

DUTY OF DISCLOSURE AND INEQUITABLE CONDUCT RAISED AS AN AFFIRMATIVE DEFENSE

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In addition to the defenses of non-infringement and invalidity, an alleged infringer may also raise “inequitable conduct” as an affirmative defense to patent infringement. If inequitable conduct is found, the patent is rendered unenforceable.

Noncompliance with the “duty of disclosure” may give rise to inequitable conduct. The duty of disclosure and those subject to the duty are defined in 37 CFR §1.56. The burden of the alleged infringer charging inequitable conduct is to prove, by clear and convincing evidence, that the patentee misrepresented or failed to disclose material information, or submitted false material information, and that such was done with an intent to deceive the patent examiner.

The issue of inequitable conduct is decided by the judge (not the jury) at the district court level. At the appeal level, various panels of the Federal Circuit have reviewed district court decisions on the issue of inequitable conduct. The standard of review is whether the district court’s finding was “clearly erroneous.”

As you will see, decisions in cases involving inequitable conduct tend to “turn on their specific facts.”

Lastly, the MPEP provides guidance for complying with the duty of disclosure. MPEP §2004

Historical Context of Fraud

1. Common Law Fraud
 - a. Basis for civil liability for damages (money damages) to the defrauded party in addition to criminal liability. Serious charge.
 - b. Clear and convincing evidence standard.

2. Inequitable Conduct before the Patent Office
 - a. Unenforceability of the patent and potentially an award of attorney's fees to the accused infringer. Breach of duty of candor and good faith to the PTO.

Comparison of Inequitable Conduct and Common Law Fraud

1. Common Law Fraud
 - a. misrepresenting a material fact to another;
 - b. knowing the falsity of the misrepresentation, or with reckless disregard for its truth;
 - c. for the purpose of inducing the other person to rely on that fact; and
 - d. the other person reasonably relies on the misrepresented fact and is injured by having relied thereon.
2. Example of Common Law Fraud

A sells to B a necklace containing stones that A specifically told B were diamonds. However, A knew that the stones were really topaz. Here, A's false representation is for the purpose of inducing B to buy the necklace. B relies on A's false representation and is injured by reason of that reliance by having paid A money for a diamond necklace that was instead made of topaz. Thus, under the common law, A would be liable to B for B's damages, because A committed fraud against B.

3. Corresponding Elements of Inequitable Conduct
 - a. the patentee (or agent or representative or anyone associated with filing or prosecution of the application) misrepresented or failed to disclose material information to the PTO in prosecution of the patent,
 - b. the patentee knew or should have known that the information was material,
 - c. the misrepresentation or failure to disclose was intentional,

and

- d. the PTO relied on the material information that was misrepresented or omitted.

Injury occurs when the patent issues (the public is injured by the existence of the fraudulently procured patent), or when the patentee licenses or attempts to license the patent. Reliance is on the part of the examiner, namely, that the applicant and his attorney have not misrepresented or withheld anything material of which the examiner was not aware of before the patent issues.

Duty of Disclosure

- Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty.
- 37 C.F.R. §1.56 “...Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose ... all material known to the individual to be material to patentability.”

Persons Subject to Duty of Disclosure

- All individuals associated with the filing and prosecution of a patent application:
 - Each attorney or agent involved in preparing or prosecuting the application (including foreign agents); and
 - Every other person who is substantively involved with the preparation or prosecution of the application and who is associated with the inventor, assignee or with anyone to whom there is an obligation to assign the application (including company IP professionals) (37 C.F.R. §1.56)

What Must be Disclosed?

- Any information known to applicant, that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent – MPEP §2001.04
- Not limited to “prior art”

Examples of “Information”

- Use by others in the U.S. more than 1 year prior to the date of application in the United States
- Evidence that the applicant has abandoned the invention
- Evidence that the applicant did not invent the subject matter sought to be patented
- Information relevant to inventorship
- Information relevant to disclosure or failure to disclose best mode, enablement or written description
- Anything else that would show lack of compliance with the statutory requirement for patentability
 - Contrary decision of another examiner
 - Relevant documents cited in previous and pending prosecution
 - Relevant litigation documents
 - Information about prior uses and sales
- “Reasonable Examiner” standard
 - Would a reasonable Examiner have found the submission relevant to the examination of the claims?
 - From the perspective of the Examiner, not the applicant
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Sources of Information

- All individuals covered by 37 CFR §1.56
- Prior art cited in related foreign applications
- Information relating to or from co-pending U.S. patent applications
- Information from related litigation
- Information relating to claims copied from a patent

Compliance with the Duty of Disclosure

- Collect and submit prior art from inventor's file – inventor should understand the duty of disclosure
- Submit ISR and Written Opinion, including English translation
- Submit references cited in ISR, together with an English language abstract
- For non-English language documents, in the absence of a Search Report from a foreign patent office in a counterpart application (with English language version of the search report indicating the degree of relevance found by the foreign office), submit any of (i) a concise statement of relevance or (ii) an English translation of the pertinent portions of the reference (which may also happen to be an abstract)
- Submit prior art cited in office actions of counterpart applications foreign to the United States. Include English translation of office action, where available. Include English translation of portion of reference relied upon by foreign patent office.
- Cross-reference prior art cited in applications where the examiner has issued an obviousness-type double patenting rejection. Submit copies of office actions issued in the other application. Same for "related" applications, related by priority as well as by subject matter.
- Be careful to take consistent positions (on the meaning of claim terms or what the prior art discloses to one of ordinary skill) before the USPTO and foreign patent offices.

- Be careful not to introduce inaccurate statements into the specification, and confirm that all statements relating to the presentation of comparative test data in a Rule 132 Declaration are accurate.

Duration of the Duty

- Until:
 - Abandonment
 - Patent Grant (not just allowance)

Burden of Proof

To prove that a patent is unenforceable due to inequitable conduct, the alleged infringer must provide *clear and convincing evidence* of (1) affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information; and (2) an intent to deceive the examiner. *Impax Laboratories, Inc.*

Materiality

- If a misstatement or omission is material under 37 CFR §1.56, it is material.
- Under “old” Rule 56, information is material:
 - where there is a substantial likelihood that a reasonable examiner would consider it important in deciding to allow the application to issue as a patent.
- Under “new” 37 CFR §1.56, information is material to patentability when it is:
 - Noncumulative
 - Gives rise to a *prima facie* case of unpatentability
 - Refutes or is inconsistent with applicants’ position
- The court will freely adopt and apply either the old or new Rule 56

standard. *Molins PLC*

Intent to Deceive

- Inequitable conduct also requires proof of an intent to deceive. Intent is a state of mind in which a person seeks to accomplish a given result through a course of action.
- Intent need not be proven by direct evidence. Rather, intent to deceive is generally inferred from the facts and circumstances surrounding the applicant's conduct.
- Demeanor of witness before the judge is often key (credibility and character). *Molins PLC, McKesson Information Solutions Inc.*

Balancing of Materiality and Intent

- The withholding of information must meet thresholds of both materiality and intent.
- Once threshold finding of materiality and intent are established, the court weighs them to determine whether the equities warrant a conclusion that inequitable conduct occurred.
- In light of all the circumstances, an equitable judgment must be made concerning whether the applicant's conduct is so culpable (blameworthy) that the patent should not be enforced.
- The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct. *Impax Laboratories Inc.*

Entire Patent is Rendered Unenforceable

- If inequitable conduct occurred with respect to one or more claims of an application, the entire patent is unenforceable. *Kingsdown Med. Consultants, Ltd.*

Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.

81 USPQ2d 1001 (Fed. Cir. 2006)

Holding:

The Federal Circuit affirmed finding of district court that Aventis' U.S. Patent 5,527,814 was *not* unenforceable due to inequitable conduct. The Federal Circuit agreed with the district court that certain comparative test data withheld by applicants during prosecution was not material to examination.

Subject Matter:

Method of treating mammal with ALS (a neural motor disease), which comprises administering to a mammal in need of such treatment an effective amount of riluzole or a pharmaceutically acceptable salt thereof.

Product Development:

The inventor tested 8 compounds for activity against ALS using rat spinal cord cells, finding that only riluzole produced positive results for each of three parameters that were tested.

Prosecution History:

Aventis submitted comparative test data for two of the eight compounds (Pharm 1006 and Pharm 1007) that were tested, as showing unexpected results, in response to a rejection over prior art including the '940 patent which disclosed those two compounds. The examiner did not find this showing to be persuasive (because Aventis did not demonstrate that there was a reasonable correlation between tests conducted on rat spinal cord cells and treatment of ALS), and maintained the rejection. The application was subsequently allowed, but for other reasons.

Controversy:

Impax filed an ANDA (Abbreviated New Drug Application), seeking approval to market and sell generic riluzole tablets for the treatment of ALS. In a Declaratory Judgment action, Impax sought a ruling (by the court), that Aventis' patent was unenforceable due to inequitable conduct, among other things.

Specifically, Impax's contention was that during prosecution, Aventis withheld comparative test data for other compounds that were evaluated. According to Impax, the withheld data was material because some of the compounds showed better results than Pharm 1006 and Pharm 1007, and was therefore inconsistent with an argument (that the invention was

patentable because it showed unexpected results over two of the compounds) advanced by Aventis in support of patentability.

Basis for Holding:

The district court did not err in finding that Impax had failed to prove, by clear and convincing evidence, that Aventis' patent was unenforceable due to inequitable conduct.

(a) *Withheld Test Data Not Material*

While (i) some of the other compounds evaluated by Aventis showed positive results in one parameter, none of the Pharm compounds from the withheld tests produced significant results in all of the tested parameters. Thus, there was no evidence that the withheld comparative test data (by itself or in combination with other information) would give rise to a *prima facie* case of unpatentability (of the claimed compound producing positive results for each of the three parameters that were tested). Additionally, (ii) the court found that there was no evidence that the withheld comparative test data refutes or is inconsistent with a position that Aventis took during prosecution. Namely, the comparative test data was submitted to demonstrate unexpected results over compounds disclosed in the '940 patent and that was relied upon by the examiner. Aventis never suggested that this was the only test data or that other compounds were not tested. Most importantly, (iii) there was no evidence that a reasonable examiner would have considered the withheld test data to be important in deciding whether to allow the application. This is because the examiner specifically rejected the subject test data (based on rat cells) as not being indicative of effectiveness in treating ALS.

(b) *No Intent to Deceive*

Aventis disclosed test data relevant to distinguishing the '940 patent (cited prior art), but did not disclose comparative test data irrelevant to distinguishing the '940 patent. These facts, standing alone, are not enough to establish an intent to deceive.

Comment:

The generic maker will typically assert any and all defenses that have at least some chance of success (including non-infringement, invalidity over prior art, invalidity under §112 *and unenforceability due to inequitable conduct*) in an attempt to take out the patent of the "ethical" pharmaceutical company. The basis for the charge of inequitable conduct here was tenuous (weak).

Cargill Inc. v. Canbra Foods Ltd.

81 USPQ2d 1705 (Fed. Cir. 2007)

Holding:

Federal Circuit affirmed finding of district court that Cargill's U.S. Patent Nos. 5,969,169 and 6,201,145 are unenforceable due to inequitable conduct. The Federal Circuit agreed with the district court that certain test data withheld from the Examiner during prosecution was material to patentability, and that the omitted data's high degree of relevance also pointed to an intent to deceive.

Subject Matter:

A non-hydrogenated canola oil having a polyunsaturated fatty acid content of 7 to 17%, oleic acid content of 74 to 80% and an oxidative stability from 35 to 40 AOM in the absence of added antioxidants.

Prosecution History:

The pending claims were rejected over a prior art oil having a composition similar to one of Cargill's examples (IMC-30). The examiner took the position that the prior art oil would inherently have the claimed oxidative stability.

In response Cargill pointed to test data in its specification for an oil IMC-129 having a composition similar to that of the prior art oil, but whose oxidative stability differed from that of IMC-130. The purpose was to demonstrate that fatty acid composition does not necessarily determine oxidative stability. After rejecting the application five times on the issue of whether the oxidative stability of IMC 130 was superior to that of oil having a similar fatty acid composition, the examiner ultimately accepted this argument and allowed the application.

Basis for Holding:

Cargill had done extensive testing on IMC-129. In some of these tests, bench refined IMC-129 was found to have an oxidative stability comparable to that of commercially refined IMC-130. Relying on two documents that contained Cargill's internal testing data but that were not disclosed to the examiner during prosecution, the district court found that Cargill's patents were procured through inequitable conduct and therefore unenforceable.

The district court did not err in finding that Cargill's patents were unenforceable due to inequitable conduct.

(a) Materiality

Because a crucial issue during prosecution was the oxidative stability of IMC 130 as compared to IMC 129, the court found that a “reasonable examiner” would consider such test data to be important in deciding whether to allow the patents to issue. Whether the examiner would have ultimately allowed the patents to issue is irrelevant.

(b) Intent

Intent to deceive was properly inferred where, due to the repeated rejections on the issue of oxidative stability, Cargill knew or should have known that the withheld information would be material. Further, there was no error in the district court’s finding of intent in that Cargill had a motive to conceal test data showing that the improvement was no more than incremental (and therefore did not merit a patent). Lastly, the Federal Circuit agreed that the omitted data’s high degree of relevance also pointed to an intent to deceive.

Comment:

The issue of patentability was whether the prior art oil inherently had an oxidative stability within the claimed range, not whether the claimed oil was unobvious over the prior art oil. Cargill pointed to test data in its specification to show that oxidative stability is not necessarily determinative of oxidative stability. Thus, the withheld test data was not relevant *to Cargill’s argument*. However, that is not the test. The test is whether a reasonable examiner would consider the withheld test data to be important, and here the court found that to be the case.

McKesson Information Solutions Inc. v. Bridge Medical Inc.

82 USPQ2d 1865 (Fed. Cir. 2007)

Holding:

The Federal Circuit affirmed finding of district court that McKesson's U.S. Patent 4,857,716 is unenforceable due to inequitable conduct. The Federal Circuit agreed with the district court that McKesson's patent attorney withheld information highly material to patentability with intent to deceive the examiner (case of two different examiners handling related applications)

Subject Matter:

Patient identification system and method for relating items with patients and ensuring that an identified item corresponds to an identified patient.

Prosecution History:

The activities found to constitute inequitable conduct occurred during prosecution of three related applications, two examined by one examiner (Trafton) and a third by a different examiner (Lev). The court found inequitable conduct arising from the failure of McKesson's attorney to disclose three items of information deemed material to patentability.

(1) The first item was a prior art patent (Baker reference), cited by Examiner Lev in the third application, which reference contradicted McKesson's arguments in favor of patentability in the first and second applications. The reference disclosed "three-node means of communication," whereas McKesson's attorney represented to Examiner Trafton that the prior art did not teach "three-node" communication means. This representation was made 17 days before a telephone interview with Examiner Lev to discuss Examiner Lev's discovery of the Baker reference.

(2) The second item of non-disclosed information was that McKesson's attorney did not inform Examiner Trafton about the grounds of rejection of substantially similar claims pending before Examiner Lev (although McKesson's attorney did inform Examiner Trafton of the third application being examined by Examiner Lev), where McKesson cancelled claims in the third application in the face of the Baker reference.

(3) The third item of undisclosed material information was the allowance of one of the applications, where the allowance might have provoked an obviousness-type double patenting rejection. Specifically, McKesson's attorney did not remind Examiner Trafton that he had allowed the second, related CIP application prior to issuance of the original parent application.

Controversy:

Action by McKesson against Bridge Medical for patent infringement. McKesson appealed to the Federal Circuit after the district court found McKesson's patent unenforceable due to inequitable conduct and dismissed McKesson's infringement suit.

Basis for Holding:

The district court did not err in finding that McKesson's patent was unenforceable.

(a) Materiality

The court found that the Baker reference was not cumulative and was highly material because it discloses three-way communication, because the claims of the third application were rejected over the Baker reference, and because one of McKesson's primary arguments for patentability of the first application was the use of three-way communication. That is, the court found that "a reasonable examiner would have been substantially likely to consider the Baker patent important to the evaluation of the application" examined by Examiner Trafton. The court found Examiner Lev's rejection in the third application to be material because the rejected claims were substantially similar to the claims pending before Examiner Trafton. Regarding this last point, the court pointed to its precedent in that a contrary decision of another examiner reviewing a substantially similar claim is material and must be disclosed to the PTO. Further, the court found that the allowance in the second application was material and should have been disclosed to Examiner Trafton because due to their similarity, the allowed claims could conceivably have given rise to a double patenting rejection.

(b) Intent to Deceive

The court found that McKesson's attorney (Schumann) knew or should have known of the materiality of the Baker reference from Examiner Lev, and thus failure to disclose the Baker reference to Examiner Trafton evinced an intent to deceive Examiner Trafton. This inference was borne out when Schumann chose not to fight the rejection based on Baker, and instead cancelled the claims rejected by Examiner Lev based on Baker reference. As to the third item, the court did not find Schumann's explanation, namely, that the claims of the allowed CIP application and the parent were not sufficiently similar to qualify the allowance of the CIP as material, to be credible. Other factors in finding intent to deceive were that Schumann submitted the same prior art references to both examiners (i.e., Schumann knew that the three applications were related) and Schumann's statement to the court that he would have done nothing differently having the benefit of hindsight. The court interpreted this assertion as evidence of an intent to deceive.

Comment:

The ruling in McKesson calls for disclosure of the existence of related applications, disclosure of the course of prosecution of the related applications, and disclosure of all references cited in the related applications. This is done by submitting copies of office actions and references cited in the respective related applications. How do we know if applications are sufficiently related to require such treatment? The court's finding as to the third item (failure of the applicant to remind Examiner Trafton that he allowed the second, related CIP application prior to issuance of the original parent application) seems unrealistic. Don't we presume that the examiner is doing his job properly?

Molins PLC v. Textron Inc.
33 USPQ2d 1823 (Fed. Cir. 1995)

Holding:

The Federal Circuit affirmed the finding of the district court that Molins' U.S. patents 4,369,563 and 4,621,410 were unenforceable due to inequitable conduct. The Federal Circuit agreed with the district court that Molins' attorney withheld highly material prior art with intent to deceive the examiner.

Subject Matter:

Batch and automated (system 24) machining systems. Molins, a UK corporation, filed a British patent application for the batch process and filed counterpart applications in a number of countries, including the U.S. Subsequently, Molins filed applications for the system 24 in the UK, U.S. and in other countries. The U.S. batch application ('563 patent, issued January 1983) was combined with the U.S. system 24 application in a CIP. The '410 patent (issued November 1986) was directed to system 24 process.

Prosecution History:

Whitson, in Molins' IP department, and during prosecution of Molins' two U.S. applications, became aware of a "Wagenseil reference." Whitson concluded that the Wagenseil reference anticipated the batch process claims that Molins initially filed in the UK and in many other countries including the U.S. Whitson abandoned all of the foreign patent applications directed to the batch process. However, Whitson decided not to abandon the pending U.S. application because it contained both batch and system 24 claims.

Prosecution of the U.S. and foreign system 24 applications continued. Wagenseil was cited to and by several foreign patent offices, but was not cited by Molins to the USPTO. Eventually, Molins abandoned all foreign system 24 applications. However, the '563 patent including the system 24 claims issued in January 1983).

Hirsh succeeded Whitson as Molins' IP manager in 1983. In reviewing the system 24 foreign files that had been abandoned, he found that the Wagenseil reference had not been cited in the U.S. applications. Hirsh submitted the Wagenseil reference as a Prior Art Submission under Rule 501, even though the '563 patent had already issued.

The '563 patent survived a third party reexamination request, where the Wagenseil reference was considered and made of record (1985). The '410 patent issued in 1986.

Controversy:

Subsequently, Molins filed suit against Textron, Inc. and others (1986), alleging infringement of its two patents. In its defense, Textron asserted that the patents were

unenforceable due to inequitable conduct *in connection with the prosecution of the '563 patent*, and in particular, concealment of the Wagenseil reference. Further, the court also concluded that the inequitable conduct in prosecution of the '563 patent extended to the '410 patent, such that the '410 patent was unenforceable as well, since that patent “relied on the '563 patent.” The district court agreed, holding that the '563 patent was unenforceable. The court also found the case to be “exceptional,” and ordered Molins liable for all of the defendant’s attorney fees, costs and expenses.

Basis for Holding:

The district court did not err in finding that Molins engaged in inequitable conduct, thus rendering both patents unenforceable.

(a) Materiality

The court found that the Wagenseil reference disclosed new combinations of features and new individual features not shown in the references before the examiner (i.e., the Wagenseil reference was not cumulative). Thus, the court found that Wagenseil was material, even though the examiner did not rely on this reference in reexamination. Further the court based its finding of materiality on evidence showing that Whitson indicated during foreign prosecution that Wagenseil was the most relevant prior art to the foreign system 24 applications of which he was aware. Also of importance was that patent examiners in several foreign countries also considered Wagenseil to be material to the system 24 claims, and that Whitson had amended and distinguished system 24 claims in foreign patent offices over Wagenseil. “We cannot say that the court clearly erred in finding that a reasonable examiner would have considered Wagenseil important in deciding the patentability of the pending system 24 claims in the U.S. application.”

(b) Intent

The court rejected Molins’ argument that Whitson had acted in good faith and simply overlooked Wagenseil, since Whitson had focused on that reference several times during 10 years of foreign prosecution yet never cited this reference to the USPTO. “We cannot say that the court improperly inferred that Whitson made a deliberate decision to withhold a known, material reference. Failure to cite to the PTO a material reference cited elsewhere in the word justifies a strong inference that the withholding was intentional.”

Comment:

The Molins decision highlights the importance of submitting prior art cited in foreign counterpart applications. Note “infectious” inequitable conduct which also rendered the '410 patent unenforceable.

Therasense Inc. v. Becton, Dickinson & Co.
93 USPQ2d 1489 (Fed. Cir. 2010)

Holding:

The Federal Circuit affirmed the ruling of the district court that Abbott's U.S. Patent 5,820,551 relating to glucose test strips (for monitoring blood sugar) is unenforceable due to inequitable conduct. The Federal Circuit agreed with the district court that in prosecuting the application which issued as the '551 patent, Abbott's patent attorney and its head of R&D withheld from the USPTO contradictory statements that they made regarding relevant company prior art in proceedings at the EPO. "An applicant's earlier statements about prior art, especially one's own prior art, are material to the PTO when those statements directly contradict the applicant's position regarding that prior art in the PTO," the court said.

This holding conflicts with previous decisions that have held that statements concerning prior art made by an applicant's attorney are merely argument and are thus not material.

The Federal Circuit granted Abbott's petition for rehearing *en banc*, asking the parties to address issues relating to the inequitable conduct analysis including the proper standard for materiality, the balance between the materiality and intent elements and under what circumstances is it proper to infer intent from materiality.

Subject Matter:

Glucose test (electrode) strips for monitoring blood sugar.

Prosecution History:

Abbott pursued the '551 patent over a period of 13 years and half-a-dozen continuation applications that were repeatedly rejected for anticipation and obviousness, including repeated rejections over the '382 patent (Abbott's own prior art). New claims were drafted to distinguish over the '382 patent including electrochemical sensors lacking a membrane. Pope (Abbott's patent attorney) presented the new claims with the argument that the claims defined a new glucose sensor that did not require a protective membrane when testing whole blood. Pope and the examiner discussed a relevant passage in the '382 patent which characterized the membrane as "optionally, but preferably present." In Pope's summary of the interview, he stated that he "pointed out that [the '382 patent] teaches that active electrodes designed for use with whole blood require a protective membrane." The examiner agreed that if Abbott produced an affidavit showing that at the time of the invention such a membrane was considered essential, it would overcome the '382 patent.

In accordance with that agreement, Dr. Sanghera (Abbott's head of R&D) submitted an opinion Declaration to the effect that based on his knowledge, one skilled in the art would have

felt that a protective membrane would be required, and that he was sure that one skilled in the art would not read the passage of the '382 patent at issue as teaching that the use of a protective membrane with a whole blood sample is "optionally or merely preferred." The examiner then allowed the application which issued as the '551 patent.

However, Abbott was also involved in defending its EP 0 078 636, a counterpart of the '382 patent with virtually identical specifications, which was revoked as being obvious over a reference D1. Abbott's patent counsel submitted to the EPO a brief distinguishing EP '636 from a reference D1 (said to require a membrane), stating "Contrary to the semipermeable membrane of D1, the protective membrane [is] optionally utilized with the glucose sensor ..." and in characterizing the subject passage of EP '636 stated:

"It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood ..."

Abbott's argument was that because the membrane in EP '636 (i.e., the membrane in the counterpart '382 patent) is optionally used, it was different from the type of membrane required by D1.

Controversy:

Becton, Dickinson & Co. brought a declaratory judgment action against Abbott, asserting that two of Abbott's glucose test strip patents were not infringed. Abbott countersued, and also brought infringement suits against other defendants. The suits were consolidated. The district court issued a summary judgment order finding, among other things, that the '551 patent was unenforceable due to inequitable conduct. Abbott appealed.

Basis for Holding:

(a) *Materiality*

The court found that Abbott made directly contradictory representations to the EPO concerning the teaching of the '382 patent in the EP '636 revocation proceedings, and that Abbott had not disclosed those contradictory representations to the PTO. Particularly, the court found that Abbott had argued to the EPO that the protective membrane of EP '636 was optional, but to overcome anticipation rejections of the '551 patent based on the '382 patent (counterpart of EP '636), asserted to the PTO that the '382 patent required a protective membrane.

Abbott's position was that lawyer argument about prior art is not information material to patentability, and that since both the EPO and PTO representations were merely argument, any inconsistency between the two could not be material. However, the court found that these conflicting statements were made not only through argument by Abbott's patent attorney, but also in affidavit form from its R&D director (i.e., factual assertions as to the views of those skilled in the art, provided in affidavit form). Further, although noting that it is the court's

precedent that an applicant is free to advocate its interpretation of its claims and the teachings of the prior art to secure allowance, none of the cases cited by Abbott involved a situation in which contradictory arguments made in another forum were withheld from the PTO.

The court found that the EPO statements were highly material because they contradicted Abbott's position taken before the PTO.

(b) Intent

In concluding that Pope and Sanghera intended to deceive the PTO by withholding the EPO documents, the court found (1) that the statements made to the PTO were critical in overcoming the rejection based on the '382 patent; (2) the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO; (3) Pope and Sanghera both knew of the EPO statements and consciously withheld them from the PTO; (4) neither Pope nor Sanghera provided a credible explanation for failing to submit the EPO documents to the PTO; and (5) Pope and Sanghera's explanations for withholding the EPO documents were so unbelievable that they suggested an intent to deceive.

The court further noted that Pope relied on the R&D director who the court found was not a person having ordinary skill in the art at the time of the '382 patent (in 1983), to provide a declaration as to the teachings of the '382, rather than on the inventors of the '382 patent. Dr. Higgins, an inventor of both the '382 and '551 patents testified that his patent taught that a membrane is probably needed, but not definitely, and stated that Dr. Sanghera's declaration statements were simply "wrong."

The Federal Circuit found that the district court "amply supported" the findings that Pope and Sanghera intended to deceive the PTO by withholding the EPO documents. Agreeing that the EPO submissions were highly material to prosecution of the '551 patent and that Pope and Sanghera intended to deceive the PTO by withholding those submissions, the Federal Circuit affirmed the district court ruling.

Comment:

Be careful to take consistent positions on the meaning of claim terms or what the prior art teaches to one of ordinary skill before the U.S. examiner and in foreign patent offices (e.g., opposition briefs).

AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA Inc.

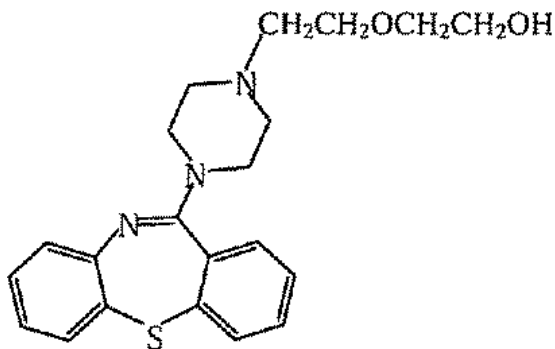
92 USPQ2d 1481 (Fed. Cir. 2009)

Holding:

The Federal Circuit affirmed the finding of the district court that AstraZeneca's U.S. Patent 4,879,288 is not unenforceable due to inequitable conduct. The Federal Circuit agreed with the district court that AstraZeneca did not commit material withholding by failing to disclose existing test data for prior art compounds, since the compounds for which AstraZeneca did submit comparative test data were structurally closer to the claimed compound than the compounds for which test data was not submitted.

Subject Matter:

An "atypical" antipsychotic drug quetiapine having the formula:



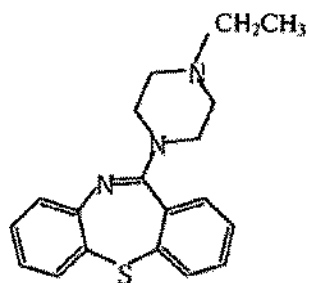
Quetiapine

Unlike "typical" antipsychotics, atypical antipsychotics do not produce involuntary body movements such as spasms, tongue protrusions, etc.

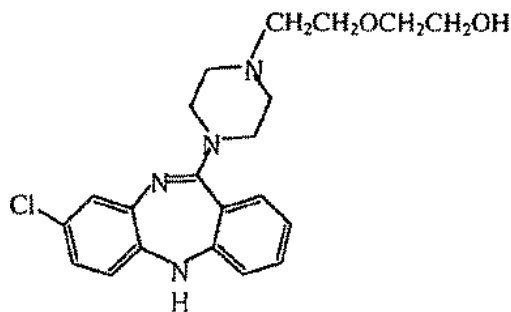
Prosecution History:

During prosecution of the '288 patent, AstraZeneca submitted an IDS disclosing various prior art compounds having structures similar to that of the claimed antipsychotic. AstraZeneca also had test data for the various prior art compounds submitted in the IDS, as well as for many other compounds. This was data generated in the course of research leading to quetiapine.

The examiner rejected the claimed compound over structurally similar prior art compounds Schmutz X and the Horrom compound having the structures shown below.



Schmutz X

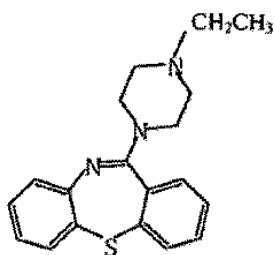


Horrom Compound

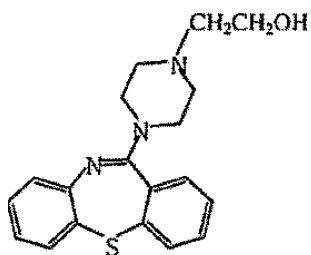
In response, AstraZeneca urged that the “atypical” property of antipsychotics was unpredictable, and that the prior art provided no reason to make the particular claimed compound for the purpose of obtaining atypical antipsychotic properties. The examiner maintained the rejection, requiring AstraZeneca to show that the prior art compounds Schmutz X and the Horrom compound did not possess the characteristics of the claimed compound:

“... it must be overcome by a side-to-side comparison with the closest art compound(s). In this case, one would test both the prior art species (Horrom Compound and Schmutz X) and the claimed compound for their ability to avoid whatever undesirable side effect that applicant wishes to focus on.”

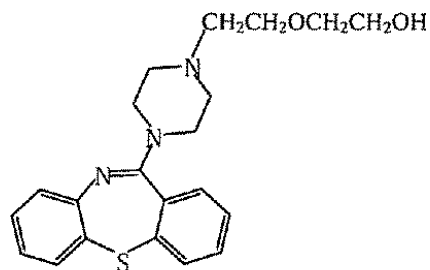
In response, AstraZeneca submitted the Declaration of one of the inventors (Dr. Migler), with test data for the Horrom Compound and a Schmutz B compound. AstraZeneca’s attorney explained that AstraZeneca did not have psychotic test data for Schmutz X, and that such data would be very expensive to generate. As a substitute, AstraZeneca offered pre-existing internal data for Schmutz B, which the inventors believed was structurally closer than Schmutz X because the hydroxyethyl side-chain of Schmutz B is more similar to quetiapine’s side-chain than is the ethyl side-chain of Schmutz X.



Schmutz X



Schmutz B



Quetiapine

The Declaration contained psychotic test data showing that the Horrom compound's properties were "typical." The Declaration also contained test data for Schmutz B, and showed that it too was "typical."

Controversy:

Teva (and Sandoz) each filed ANDA's (Abbreviated New Drug Application) for approval to sell generic quetiapine, certifying that the '288 patent is invalid and/or not infringed. AstraZeneca filed infringement suits against Teva and Sandoz. On appeal is the holding of the district court that there was no inequitable conduct in prosecution of the '288 patent application. Teva appeals from the decision of the district court.

Teva's inequitable conduct charge was based on the fact that AstraZeneca did not submit to the PTO its internal test data for other prior art compounds. Particularly, Teva alleged that it was a material withholding to provide test data only for the compounds relied upon by the examiner, stating that AstraZeneca's internal test data showed that compounds other than quetiapine possessed potential "atypical" antipsychotic activity. Thus, Teva argued that AstraZeneca's Declaration was deliberately misleading.

Holding:

The district court found that AstraZeneca properly addressed the closest prior art, and in response to the examiner's specific requests

(a) Materiality

Teva failed to provide any evidence of its assertions that AstraZeneca made any material misrepresentations during prosecution (namely, that it was "too expensive" to provide test data for the Schmutz X compound, or that AstraZeneca did not have test data for the Schmutz X compound). Further, the court found that "a reasonable examiner would not have understood the Migler Declaration as stating that no prior art product had the atypical property shown by quetiapine ... a reasonable examiner would have understood AstraZeneca's statements to refer to the closest prior art compounds, not all prior art compounds." Thus, the evidence did not support a finding that AstraZeneca misrepresented or omitted material information, despite AstraZeneca's failure to disclose all its prior art compound data.

(b) Intent

The court also found that Teva did not establish deceptive intent by clear and convincing evidence. Teva argued that due to the "high degree of materiality" of AstraZeneca's withheld information, Teva therefore needed a proportionally less showing of intent to deceive to establish the requisite threshold level of intent. Teva's only evidence of deceptive intent was the existence of undisclosed test data. The court noted, however, intent to withhold is not the same as intent to deceive. In the absence of any evidence of bad faith, the court found that AstraZeneca

“presented plausible reasons for its presentation of arguments and data during prosecution” which did not support a finding of deceptive intent.

Comment:

Here, AstraZeneca provided test data for a compound that it argued was structurally closer to the claimed compound than the cited prior art compound, and the examiner accepted that argument. If Teva had uncovered evidence that AstraZeneca did have test data for the cited prior art compound, but instead withheld that test data and offered the substitute test data instead, then Teva would have had stronger grounds for its inequitable conduct charge.

Exergen Corp. v. Wal-Mart Stores Inc.
91 USPQ2d 1565 (Fed. Cir. 2009)

Holding:

Defendant in an infringement lawsuit must plead a charge of inequitable conduct with particularity as to facts alleged (naming specific individual associated with filing of application, who knew of material information and deliberately withheld or misrepresented it, identifying patent claims and limitations to which the withheld reference is relevant, and where in those references material information is found – who, what, where, when and why), and allege sufficient facts from which a court may reasonably infer an intent to deceive or intent to withhold material information.

Subject Matter:

Infrared thermometers and methods for measuring human body temperature.

Controversy:

Exergen sued SAAT, Wal-Mart and others for infringement of its patents relating to infrared thermometers. SAAT moved the district court to add inequitable conduct as an affirmative defense. The district court denied SAAT's motion, holding that SAAT's pleading failed to allege inequitable conduct with particularity.

Basis for Holding:

Rule 9(b) – Rules of Civil Procedure

9(b) Fraud or Mistake; Condition of Mind.

In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

SAAT's pleading included allegations that during prosecution, Exergen was aware of material prior art that Exergen cited in prosecution of other patent applications, but failed to submit in prosecution of the application at issue. SAAT also alleged that information on its website was inconsistent with certain arguments made in the Remarks portion of an Amendment as to what had not been generally appreciated by those skilled in the art of temperature measurement.

The court found SAAT's pleadings to be insufficient, because the pleading referred generally to Exergen, its agents and/or attorneys, but failed to name the specific individual

associated with prosecution of the application, who both knew of the material information and deliberately withheld or misrepresented it (noting that the duty applies to individuals, not to organizations).

Second, the pleadings failed to identify which claims, and which limitations in those claims, the withheld references were relevant to, and where in those references the material information is found.

Third, the pleadings did not explain “why” the withheld information was material and not cumulative.

Further, the court found that the facts alleged by SAAT do not give rise to a reasonable inference of intent to deceive or withhold material information.

For example, the pleading states that Exergen was aware of the subject prior art that was allegedly withheld during prosecution of Exergen’s other patent applications, but provides no factual basis to infer that any specific individual, who owed a duty of disclosure in prosecution of the application at issue, knew of the specific information in the prior art reference that is alleged to be material. Particularly, the court noted that one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material information contained in that reference.

“The mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct.”

Comments:

Allegations of infringement, noninfringement and invalidity may be pleaded generally “on information and belief” (e.g., patent claims 1-10 are invalid as being obvious over reference A in view of B) . However, inequitable conduct as an affirmative defense by the accused infringer must be pleaded with particularity. Although Rule 9(b) states that “Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally,” the law of the Federal Circuit “requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.”

Some practitioners consider that the holding of this panel of the Federal Circuit is at odds with the holding in the McKesson decision, where another panel of the Federal Circuit found that patentee’s counsel “knew or should have known” of the materiality of a reference cited by one examiner and thus was under an affirmative obligation to disclose the reference to another examiner in a related application. However, all of these inequitable conduct decisions turn on their specific facts. In McKesson, the same attorney that cancelled claims in a second

application before a second examiner in view of a reference disclosing X didn't submit X to a first examiner in examination of a first application with substantially similar claims, and where the attorney had previously argued to the first examiner that the prior art did not teach X. There is plenty in the facts of McKesson which would allow a court to reasonably infer an intent to deceive.