

Abstract

The court held that a PCT publication is a public document, suitable for use as prior art that can be used against the PCT applicant if it is published more than 1 year before the filing of the applicant's U.S. national application. Here, applicant was unable to invoke a priority date due to not meeting the minimum statutory filing requirements necessary to secure the earlier date, which was ahead of the PCT publication date.

BAXTER INTERNATIONAL, INC., and BAXTER HEALTHCARE CORPORATION,
Plaintiffs-Appellants, v. MCGAW, INC., Defendant-Cross Appellant.

96-1329, 96-1342, 97-1331, 97-1350

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

June 30, 1998, Decided

COUNSEL: James F. Davis, Howrey & Simon, of Washington, DC, argued for plaintiffs-appellants. With him on the brief were Jerrold J. Ganzfried, Richard H. Kjeldgaard, and Thomas M. Dunham. Also on the brief were Timothy J. Malloy, Gregory J. Volger, and Sharon A. Hwang, McAndrews, Held & Malloy, Ltd., of Chicago, Illinois. Of counsel on the brief was Mark J. Buonaiuto, Baxter International, Inc., of Deerfield, Illinois. Of counsel was Stephen F. Sherry, McAndrews, Held & Malloy, Ltd.

Roderick G. Dorman, and William J. O'Brien, Christie, Parker & Hale, LLP, of Pasadena, California, argued for defendant-cross appellant. With them on the brief was Yar R. Chaikovsky. Also on the brief was Marvin A. Miller, Miller Faucher Chertow Cafferty and Wexler, of Chicago, Illinois. Of counsel was John D. Carpenter, Christie, Parker & Hale, LLP.

JUDGES: Before PLAGER, RADER, and GAJARSA, Circuit Judges.

OPINIONBY: GAJARSA

GAJARSA, Circuit Judge.

DECISION

Baxter International, Inc. and Baxter Healthcare Corporation (collectively Baxter), appeal the judgment of the U.S. District Court for the Northern District

of Illinois that U.S. Patent No. 5,171,234 (the '234 patent), U.S. Patent No. 5,167,648 (the '648 patent) and U.S. Patent No. 5,158,554 (the '554 patent) assigned to Baxter are unenforceable due to inequitable conduct for failure to cite material prior art to the U.S. Patent and Trademark Office (PTO). We affirm the district court's decision with respect to the '648 and '234 patents but reverse the district court's holding that the '554 patent is similarly unenforceable. Baxter also appeals the district court's construction of claim 16 of the '648 patent and claim 3 of the '554 patent which Baxter alleges led to an improper validity and infringement analysis by the jury. Finally, Baxter argues that the district court erred in refusing to grant it a new trial based upon what Baxter deems an unreasonable delay between the close of trial and submission of the case to the jury. We affirm the district court's denial of Baxter's request for a new trial.

OPINION:

McGaw, Inc. (McGaw) cross-appeals the district court's decision and alleges that the applications from which the '554, '234, and '648 patents issued failed to satisfy the requirements of 35 U.S.C. § 120¹ and that those patents are therefore invalid under 35 U.S.C. § 102(b) as anticipated by prior art. McGaw cross-appeals the district court's denial of its motion for judgment as a matter of law (JMOL) based upon the alleged invalidity of the '234, '554, and '648 patents. We reverse the district court's failure to enter JMOL in favor of McGaw with respect to the '554 patent based upon that patent's anticipation under 35 U.S.C. § 102(b). Because we affirm the district court's decision that the '234 and '648 patents are unenforceable due to inequitable conduct, we do not address their validity.

BACKGROUND²

The present case involves three patents directed to an improved method for administering intravenous fluids and medications. Conventionally, when a hospital patient requires intravenous (IV) fluids, a catheter is inserted into the patient's vein through the skin. An IV administration set is then used to connect an IV fluid source to the catheter. The administration set includes access ports called injection sites through which medicine or other necessary fluids can be added to the IV fluid source as it passes to the catheter. Conventional injection sites typically include a solid rubber septum that is pierced by a sharp steel needle in order to introduce fluids and medication into the IV system. A typical injection site 16 and its relationship to the entire IV system is depicted below:

¹ Because the operative facts of this case occurred in 1988, all United States Code and Code of Federal Regulations citations are to the 1988 editions

² In its Memorandum Opinion and Order, *Baxter Int'l, Inc. v. McGaw Inc.*, 1996 U.S. Dist. LEXIS 3768, No. 95-C-2723, 1996 WL 145778 (N.D. Ill. Mar. 27, 1996), the district court fully expounds the technological and procedural background surrounding the invention and accused device at issue. Provided here is only that background necessary to understand the disposition of the issues on appeal

Although using sharp needles to pierce the rubber septum is desirable in administering medications in an IV system, it also presents a dangerous risk of accidental pricks from contaminated needles, causing a significant health risk to hospital personnel. Attempts to use blunt instruments to insert medication into the IV system have in the past resulted in unacceptable leakage problems.

In 1986, Baxter engineers, Dr. Thomas Dudar and Mr. Steven Jepson, were involved in a project ("the Volts project") which attempted to solve the problems of leakage and coring of a solid rubber septum when punctured multiple times by large needles. During the course of this project, Dudar and Jepson experimented with an injection site made by Borla S.p.A., an Italian manufacturer of rubber septa and other medical products. The district court found that the Borla injection site model PF0084 ("the Borla Device") used a solid rubber septum which was placed under radial pressure and was designed to be pierced with a sharp needle. The radial pressure increased resealability and reduced leakage. The district court found that the Borla Device also included annular channels which received the displaced septum when a large needle punctured the rubber septum and reduced tearing upon insertion of the needle. The district court also found that the Borla Device used a supportive annular lip underlying the septum. Finally, the district court found that the Borla Device included a deformation of the injection site housing which caused axial forces to act upon the septum and resulted in an outwardly curved septum surface. Each of these features was claimed in differing forms in the '648 and '234 patents.

During the course of the Volts project, Dudar and Jepson developed an injection site that included an annular channel and a septum under radial compression as in the Borla Device, but with the added feature that the septum was partially slit. The pre-slit septum was designed to be pierced by a blunt cannula instead of a sharp needle. The resulting system not only solved the problems of leakage due to multiple punctures and coring, but also eliminated the sharp needle from the injection system. Baxter commercially developed this invention and incorporated it into its InterLink injection system. On January 25, 1988, Baxter filed patent application number 07/147,414 (the '414 application) on this invention in the PTO.

Baxter's '414 application was originally filed containing claims numbered 1-59. On July 5, 1988, Baxter filed a preliminary amendment canceling claims 1-59 and adding new claims 60-120. The PTO entered this amendment and on January 13, 1989, the PTO issued a restriction requirement pursuant to 35 U.S.C. § 121. The January 13, 1989, Office Action stated that there were a total of four separate inventions defined by the '414 application. Claims 60-87 and 101-08 were drawn to an injection site and method of manufacturing; claims

110-17 were drawn to a cannula; claims 95-99 and 118-20 were drawn to a combination of an injection site and cannula; and claims 100 and 109 were drawn to a method of transferring liquids. In a response dated April 9, 1989, Baxter amended claims 95 and 96, cancelled claims 118-20 and added new claims 121-24. The examiner issued a final rejection of this application on December 14, 1989. On June 11, 1990, Baxter mailed a request under 37 C.F.R. § 1.60 to file the divisional application that resulted in the issuance of the '648 patent. In the filing, Baxter simultaneously requested that claims 1-59, 95-100, and 109-24 be formally cancelled from the application. However, the filing only included a copy of the original application with claims 1-59. The PTO assigned this application the number 07/535,935 (the '935 application). On June 26, 1990, the PTO Application Branch mailed Baxter a Notice of Incomplete Application which indicated that the divisional application could not be assigned a filing date because claims 60-124 were missing from the application. The notice indicated that the '935 application's filing date would be the date the PTO received these claims. The '414 application became abandoned by operation of law on June 14, 1990. On July 16, 1990, Baxter submitted the claims 60-124 that had been omitted from the divisional application. The PTO then gave notice of abandonment of the '414 application on July 17, 1990 and assigned the '935 application a filing date of July 16, 1990. Upon Baxter's petition to correct the filing date, the PTO changed the effective filing date of the '935 application to June 11, 1990. The '935 application ultimately issued on December 1, 1992 as the '648 patent.

On June 12, 1990, Baxter mailed the divisional applications that resulted in the '554 and '234 patents. These applications were assigned application numbers 07/537,395 (the '395 application) and 07/536,823 (the '823 application), respectively. Similar to the '935 application, the '395 and the '823 applications also lacked claims 60-124 and requested cancellation of, among others, claims 1-59, the only claims mailed with the applications. On December 17, 1990, the PTO notified Baxter that all claims in both of these applications had been cancelled. On January 4, 1991, Baxter mailed copies of claims 60-124 for inclusion in both applications. The '395 and '823 applications were ultimately issued as the '554 and '234 patents, respectively.

In addition to the United States applications, Baxter filed an International Patent Application under the Patent Cooperation Treaty (PCT) on January 23, 1989. The application was published on July 27, 1989, and became a public document on that date. Baxter's PCT application contained a written description that was identical to that filed in each of its U.S. applications.

On May 5, 1995, Baxter filed a complaint in the Northern District of Illinois alleging that McGaw's Safeline needleless injection system infringed Baxter's

'234, '554, and '648 patents. McGaw defended by alleging that Baxter's patents were invalid and unenforceable due to inequitable conduct before the PTO. Opening statements began December 13, 1995. At the close of evidence on February 2, 1996, the jury was excused until March 6, 1996, at which time the court instructed the jury. The jury then began deliberations. The jury found that the asserted claims of the '234 and the '648 patents were valid but were not infringed and found that the asserted claims of the '554 patent were infringed under the doctrine of equivalents, but that they were also invalid over the prior art.

In a written opinion dated March 26, 1996, the district court found that Baxter had committed inequitable conduct in the course of prosecuting the '234 and '648 patents because the inventors failed to disclose the Borla Device to the PTO as prior art. At that time, the court declined to find the '554 patent unenforceable due to inequitable conduct. McGaw subsequently moved the court to find the '554 patent unenforceable due to inequitable conduct because all three patents stemmed from the same parent application. In a Memorandum Opinion and Order dated March 17, 1997, the district court granted McGaw's motion to supplement the March 26, 1996 judgment and held the '554 patent unenforceable for inequitable conduct under a theory the district court termed as "infectious unenforceability" presumably based upon the finding of inequitable conduct attributable to the '414 application. See *Baxter Int'l, Inc. v. McGaw, Inc.*, 958 F. Supp. 1313, 1315 (N.D. Ill. 1997).

Baxter appeals the district court's judgment that the '234, '554, and '648 patents are unenforceable for inequitable conduct; the district court's construction of claim 16 of the '648 patent; and the district court's instructions to the jury. Baxter additionally claims that the district court abused its discretion in refusing to grant a new trial due to the delay between the close of evidence and the beginning of jury deliberations. McGaw cross-appeals the district court's denial of its motion for JMOL on the issue of invalidity under 35 U.S.C. § 102(b). McGaw asserts that the '234, '554, and '648 patents are anticipated by Baxter's published PCT application because the patents in suit are not entitled to the filing date of the '414 application due to a lack of co-pendency pursuant to 35 U.S.C. § 120. Our jurisdiction over this appeal is authorized by 28 U.S.C. § 1295(a)(1).

DISCUSSION

B. Inequitable Conduct in the Prosecution of the '234 and '648 Patents

Baxter first challenges the district court's finding that the '234 and '648 patents are unenforceable due to inequitable conduct. Although Baxter does not

specifically appeal the district court's March 17, 1997, Opinion and Order extending this finding to the '554 patent as well, we presume that the arguments made regarding the '234 and '648 patents are intended to be equally applicable to the '554 patent.

Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. See *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 U.S.P.Q.2D (BNA) 1097, 1105-06 (Fed. Cir. 1998) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 U.S.P.Q.2D (BNA) 1823, 1826 (Fed. Cir. 1995)). Determination of inequitable conduct requires a two step analysis. First, the trial court must determine whether the withheld reference meets a threshold level of materiality. The trial court must then also determine whether the evidence shows a threshold level of intent to mislead the PTO. See *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439, 17 U.S.P.Q.2D (BNA) 1834, 1838 (Fed. Cir. 1991). These threshold determinations are reviewed by this court under the clearly erroneous standard of Federal Rule of Civil Procedure 52(a). See *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872, 9 U.S.P.Q.2D (BNA) 1384, 1389 (Fed. Cir. 1988) (in banc). Once the threshold levels of materiality and intent have been established, the trial court is required to weigh materiality and intent. See *Molins*, 48 F.3d at 1178. The more material the omission, the less evidence of intent will be required in order to find that inequitable conduct has occurred. See *N.V. Akzo v. E.I. du Pont de Nemours & Co.*, 810 F.2d 1148, 1153, 1 U.S.P.Q.2D (BNA) 1704, 1708 (Fed. Cir. 1987). In light of all the circumstances, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable. See *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1070, 22 U.S.P.Q.2D (BNA) 1025, 1028 (Fed. Cir. 1992). We review the district court's ultimate determination of inequitable conduct under an abuse of discretion standard. See *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1541, 41 U.S.P.Q.2D (BNA) 1829, 1834 (Fed. Cir. 1997); *Halliburton*, 925 F.2d at 1440; *Kingsdown*, 863 F.2d at 876.

A reference is deemed material if there "is a 'substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'" *Halliburton*, 925 F.2d at 1440 (quoting 37 C.F.R. § 1.56 (1989)); see also *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559, 223 U.S.P.Q. (BNA) 1089, 1092 (Fed. Cir. 1984). Thus, the initial question before this court is whether the district court was clearly erroneous in

finding that the Borla Device would have been important to a reasonable examiner in deciding whether to allow the applications to issue³. However, we also note that a patentee need not cite an otherwise material reference to the PTO if that reference is merely cumulative or is less material than other references already before the examiner. See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582, 18 U.S.P.Q.2D (BNA) 1001, 1014-15 (Fed. Cir. 1991); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 992, 6 U.S.P.Q.2D (BNA) 1601, 1609 (Fed. Cir. 1988).

Baxter makes two arguments with respect to the materiality of the Borla Device. First, Baxter argues that the Borla Device is not material to the claimed inventions because it does not contain all of the claimed limitations and therefore it is less material than other prior art cited to the examiner. In particular, Baxter argues that because the Borla Device does not use a pre-slit septum in conjunction with a blunt cannula, it cannot be more material than other cited references. Second, Baxter argues that the Borla Device is merely cumulative of other prior art already cited to the examiner. We address each of these arguments in turn.

In its analysis of the materiality of the Borla Device, the district court concluded that the Borla Device "has all of the features of the InterLink injection site, in the exact same form, except for the slit in the septum." Baxter's main argument on appeal is that, given the importance of the pre-slit septum to the claimed invention, this difference alone is sufficient to make the Borla Device non-material. We disagree. A difference in a single element, however important to the patented invention, is not automatically dispositive of the issue of materiality. The patent claims require more than merely a pre-slit septum and a blunt cannula, they also require an annular channel, an annular lip, a deformation of the first end of the housing, and axial and radial forces. References lacking different elements are often combined to reject an application under 35 U.S.C. § 103. Simply because the Borla Device lacked a pre-slit septum does not make it likely that a reasonable examiner would consider the reference unimportant in deciding whether to allow the patent. In other words, materiality is not analyzed in a vacuum. It is not dependent on a single element viewed in isolation. Rather, it is judged based upon the overall degree of similarity between the omitted reference and the claimed invention in light of the other prior art before the examiner. See *Halliburton*, 925 F.2d at 1441-42. The district court therefore properly considered the totality of the

³ We recognize that this standard reflects an older PTO rule in effect at the time the instant patents were prosecuted and that the current PTO rule defines materiality differently. See *Nobelpharma*, F.3d at , 46 U.S.P.Q.2D (BNA) at 1107 n.8 (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257, 43 U.S.P.Q.2D (BNA) 1666, 1669-70 (Fed. Cir. 1997) (quoting 37 C.F.R. § 1.56(b)(2)(ii) (1996)))

claimed features in determining whether the Borla Device was material to the patentee's application.

Baxter's argument that the Borla Device "teaches away" from the claimed invention is similarly without merit. While "the trial court must consider portions of prior art references which teach away from the claimed invention," *id.* at 1441, Baxter apparently misapprehends what it means to "teach away" from a patented invention. "In general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2D (BNA) 1130, 1131 (Fed. Cir. 1994). There is nothing in the Borla Device to suggest to one of skill in the art that a similar device under radial compression with a pre-slit septum was unlikely to work. While the Borla Device does not teach that a pre-slit septum is likely to succeed in overcoming the coring and leakage problems of the prior art, it certainly does nothing to teach away from the use of a pre-slit septum.

To the extent that Baxter challenges the district court's factual findings relating to the construction and operation of the Borla Device, we detect no clear error in the district court's findings. The trial court found that the Borla Device included a rubber septum that was under radial compression based upon statements by the inventors. This finding is not contradicted by the other evidence at trial to such an extent that we may say that the district court's judgment is clearly erroneous. Baxter points to a crude representational drawing and a cutaway photograph of the Borla Device purportedly showing small gaps between the rubber septum and the side wall of the housing to buttress its argument that the Borla Device did not apply radial forces to the rubber septum. Contrary to Baxter's assertion, the cut away photograph does not clearly disclose gaps between the rubber septum and the housing. Similarly, the small gaps shown by the representational drawing cannot overcome the clear statements of the inventors to the contrary. The judgment of the district court that the Borla Device contained some amount of radial compression is neither contrary to the factual record as a whole nor clearly erroneous.

Baxter's argument that the Herlitz EPO reference is more material than the Borla Device also fails. The district court found that while the Herlitz EPO reference "does have a septum contained by a swaged housing, it does not have a large annular channel for receiving displaced septum or an annular lip for supporting the septum. Nor has any evidence been presented that it has radial forces." The Herlitz EPO reference does not disclose the annular channel or radial forces. Lacking two of the claimed limitations, the Herlitz EPO reference cannot be more material than the Borla Device. The Borla Device was the only item in the prior art that combined every claimed element of the '234

and '648 patents save the pre-slit rubber septum and blunt cannula. Likewise, while various other references separately disclosed a pre-slit rubber septum and a blunt cannula, this does not render the Borla Device immaterial as cumulative of the references already before the examiner. The fact that the Borla Device contained all of these features in a single device would likely have been important to an examiner in determining whether to allow Baxter's applications. Therefore we cannot say that the district court's finding that the Borla Device was "highly material" was clearly erroneous.

Baxter also challenges the district court's finding that the inventors intended to deceive the PTO in failing to disclose the Borla Device. Intent need not be proven by direct evidence. Indeed, "direct proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." *LaBounty*, 958 F.2d at 1076; see *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1189-90, 25 U.S.P.Q.2D (BNA) 1561, 1567 (Fed. Cir. 1993) (explaining that intent must be generally inferred from the facts and circumstances surrounding the applicant's conduct). Our prior decisions are also clear that although intent may be inferred from circumstantial evidence, mere gross negligence is insufficient to justify an inference of an intent to deceive the PTO. See *Kingsdown*, 863 F.2d at 876; *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n.9, 5 U.S.P.Q.2D (BNA) 1112, 1116 n.9 (Fed. Cir. 1987). In a case involving an omission of a material reference to the PTO, there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference. See *Molins*, 48 F.3d at 1181.

In its opinion, the district court expressly recognized the above principles and found that based on the high materiality of the Borla Device and the absence of any evidence of mitigating good faith on the part of the inventors, Jepson and Dudar did intend to mislead the PTO in failing to disclose the Borla Device. Although Baxter asserts that there is no proof that the inventors knew of the materiality of the Borla Device, the district court pointed out that documentary evidence was clear that the Borla Device formed the basis of the claimed inventions and that the inventors were clearly acquainted with the critical features of the Borla Device. In support, the district court pointed to Jepson's statement in his November 17, 1986 memorandum that the original Volts access site cap was similar to the Borla Device except for increased compression and a change in the dimensions of the swaged parts. Jepson even visited the Borla location in Italy to evaluate the company as a potential manufacturer of the InterLink device. Baxter is stuck with the statements and actions of its own witnesses. The district court further found unconvincing Baxter's argument that the disclosure of over fifty prior art references demonstrated its good faith in prosecuting the patent. "Plaintiffs may have disclosed to the patent office

multitudes of prior art, but they did not disclose the single most relevant piece of prior art that was used extensively in the development of the invention." The district court pointedly concluded that the inventors' conduct, in its entirety, manifested a culpable state of mind sufficient to warrant a finding of an intent to deceive the PTO. See *id.* This court finds no clear error in that decision.

Baxter argues that the inventors' testimony, memoranda and lab notebook entries do no more than establish knowledge of the Borla Device and that this knowledge alone is insufficient to show knowledge of materiality. Baxter cites the case of *FMC Corp. v. Hennessy Industries*, 836 F.2d 521, 524-25, 5 U.S.P.Q.2D (BNA) 1272, 1274-75 (Fed. Cir. 1987), for this proposition. FMC creates no such bright line test for determining whether intent to deceive the PTO may be inferred. In *FMC*, this court merely held that the district court was not clearly erroneous in failing to infer knowledge of materiality from the evidence before it. See *id.* As we have stated above, intent is generally inferred from the sum total of the applicant's conduct. It is the totality of the applicant's conduct that creates the inference upon which the applicant's intent can be ascertained.

Baxter's argument that the inventors were unaware of the materiality of the Borla Device relies heavily on the inventors' testimony. However, the district court expressly found the inventors' testimony to be self-serving and inconsistent with the documentary evidence. The trial court's assessment of credibility is typically given great weight. "Since the fact-finder has personally heard the testimony and observed the demeanor of the witnesses, we accord deference to the fact-finder's assessment of a witness's credibility and character." *Molins*, 48 F.3d at 1181. Accordingly, "the drawing of inferences, particularly in respect of an intent-implicating question . . . is peculiarly within the province of the fact finder that observed the witnesses." *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110, 231 U.S.P.Q. (BNA) 185, 192 (Fed. Cir. 1986). Having considered Baxter's arguments to the contrary, we see no reason to disturb the trial court's findings on appeal.

Finally, Baxter argues that the district court clearly erred in finding an absence of good faith on the part of the inventors. It is true that evidence of good faith must be considered in determining whether inequitable conduct has been shown by clear and convincing evidence. See *Kingsdown*, 863 F.2d at 876 ("The involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."). However, good faith is only one factor to be considered along with the totality of the evidence. The district court considered Baxter's proffered evidence of good faith and found it lacking. Baxter argues on appeal that its efforts to point out relevant prior art to the PTO demonstrates its good faith in prosecuting the '234 and '648 patents. However, as we have stated above, the Borla Device was clearly relevant and the inventors were clearly aware of its existence. Moreover, given the degree to which the patented inventions were based upon the Borla Device, an inference that the inventors were aware of its importance is justified. On balance we cannot say that the district court abused its discretion in determining that the inventors' conduct, in

its entirety, warrants a determination that the '234 and '648 patents are unenforceable due to inequitable conduct.

B. Inequitable Conduct in the Prosecution of the '554 Patent

While we agree with the district court's disposition with respect to the '234 and '648 patents, we disagree with the district court's March 17, 1997 decision⁴ holding the '554 patent unenforceable for inequitable conduct. The district court's Memorandum Opinion and Order of March 17, 1997 granted McGaw's motion to supplement the judgment of March 26, 1996 to hold the '554 divisional patent unenforceable for inequitable conduct stemming from the failure to cite the Borla Device during the prosecution of the '414 application.

The '234, '648, and '554 patents all issued from the '414 application. The district court held that because the inequitable conduct was committed during the prosecution of the '414 application, the '554 patent resulting from this initial application is also unenforceable because "the duty of candor extends throughout the patent's entire prosecution history." *Baxter*, 958 F. Supp. at 1316 (citing *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803, 17 U.S.P.Q.2D (BNA) 1579, 1581 (Fed. Cir. 1990)). Relying primarily on *Fox*, the district court concluded that in withholding the Borla Device during the prosecution of the '414 application, all descendants of that application, regardless of whether the reference is material to those claims, are also "infected" and unenforceable due to inequitable conduct in the parent application. See *id.* at 1316-17. However, a close reading of *Fox* reveals that the holding in that case is not so broad as the district court presumes.

Fox involved a series of three continuation applications and the publication of a highly material sales brochure more than one year before the effective filing date of the earliest application. The brochure was not disclosed during prosecution. The appellant argued that the inequitable conduct was committed only by the first attorney prosecuting the case and that all of the claims prosecuted by that attorney had been rejected and subsequently abandoned. See *Fox*, 922 F.2d at 803. Therefore, the appellant reasoned that because the inequitable conduct could not be attributed to the issued claims, the patent remained enforceable despite the earlier breach of the duty of candor. See *id.* In particular, the appellant in *Fox* argued that the statement in *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1457, 223 U.S.P.Q. (BNA) 603, 616 (Fed. Cir. 1984) that issues of materiality and intent should be decided with reference to the issued claims of the patent meant that there could be no inequitable conduct with respect to claims cancelled during prosecution. See *Fox*, 922 F.2d at 803. In

⁴ See *Baxter Int'l, Inc. v. McGaw, Inc.*, 958 F. Supp. 1313 (N.D. Ill. 1997) (granting McGaw's motion to supplement the judgment to hold the '554 patent invalid for inequitable conduct)

Fox, this court sharply disagreed with the appellant, stating that in *Kimberly-Clark*, the non-disclosed prior art was not material to the allowed claims. See *id.* The court went on to say that "in determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. 'Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it.'" *Id.* at 803-04 (quoting *Kingsdown*, 863 F.2d at 874). The Fox court concluded that "a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." *Fox*, 922 F.2d at 803 (emphasis added). The quoted language from Fox simply applies the principle long held in this court that omission of a reference material to certain claims cannot be cured simply by canceling or amending those claims during prosecution so that they do not issue in the same form in which they were drafted. See *Driscoll v. Cebalo*, 731 F.2d 878, 885, 221 U.S.P.Q. (BNA) 745, 751 (Fed. Cir. 1984) ("An applicant who . . . has withheld from the PTO prior art material to a claim in a parent application should not be exculpated simply because, by fortuitous circumstances, the PTO has not reached the stage of allowing claims in a continuing application."). In Fox and in *Driscoll*, the omitted references were not only material to the claims that were cancelled, but were also material to the issued claims. See *Fox*, 922 F.2d at 804 ("Moreover, the brochure discloses the entirety of the structure set forth in most of the issued claims."); *Driscoll*, 731 F.2d at 884 ("[The substituted claim] would have been prima facie obvious from the [omitted reference].").

In the present appeal, the PTO issued a restriction requirement under 35 U.S.C. § 121, stating that the '414 application actually involved several different inventions. The claims of the '395 application which resulted in the '554 patent were at all times directed to the structure of the blunt cannula for use with the separately patented injection site. It is clear that the Borla Device was in no way material to the claims of the '554 patent at any time during its prosecution. The Borla Device disclosed an injection site that was to be used with sharp needles. It is not relevant to the claims directed to the blunt cannula in the '554 patent. Thus, the present action is unlike Fox and *Driscoll*, where the cancelled claims to which the omitted reference was relevant were intimately related to the issued claims. "In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents." *Fox*, 922 F.2d at 803. In the present appeal, the claims in the '414 application to which the omitted reference was material were not antecedents to the claims of the '554 patent. The claims of the '554 patent were drawn to an entirely different invention that, as the PTO pointed out in its restriction requirement, should never have been included in the '414 application in the first place. The '554 patent is not unenforceable due to inequitable conduct merely because its claims were improperly included in an

application with other patentable inventions that were ultimately held unenforceable for inequitable conduct.

Fox and Driscoll clearly stand for the proposition that cancellation or amendment of a claim "tainted" by inequitable conduct will not excuse the patentee's intentional failure to disclose material references. See *id.* at 803-04; Driscoll, 731 F.2d at 884. It is also settled law that inequitable conduct with respect to one claim renders the entire patent unenforceable. See *Kingsdown*, 863 F.2d at 874; *J.P. Stevens*, 747 F.2d at 1561. However, where the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application. The district court erred in reading our previous decisions to the contrary. We therefore hold that the '554 patent is not unenforceable due to the breach of the patentee's duty of candor to the PTO committed during the prosecution of the '414 application and reverse the decision of the district court that the '554 patent is unenforceable due to inequitable conduct.

C. Validity

We next address McGaw's argument that the '234, '648, and '554 patent are all invalid under 35 U.S.C. § 102(b). McGaw argues that because the patents in suit are not entitled to the January 25, 1988 filing date of the '414 parent application, they are each invalid as a matter of law under 35 U.S.C. § 102(b) as anticipated by Baxter's published PCT application and product demonstrations more than one year before the effective filing dates of '234, '648, and '554 patents. In its special verdict, the jury found that McGaw had not shown by clear and convincing evidence that the patents in suit were not entitled to the effective filing date of the '414 application. The district court subsequently denied McGaw's motion for JMOL on this issue.

This court reviews a denial of a motion for JMOL de novo by reapplying the JMOL standard. See *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821, 23 U.S.P.Q.2D (BNA) 1426, 1431 (Fed. Cir. 1992). We may reverse a denial of a motion for JMOL only if the jury's factual findings are not supported by substantial evidence or if the legal conclusions drawn from the jury's findings cannot as a matter of law be supported by those findings. See *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1559, 41 U.S.P.Q.2D (BNA) 1225, 1228-29 (Fed. Cir.), cert. denied, 139 L. Ed. 2d 287, 118 S. Ct. 369 (1997); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1547-48, 31 U.S.P.Q.2D (BNA) 1746, 1751 (Fed. Cir. 1994).

We note that in light of our holding that the '234 and '648 patents are unenforceable due to inequitable conduct, McGaw's arguments that these patents are invalid are moot. Consequently, we address only the validity of the '554 patent.

The '554 patent was issued on a divisional application pursuant to 35 U.S.C. § 121 which allows a divisional application to claim priority from the parent if the divisional application complies with the requirements of 35 U.S.C. § 120.⁵ According to 35 U.S.C. § 120, "an application for patent . . . shall have the same effect . . . as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of the proceedings on the first application." Section 120 requires that the two applications be co-pendent and that the later-filed application reference the earlier-filed application. See *In re Costello*, 717 F.2d 1346, 1348, 219 U.S.P.Q. (BNA) 389, 390 (Fed. Cir. 1983).

For its part, Baxter argues that the evidence is clear that Baxter intended to file claims 1 through 124 and that Baxter intended each divisional application to cover the groups designated by the PTO in its restriction requirement. While we agree that the evidence is clear that Baxter intended to file claims 60-124, section 120 does not require an intent to file a complete application, it requires a divisional application to be filed in compliance with section 112 before the parent application is abandoned. Section 112 requires that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P 2.

The sole question before this court, then, is whether the submission of a set of claims, accompanied by instructions to the PTO to cancel those claims, satisfies the requirement of 35 U.S.C. § 120 that the applicant submit "an application for patent" where the term "application" is defined by 35 U.S.C. § 111. As this court stated in *Litton Systems, Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1437, 221 U.S.P.Q. (BNA) 97, 105 (Fed. Cir. 1984):

Both statute, 35 U.S.C. § 111, and federal regulation, 37 C.F.R. § 1.51, make clear the requirement that an application for a patent *must* include (1) a specification (which includes both the written description and the claims) and claims [sic], (2) a drawing, (3) an oath or declaration, and (4) a filing fee. The omission of any *one* of these component parts makes a patent application incomplete and thus not entitled to a filing date.

⁵ 35 U.S.C. § 121 provides in relevant part: "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application."

(emphasis in original, citations omitted).

We conclude that where the applicant has submitted a set of claims with an accompanying instruction to the PTO to cancel all of those claims, without the substitution of new claims, the applicant has not fulfilled the requirements of 35 U.S.C. § 112, paragraph 2, and is not entitled to a filing date until at least one claim has been submitted.

Baxter argues by analogy that the filing of claims 1-59 satisfies its requirement under § 112 despite its simultaneous request that the PTO cancel those claims, because there is no statutory requirement that the PTO actually enter an amendment seeking to cancel the claims. Baxter then argues that the decision whether to enter Baxter's request to cancel all of the claims of the '395 application is discretionary on the part of the PTO and that the PTO, by its own regulations, ordinarily denies entry of amendments to cancel all the claims in an application. The Manual of Patent Examining Procedure (MPEP), section 714.19 states that: "The following types of amendments are ordinarily denied entry: . . . 8. An amendment canceling all of the claims and presenting no substitute claim or claims." Thus, Baxter argues that its request to cancel all of the claims in the '395 application could not be acted upon by the PTO following its usual procedure and that such an act would have no legal effect under MPEP § 714.21. "If the clerk enters an amendment when it should not have been entered, such entry is of no legal effect." MPEP § 714.21.

We disagree. First, Baxter mischaracterizes an instruction sent to the PTO along with the application as an amendment. In instructing the PTO to ignore claims 1-59 as of the time the application was received at the PTO, Baxter has essentially stated that claims 1-59 were never part of the application from the beginning. These claims were not submitted as part of the original application due to the clear instruction of the applicant to cancel these claims upon receipt. It is further instructive that Baxter requested that these claims be cancelled before the calculation of the filing fee. The PTO did cancel these claims before calculating the filing fee, and Baxter has never paid a filing fee for claims 1-59. It is clear that neither Baxter, nor the PTO ever regarded claims 1-59 as having been part of the '395 application. Because Baxter filed an application without any claims, the application failed to meet the statutory requirement that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, para. 2. Therefore, because Baxter's submission failed to meet the requirements of § 112, it also failed to meet the definition of "application" in 35 U.S.C. § 111 and is not an "application" entitled to the filing date of the '414 application under § 120.

Baxter next argues that the PTO nonetheless had the discretion to suspend its regulations, sua sponte, in the interests of justice under 37 C.F.R. § 1.183. Section 1.183 provides in relevant part: "In an extraordinary situation, when justice requires, a requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Commissioner . . . sua sponte, or on petition of the interested party." According to Baxter, the PTO's indication that the '395 application was filed on June 12, 1990 and the grant of the effective filing date of January 25, 1988, is a valid exercise of its power to suspend its regulations under § 1.183. However, § 1.183 explicitly acknowledges (as it must) that statutory requirements may not be waived. The requirements of § 112 that require the applicant to submit a set of claims are clearly statutory, as are the requirements of § 120 that the divisional application co-pend with the parent application. These requirements may not be waived by the PTO. While the PTO is presumed to have complied with all applicable rules, that presumption cannot overcome a clear statutory violation. We therefore hold that the earliest date to which the '395 application is entitled is January 7, 1991, long after the '414 application had been abandoned.

Because the effective filing date of the '554 patent is January 7, 1991, Baxter's counterpart PCT application, published on July 27, 1989, is prior art under 35 U.S.C. § 102(b) as a foreign publication published more than one year before the date of application in the United States. See 35 U.S.C. § 102(b). Baxter's counterpart PCT application, entitled "Pre-slit Injection Site and Tapered Cannula," International Application Number PCT/US89/00273 contains the exact same written description as the '554 patent. The specification of Baxter's PCT application clearly anticipates the claims of the '554 patent. Baxter does not dispute McGaw's argument that if the '554 application is not entitled to a priority date based upon the '414 application, that it is invalid as a matter of law under § 102(b). We see no reason to remand to the district court on this issue and therefore hold that the '554 patent is therefore invalid as a matter of law under § 102(b) as anticipated by Baxter's counterpart PCT application.

D. Claim Construction

Because we find the '234 and '648 patents unenforceable for inequitable conduct, and the '554 patent invalid under 35 U.S.C. § 102(b), we find it unnecessary to address the parties' respective arguments regarding claim construction and validity under 35 U.S.C. § 103.

D. Baxter's Motion for a New Trial

Finally, we turn to Baxter's argument that it is entitled to a new trial on all issues due to the delay between the close of evidence and the trial judge's submission

of the case to the jury. We review the district court's decision not to grant a new trial for abuse of discretion. See *Nobelpharma*, 985 F.3d at 1103, 46 U.S.P.Q.2D (BNA) at 1103. We may reverse this aspect of the district court's decision only if we find that the district court prejudiced Baxter's substantive rights by abusing its discretion in allowing the delay between the close of evidence and submission of the case to the jury.

While the district court recognized that there was a danger that the delay might cause the jury to forget portions of the previously presented evidence, the district court counteracted this danger by allowing greatly increased time for the parties to make their closing arguments. We believe that on the facts of this case the trial judge did not abuse his discretion in allowing a several week delay between the close of evidence and submission of the case to the jury for deliberations. Moreover, it is clear that the jury carefully considered the evidence in the case in making its decision. Jury deliberations lasted one week with the jury finding for Baxter on some issues and for McGaw on others. We can detect no abuse of discretion by the district court that has prejudiced Baxter's substantive rights.

Finally, we have considered Baxter's arguments that portions of opposing counsel's opening and closing statements were prejudicial and inflammatory and find them to be without merit.

CONCLUSION

We agree with McGaw that the trial court did not abuse its discretion in holding that the '648 and '234 patents are unenforceable for inequitable conduct and affirm the decision below with respect to those patents. However, we reverse the district court's determination that the '554 patent is rendered unenforceable due to inequitable conduct committed during the prosecution of the '414 application. We also hold that the earliest filing date that can be attributed to the '554 patent is that of January 7, 1991, and that the '554 patent is invalid as anticipated by Baxter's counterpart PCT application published on July 27, 1989. Finally, we find no abuse of discretion in the district court's refusal to grant a new trial.

COSTS

Each party to bear its own costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART