

OUT OF THE FRYING PAN AND INTO THE FIRE –
A PATENT MAY SURVIVE AN ATTACK ON ENFORCEABILITY
ONLY TO BE DECLARED INVALID

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Introduction

Patent invalidity and patent unenforceability are two different defenses which may be asserted in response to an allegation of patent infringement. Each can be equally effective in destroying a patentee's ability to establish infringement liability for a product or process which otherwise clearly falls within the scope of the patent claims.¹

Generally, either defense may be based upon events which occurred (or which failed to occur) during the patent application process. For example, a patent may be declared invalid if the patent applicant failed to submit a patent application which contained an adequate written description and definition of the invention. A patent may be found unenforceable if the patent applicant committed an act of inequitable conduct during the patent application process (by, for example, failing to inform the PTO of a relevant prior art reference).

It is therefore important for companies to recognize and understand those actions (or inactions) which might result in a holding of patent invalidity or unenforceability. It is perhaps more important for companies to recognize whether, and under what circumstance, such actions can be corrected, so that a finding of patent invalidity or unenforceability can be avoided. For example, if an applicant commits an act of inequitable conduct during the patent application process, does this automatically result in the unenforceability of all claims resulting from that patent application? Is there a procedure by which an applicant might shield at least some of the claims from a finding of unenforceability?

These and other basic questions were considered in the recent decision of the U.S. Court of Appeals for the Federal Circuit ("the CAFC")² in the case of Baxter International, Inc. v. McGaw, Inc.³ A detailed discussion of the Baxter case and the CAFC's decision is provided below. This is followed by a description of some guidelines which companies should now consider when evaluating the validity and enforceability of a U.S. patent.

The Facts

The Invention

The Baxter International case involved three patents⁴ directed to a system for administering intravenous fluids. Conventionally, intravenous fluids are administered through a catheter inserted into a patient's vein. An administration set is used to connect the fluid source to the catheter. The administration set includes injection sites through which medicines or other fluids are added as the fluid passes to the catheter.

Conventional injection sites typically include a solid rubber septum that is pierced by a sharp needle to introduce medicines and other fluids into the system. Using sharp needles to pierce the septum presents a risk of accidental pricks from contaminated needles. The use of blunt instruments to insert medication into the system results in leakage problems.

In 1986 the patentee attempted to solve these problems. The patentee experimented with a prior art injection site which had a solid septum designed to be pierced by a sharp needle. The patentee used this prior art septum to develop an injection site that included a pre-slit septum designed to be pierced by a blunt cannula instead of a sharp needle. The patentee's system solved the problem of leakage and eliminated the need for sharp needles.

The Prosecution

In January 1988 the patentee filed a so-called "parent" patent application containing claims 1-59. In July 1988 the patentee filed a preliminary amendment canceling claims 1-59 and adding new claims 60-120. The PTO entered this amendment.

In January 1989 the PTO issued a restriction requirement, stating that the claims in the parent application defined four separate and distinct inventions. In April 1989 the patentee amended claims 95 and 96, canceled claims 118-120 and added new claims 121-124.

On December 14, 1989, the PTO issued a final rejection.

On June 11, 1990, the patentee mailed a request to file a first divisional patent application. The patentee simultaneously requested that claims 1-59, 95-100 and 109-

124 be canceled from this first divisional patent application. However, the material which the patentee submitted to the PTO included only a copy of the parent patent application, which contained only claims 1-59.

On June 14, 1990, the parent application became abandoned.

On June 26, 1990, the PTO mailed the patentee a Notice of Incomplete Application indicating that the first divisional patent application could not be assigned a filing date because claims 60-124 were missing from the application. The Notice indicated that the filing date of the first divisional patent application would be the date on which the PTO received claims 60-124.

On July 16, 1990, the patentee submitted claims 60-124, and the PTO assigned the first divisional patent application a filing date of July 16, 1990. Upon the patentee's petition to correct the filing date, the PTO changed the effective filing date of the first divisional patent application to June 11, 1990. The first divisional patent application ultimately issued as patent "A".

Meanwhile, on June 12, 1990, the patentee mailed a second divisional patent application and a third divisional patent application. Like the first divisional patent application, the second and third divisional patent applications also lacked claims 60-124 and requested cancellation of claims 1-59, the only claims mailed with the applications. On December 17, 1990, the PTO notified the patentee that all claims in both the second and third divisional patent applications had been canceled.

On January 4, 1991, the patentee mailed copies of claims 60-124 for inclusion in both the second and third divisional patent applications. The second and third divisional patent applications were ultimately issued as patents "B" and "C", respectively. Patent C (like patent A) was generally directed to a system for administering intravenous fluids. Patent B, in contrast, was directed to a blunt cannula which could be used with such a system.

In addition to the U.S. patent applications, in January 1989 the patentee filed an International Patent Application under the Patent Cooperation Treaty (PCT). The PCT application, which contained a written description identical to that filed in each of the corresponding U.S. applications, was published in July 1989.

The Trial

After issuance, the patentee sued for infringement of patents A, B and C. The alleged

infringer responded by asserting that all three patents were anticipated by the patentee's own published PCT application, because the divisional patent applications were not entitled to the filing date of the parent patent application due to a lack of co-pendency.

The trial court denied the alleged infringer's motion for judgment as a matter of law on the issue of anticipation by the PCT publication. However, the trial court found that the patentee had committed inequitable conduct in prosecuting patents A and C, because the patentee had failed to disclose the prior art septum to the PTO. The trial court also held patent B (the cannula patent) unenforceable due to the inequitable conduct which occurred during the prosecution of the parent application.⁵

The patentee appealed. The alleged infringer cross-appealed the denial of its motion for judgment as a matter of law on the issue of patent invalidity.

The Appeal

The Enforceability of Patents A and C

On appeal, the CAFC first addressed the issue of inequitable conduct in the prosecution of patents A and C. The CAFC noted that the determination of inequitable conduct requires a two step analysis. First, it must be determined whether the non-disclosed reference meets a threshold level of materiality. Second, it must be determined whether the evidence shows a threshold level of intent to mislead the PTO. Once the threshold levels of materiality and intent have been established, the trial court must weigh materiality and intent. The more material the omission, the less evidence of intent will be required to find that inequitable conduct has occurred. In light of all the circumstances, the trial court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable.

The initial question on appeal was whether the trial court had erred in finding that the prior art septum would have been material. A reference is considered 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.⁶ However, an applicant is not required to cite an otherwise material reference to the PTO if that reference is merely cumulative of, or is less material than, other references already before the examiner.

The CAFC noted that the prior art septum contained all features of the claimed injection site, except for a slit in the septum. The CAFC stated that although a pre-slit septum was an important element of the invention, the mere absence of a slit in the prior art septum

was not sufficient to make the prior art septum non-material or less material than the other cited references. A difference in a single element, even an element important to the invention, does not make it likely that a reasonable examiner would consider the reference unimportant in deciding whether to allow the patent, and does not automatically make a reference non-material. In other words, materiality does not depend on a single element viewed in isolation, but instead depends upon the overall degree of similarity between the non-disclosed reference and the claimed invention in light of the other prior art before the examiner. The CAFC concluded that the trial court had properly considered the totality of the claimed features in determining whether the prior art septum was material.

Nor, according to the CAFC, did the prior art septum "teach away" from the claimed invention. The CAFC stated that, in general, a reference teaches 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. Nothing in the prior art septum suggested to a skilled person that a similar device with a pre-slit septum was unlikely to work. Although the prior art septum did not teach that a pre-slit septum was likely to succeed in overcoming the problems of the prior art, it did not teach away from the use of a pre-slit septum.

Nor was the prior art septum merely cumulative of the other cited references. The prior art septum was the only item in the prior art that combined every element claimed in patents A and C, except for the pre-slit septum and the cannula. Although other references separately disclosed a pre-slit septum and a cannula, the fact that the prior art septum contained all of these features in a single device would likely have been important to an examiner in determining whether to allow the applications. Therefore, according to the CAFC, a finding that the prior art septum was "highly material" was not clearly erroneous.

The patentee's disclosure of over fifty prior art references did not demonstrate its good faith in prosecuting the patent. The patentee had failed to disclose the single most relevant piece of prior art that was used extensively in the development of the invention. The prior art septum was clearly relevant and the inventors were clearly aware of its existence. Moreover, given the degree to which the patented invention was based upon the prior art septum, an inference that the inventors were aware of its importance was justified. The CAFC found no clear error in the conclusion 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. The CAFC concluded that the trial court had not abused its discretion in determining that the inventors' conduct, in its entirety, warranted a determination that patents A and C were unenforceable due to inequitable conduct.

The Enforceability of Patent B

The CAFC then addressed the enforceability of patent B, which had resulted from the same parent application as patents A and C. The trial court had held that because inequitable conduct occurred during the prosecution of the parent application, patent B was also unenforceable because the patentee's duty of candor extends throughout the patent's entire prosecution history. The trial court had concluded that the failure to disclose the prior art septum during the prosecution of the parent application had "tainted" all descendants of the parent application, and had rendered all such descendants unenforceable due to inequitable conduct.

The CAFC acknowledged that a breach of the duty of candor during the early stages of prosecution may render unenforceable all claims which eventually issue from the same or a related application. However, in Baxter the PTO had issued a restriction requirement, stating that the parent application contained claims directed to several different inventions. In particular, the claims of the second divisional application, which resulted in patent B, were at all times directed to the structure of a blunt cannula. The non-disclosed prior art septum was not material to the claims of patent B at any time during the prosecution of patent B.

On this basis, the CAFC found the case to be distinguishable from one in which the non-disclosed reference was material to the claims that were canceled, and was also material to the issued claims.⁷ In Baxter the claims in the parent application, to which the non-disclosed prior art septum was material, were not antecedents to the claims of patent B. The claims of patent B were drawn to an entirely different invention, and should have been included in a different application (as noted in the restriction requirement). The CAFC concluded that patent B should not be unenforceable due to inequitable conduct merely because the claims of patent B were improperly included in an application with other claims that were ultimately held unenforceable due to inequitable conduct.

The CAFC acknowledged that inequitable conduct with respect to one claim still renders the entire patent unenforceable, and that the cancellation or amendment of a claim "tainted" by inequitable conduct will not excuse the patentee's intentional failure to disclose a material reference. In other words, omission of a reference material to certain claims cannot be cured by simply canceling or amending those claims during prosecution so that the claims do not issue in the same form in which they were drafted. The CAFC stated, however, that: (a) where the claims are subsequently separated from those tainted by inequitable conduct through a divisional application,

and (b) where the issued claims have no relation to the non-disclosed prior art, the patent issued from the divisional application will not be unenforceable due to inequitable conduct committed in the parent application. The CAFC therefore held that patent B was not unenforceable due to the breach of the patentee's duty of candor to the PTO committed during the prosecution of the parent application. The CAFC therefore reversed the decision of the trial court that patent B was unenforceable due to inequitable conduct.

The Validity of Patent B

The CAFC then addressed the validity of patent B. Patent B had resulted from a divisional application submitted to the PTO in June 1990, claiming priority from a parent application filed in January 1988. The divisional application had included only claims 1-59. Simultaneously with the submission of the divisional application, the patentee had submitted a request for the PTO to cancel all of claims 1-59. The patentee had not submitted claims 60-124 to the PTO until January 1991. The PTO thereafter treated the divisional application as having been filed in June 1990, and having an effective filing date of January 1988.

The alleged infringer argued that the earliest effective filing date to which the divisional application was entitled was not January 1988 (the filing date of the parent application), but was instead January 1991 (the filing date of claims 60-124). Therefore, according to the alleged infringer, patent B was anticipated by the patentee's own corresponding PCT application published in July 1989, more than one year before the effective filing date of patent B.

The CAFC observed that the Patent Statute requires each application for a patent to include at least one claim.⁸ The complete absence of claims from an application makes that patent application incomplete, and thus not entitled to a filing date. Consequently, the issue on appeal was whether the submission of claims 1-59 to the PTO, accompanied by instructions to cancel claims 1-59 without simultaneously adding new claims, satisfied the statutory requirement for a patent application entitled to a filing date.

The CAFC reasoned that, by clearly instructing the PTO to ignore claims 1-59 when the divisional application was submitted, the patentee had essentially stated that claims 1-59 were never part of the divisional application. Moreover, in accordance with the patentee's clear instructions, the PTO had canceled claims 1-59 before calculating the filing fee, and the patentee had never paid a filing fee for claims 1-59. In the opinion of the CAFC, this confirmed that neither the patentee nor the PTO had ever regarded

claims 1-59 as having been part of the divisional application. The CAFC stated that if an applicant submits a set of claims with an accompanying instruction to the PTO to cancel all of those claims, and does not substitute new claims, then the applicant has not fulfilled the requirements of the Patent Statute and is not entitled to a filing date until at least one claim has been submitted. Because the patentee had filed a divisional application without any claims, the divisional application failed to meet the statutory definition of an "application" entitled to a filing date.

The CAFC further observed that the requirements that an application must contain at least one claim, and the requirement that a divisional application must co-pend with the parent application, are statutory requirements. The PTO does not have the authority to suspend or waive these statutory requirements. Therefore, the earliest filing date to which the second divisional application was entitled was January 1991, the date on which the patentee filed claims 60-124. This filing date was after the June 1990 date of abandonment of the parent application, and more than one year after the July 1989 publication of the patentee's own PCT application, which PCT application contained the same written description as patent B. The CAFC therefore held that patent B was not entitled to a priority date based upon the parent application, and that patent B was invalid as a matter of law under §102(b) as anticipated by the patentee's counterpart PCT application.

Conclusion

Companies seeking to obtain and enforce a U.S. patent, as well as companies seeking to avoid liability for alleged patent infringement, are well advised to study the Baxter case and carefully consider the following guidelines regarding U.S. patent validity and enforceability:

- A breach of the duty of candor during the prosecution of a patent application may render unenforceable all claims which issue from the patent application or from related patent applications. However, a failure to disclose a prior art reference during the prosecution of a patent application does not necessarily affect all descendants of the patent application, and does not necessarily render all such descendants unenforceable. If an applicant files a divisional patent application containing claims which have no relation to the non-disclosed prior art reference, and which are therefore unaffected by the inequitable conduct, then a patent resulting from the divisional application will not be unenforceable due to inequitable conduct committed in the parent application. In other words, by dividing out claims

which are unrelated to a non-disclosed reference, and by making such claims the subject of a separate patent application, an applicant may be able to “shield” such claims from a finding of inequitable conduct.

- The submission of a set of claims to the PTO, accompanied by instructions to cancel those claims without simultaneously adding new claims, does not satisfy the statutory requirement for a patent application entitled to a filing date. An applicant that submits a set of claims to the PTO with accompanying instructions to cancel those claims is not entitled to a filing date until at least one new claim has been submitted.

Consideration of the guidelines suggested by the CAFC in the Baxter International, Inc. v. McGaw, Inc. decision and expressed in this article should provide companies with some useful insights into the U.S. law of patent validity and patent unenforceability.

Biography

Alex Chartove practices in the Washington D.C. office of Akin, Gump, Strauss, Hauer & Feld, LLP (<http://www.akingump.com>), a full-service international law firm with offices in the U.S. and Europe. Mr. Chartove attended Brandeis University (BA, Physics, magna cum laude, 1976) and the Massachusetts Institute of Technology (Ph.D. Candidate). He received his JD degree in 1980 from Duke University Law School, and is a member of the Bars of California, New York and the District of Columbia. His practice is directed to the representation of client matters before the various federal tribunals and agencies located in Washington D.C., including the U.S. Patent and Trademark Office, the Court of Appeals for the Federal Circuit, the International Trade Commission and the Copyright Office. For the past five years, Mr. Chartove has been the author of the “Federal Circuit Yearbook”, published by the Practising Law Institute (<http://www.pli.edu>). Mr. Chartove’s “Yearbook” provides a comprehensive summary and analysis of every patent law decision published by the CAFC during the past year. E-mail: achartove@akingump.com.

¹ The claims are the separately numbered paragraphs which are found at the end of every U.S. patent and which specifically define the invention protected by the patent.

² By law, the decisions of the U.S. Court of Appeals for the Federal Circuit are controlling in all U.S. patent disputes. See 28 U.S.C. § 1295(a). The U.S. Court of Appeals for the Federal Circuit (also referred to as the “Federal Circuit,” “Fed. Cir.” or “CAFC”) is

therefore generally recognized as being the most important U.S. court regarding patent law issues.

³ ___ USPQ2d ___ (Fed. Cir. 1998).

⁴ U.S. Patent No. 5,171,234; U.S. Patent No. 5,167,648; and U.S. Patent No. 5,158,554.

⁵ Baxter Int'l, Inc. v. McGaw, Inc., 958 F. Supp. 1313 (N.D. Ill. 1997).

⁶ This standard reflects an older PTO rule in effect at the time patents A, B and C were prosecuted. The current PTO rule defines materiality differently.

⁷ See Fox Indus., Inc. v. Structural Preservation Sys., Inc., 922 F.2d 801, 17 USPQ2d 1577 (Fed. Cir. 1990); Driscoll v. Cebalo, 731 F.2d 878, 221 USPQ 745 (Fed. Cir. 1984).

⁸ 35 U.S.C. §112.