLUSION

No judge takes any satisfaction in finding fault in the conduct of a professional. That is certainly true here. For the reasons stated, however, the district judge feels it is his duty to find that Attorney Pope and Dr. Sanghera committed inequitable conduct, even under the new law to be applied on remand. U.S. Patent No. 5,820,551 is unenforceable.

IT IS SO ORDERED.

Dated: March 27, 2012.



WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE