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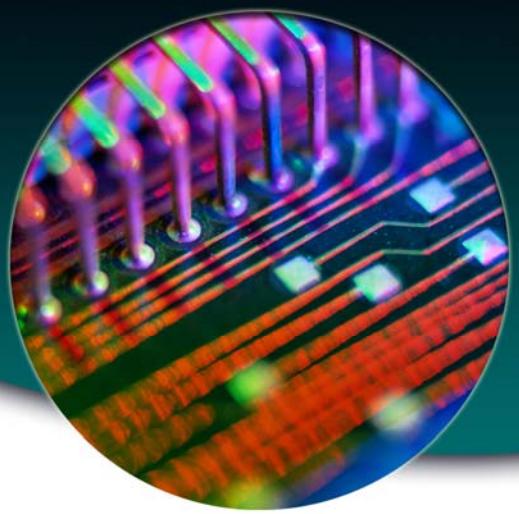

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The Death of the Written Description Requirement? Analysis and Potential Outcomes of the *Ariad* Case

There is significant disagreement among judges of the Court of Appeals for the Federal Circuit (CAFC) regarding the requirements for adequate written description in the specification of a US patent application. The CAFC is considering whether to modify, or perhaps remove entirely, the so-called "written description" requirement in light of a decision to grant an *en banc*[1] rehearing in the *Ariad Pharmaceuticals, Inc.*[2] case. Modifying or removing the written description requirement would change US patent law that has been in place since the *Lilly*[3] decision in 1997, and the *Ariad* case merits close attention due to its potential impact on patent prosecution and patent litigation.

Background

To understand the full scope and intricacies of the issue, a discussion of the background thereof should prove helpful. The requirements for the specification of a patent application are provided for by the first paragraph of 35 USC §112.[4]

The section has been interpreted to have three requirements: (1) written description; (2) enablement; and (3) best mode. The enablement requirement has been interpreted to require the specification to enable one of ordinary skill in the art of the claimed invention to make or use the claimed invention without undue experimentation.[5] The best mode requirement is a safeguard against the desire on the part of a patent applicant to obtain patent protection without making a full disclosure as required by the statute. This requirement prevents inventors from disclosing only what they know to be an inferior embodiment, while retaining the best embodiment for themselves.[6]

The current written description requirement was established in 1997 in the *Lilly* case. This requirement mandates that a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude the inventor had possession of the claimed invention.[7] The requirement is said to (1) satisfy an inventor's obligation to disclose the technological knowledge upon which the patent is based and (2) demonstrate that the patentee was in possession of the claimed invention.[8] The enablement requirement is also said to serve a teaching function in its role as a *quid pro quo* in which the public is given meaningful disclosure in exchange for exclusion from practicing the invention for a limited period of time.[9] Thus, the underpinnings of the written description requirement appear to be primarily equitable in nature, giving the public disclosure of specific embodiments of an invention in exchange for the grant of a limited monopoly on the claimed technology.

In litigation, courts may decide that a patent fails to meet the written description requirement without reaching important enablement issues.[10] The written description requirement has been described as a form of "super-enablement" that courts turn to first because the written description requirement is generally more stringent than the enablement requirement.[11] As such, courts often choose to bypass enablement issues in favor of analyzing the written description requirement. Further, it is considerably easier for an Examiner to make a proper rejection for alleged lack of compliance with the written description requirement than to reject claims as allegedly not being enabled.

This failure to address enablement in favor of only addressing the written description requirement is precisely what happened in *Ariad*. In that case, the CAFC held that Ariad's patent[12] was invalid for failing to meet the written description requirement. Because the CAFC determined that the written description requirement was not met, the issue of enablement was never considered.[13] After failing to win its argument that the patent satisfied the written

description requirement, Ariad filed a petition for an *en banc* rehearing. In the petition, Ariad boldly argued that the written description analysis is not consistent with the plain text of the statute and that the written description requirement conflicts with precedent set both by the US Supreme Court[14] and the CAFC. The CAFC granted Ariad's petition and asked the parties to file briefs addressing:

(a) whether the first paragraph of 35 USC §112 contains a written description requirement separate from the enablement requirement; and

(b) if a separate written description requirement is set forth in the statute, what the scope and purpose of the requirement is.

If the answer to (a) is no, the separate written description requirement from *Lilly* will be removed. If the answer is yes, the scope of the written description requirement may be maintained or altered. Accordingly, the *Ariad* case has the potential to be of considerable significance.

Removing the written description requirement will make patent prosecution easier in some cases.

Where the Judges Stand

While it is difficult to predict how a court will decide a case with respect to the written description requirement, there is a helpful history from CAFC judges that may tip their hand. From the unequivocal language of past opinions, it is clear that three of the judges[15] believe there is no separate written description requirement.[16]

On the other side, Judge Lourie has unequivocally expressed his belief that a separate written description requirement does indeed exist.[17] The judges that authored the opinion in *Ariad* are also likely to be against removing the written description requirement since they disagreed with Judge Linn's suggestion to do so. Judge Newman has indicated it would be a public disservice to eliminate the written description requirement entirely, but she may be amenable to changing the requirement and favors the *en banc* rehearing.[18] Judge Dyk favors articulating clear standards for the written description requirement that can be applied to all technologies.[19] It is not clearly inferable from the known opinions of the judges that the written description requirement will be removed. Rather, it appears more likely that the opinion will be modified. Given the strong opinions of several of the judges against the requirement, coupled with the fact that no judge has expressed an opinion that the requirement should be bolstered, it seems unlikely that the requirement will be further strengthened. If anything, a modification to the requirement would likely maintain or lessen it.

Potential Impact on Prosecution and Litigation

Removing the Written Description Requirement

With respect to patent prosecution, elimination of the written description requirement may have an immediate beneficial impact in some cases. Written description rejections would be rendered moot. The removal of the requirement would also provide an indirect benefit to rejections for an alleged lack of enablement. Enablement rejections are hard for Examiners to establish and maintain due to the lengthy list of factors[20] that must be addressed. Under current examining practices, these rejections often are morphed into written description rejections in subsequent Office Actions when the original enablement rejection is challenged by applicants as being improper because written description rejections are considerably easier to make.

Written description rejections may be changed into claim objections under MPEP §608.01(o) and, in the absence of the written description requirement, such claim objections may be made more frequently. While Office Actions sometimes state that the specification must provide "antecedent basis" for claim recitations (i.e., using the same exact words), the actual standard is clear support *or* antecedent basis, so arguments in favor of clear support

are still possible. It is also possible that any claim amendments reciting features that may be enabled, but are not specifically described in the specification, would be rejected as reciting new matter. With respect to litigation, proving a failure to meet the written description requirement would no longer be an option. Instead, if the disclosure in the specification is sufficient to enable one of ordinary skill in the art to make or use the invention, and if the best mode requirement is met,[21] the patent would satisfy the first paragraph of 35 USC §112.

Modifying the Written Description Requirement

The effects of modifying the written description requirement are difficult to predict because the potential modifications are difficult to determine. It is clear that Ariad will argue there is no separate written description requirement, and Eli Lilly will likely argue that the current enablement requirement is proper. However, it is not known whether *Ariad* will provide an alternative position that endorses easing the written description requirement, should the CAFC not agree to remove it.

Conclusion

The judges of the CAFC disagree as to the existence and nature of the written description requirement. Removing the written description requirement will make patent prosecution easier in some cases, but proving a lack of compliance with the first paragraph of 35 USC §112 for adverse patents will hinge on whether the disclosure meets the less stringent enablement requirement instead of the written description requirement. The effects of modification to the written description requirement are unpredictable. Accordingly, because *Ariad* may alter disclosure requirements for patent prosecution and litigation the case merits close attention.

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1. Cases are typically heard before a three-judge panel, but an *en banc* hearing involves an enlarged panel of the CAFC judges. In *Ariad*, a poll was circulated to all 12 judges and at least seven decided to rehear the case *en banc*.
2. *Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and The President and Fellows of Harvard College v. Eli Lilly and Co.*, 560 F.3d 1366 (Fed. Cir. 2009).
3. *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559 (Fed. Cir. 1997).
4. The specification shall contain *a written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth *the best mode* contemplated by the inventor of carrying out his invention (emphasis added).
5. *See* Manual of Patent Examining Procedure (MPEP) §2164.01; *see also In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).
6. *See* MPEP §2165; *see also In re Nelson,* 280 F.2d 172 (CCPA 1960).
7. *See* MPEP §2163(I); *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003).
8. *See Ariad*, 560 F.3d at 1373 and 1374; *see also Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).
9. *See Ariad*, 560 F.3d at 1374; *see also Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002).
10. *See Ariad*, 560 F.3d at 1404.
11. *See Enzo*, 323 F.3d at 982.
12. *See Baltimore et al.* (U.S. Patent No. 6,410,516). The patent is a complex biotechnology patent titled "Nuclear Factors Associated with Transcriptional Regulation" that pertains to artificially reducing the activity of a transcription factor called "NF-KB."
13. *See Ariad*, 560 F.3d at 1402.
14. The petition alleged that the written description requirement is counter to both The Telephone Cases, 126 US 1 (1888) and *Tilghman v. Proctor*, 102 US 707 (1881).
15. Judges Linn, Rader and Gajarsa
16. *See e.g., Rochester* denial; *see also Enzo Biochem, Inc. v. Gen-Probe, Inc.*, denial of rehearing en banc, 42 Fed. Appx. 439 (Fed. Cir. 2002).
17. *See e.g., Enzo* denial; *see also Rochester* denial.
18. *See Rochester* denial, 375 F.3d at 1315 and 1316.
19. *See Rochester* denial, 375 F.3d at 1312.
20. *See Wands*, 858 F.2d at 737. These factors include the level of one of ordinary skill in the art, the level of predictability in the art and the state of the prior art, among many others. The list is not exhaustive and it may be necessary to consider other factors to find a lack of enablement.
21. It is generally hard to prove that the best mode requirement has not been met since applicants need not indicate which embodiment is contemplated to be the best mode of carrying out the invention.

Patenting Incremental Improvements in Renewable Energy

Present-day opportunities in renewable energy have been compared to the growth opportunities presented in the telecommunications sector in the early 1990s. That pre-millennium period also saw a boom in patent use to protect or exploit intellectual property as the marketplace matured. But while renewable energy may be the next big thing in "tech" for the coming decade, as telecommunications was for the 1990s, access to patents as a means to defend turf or generate income has, contrarily, become more challenging.

Investment in solar, wind, biofuels or energy storage, for example, will spur innovations that are unquestionably groundbreaking and patent-worthy. There will also be innovations that provide only an incremental improvement to the art. These are the inventions that build on well developed, pre-existing technologies. Naturally, a higher bar to patentability should be placed in front of the applicant who seeks a patent on such technologies. So it has been for many, many years in the patent law. The difference now, however, is the benefit of doubt tends to swing in favor of the patent skeptic, not the patent proponent. This changed view is expressed in the Supreme Court's 2007 opinion addressing the legal standard for deciding whether an invention is "obvious",[1] which, roughly translated, means novel but not patent worthy.

According to the Supreme Court, an invention that is "predictable," either in its combination of parts or the result it produces, may be proven unpatentable as obvious, even in the absence of evidence to suggest that those working in the art would have had a reason to construct a device similar to that invented. This pronouncement, while not altering black letter law, has profoundly reduced a patent opponent's, or skeptical patent examiner's, burden of showing obviousness for the following reason: the counter-balance, or pro-patent side of the coin – one should not be denied a patent when a conclusion of obviousness is unfairly influenced by hindsight – is simply not given as much attention as in the 1990s.

What Can be Done?

While a patent office Examiner, empowered by the words of the Supreme Court, may be entitled to make rather liberal inferences, his or her intellectual leap from a novel invention to an obvious one must still be firmly grounded in predicate factual findings, so that the examination is not guided by personal opinion. In patent law, these factual findings are known as the *Graham* factors.[2] If the opponent of a patent right does not correctly resolve each of these factors then, regardless of the opponent's opinion, the analysis is flawed and a patent cannot be denied. For example, the question "would one of ordinary skill in the art at the time of invention have arrived at the same result?" cannot be properly answered until the predicate of the question, i.e., the *Graham* factors, are determined. Hence, the answer to this question depends on the qualities possessed by this person of ordinary skill and where he or she would have looked, or not looked, to find a solution to the problem.

Patent applicants for incremental improvements in renewable energy should benefit if the disclosure of invention is written both to describe the invention and to achieve a favorable resolution of the *Graham* factors. This preemptive approach to a future obviousness challenge might, for instance, assume at the outset that every part of the novel invention was a predictable combination of known things. The writing will then naturally focus on the reasons why the invention would not have been obvious. In taking this approach, "obvious" should not be thought of in its colloquial sense or by its dictionary definition. Rather, it is a legal construct embodied in the patent code and a plethora of court decisions.

Wind Turbines

Consider the following example of a patent application directed to an incremental improvement in wind turbines. The application describes a simple, but ingenious invention that addresses premature failures in wind turbine gearboxes. The inspiration for the invention came from an obscure technical journal, unrelated to wind turbines. Although the arrangement of parts that produced the desired result is novel, the parts themselves, and combinability of those parts, clearly are not. Moreover, with the benefit of only the inventor's rather crude mechanical drawing, one can easily see how to make or use the invention. No further explanation is required. An Examiner may take this patent application and conclude, at the outset, that the invention is not patent-worthy because it would have been obvious. Then the Examiner – one who is highly skilled in the art of searching through vast databases of patent publications – will conduct literature-based searches for each piece of the invention to justify the denial of a patent right.

The Examiner's erroneous conclusion can be revealed by identifying flaws in the Examiner's resolution of the *Graham* factors, such as the level of ordinary skill or scope of knowledge in the wind turbine art at the time of the invention. The flaws may, on the one hand, be communicated in the first instance during patent prosecution by producing documents or filing declarations with the Examiner. On the other hand, if the patent application already provides insight into the *Graham* factors, then the case for patentability ought to be more persuasive. Evidence of nonobviousness taken straight from the application should deserve more respect than similar evidence presented for the first time and in response to an examination report rejecting the application.

A more persuasive application, therefore, might tell the story of how the inventor's inspiration for the solution to the gearbox problem came from a source wholly outside the field of wind turbines. This can rebut a finding of obviousness because it raises the specter of an Examiner who is being improperly influenced by hindsight. One of ordinary skill in wind turbines would not have looked outside of his or her field to find a novel solution to the problem. The inventor's discovery, therefore, was not the product of ordinary skill but extra-ordinary effort.

Biofuels

Biofuel technologies include the production of liquid fuels such as ethanol and diesel from plant matter. Technologies for producing biodiesel from vegetable oils and ethanol from sugar cane and corn are relatively mature. On the other side of the spectrum is cellulosic ethanol production from sources such as crop residues and switch grass.[3] When pursuing a patent for an incremental improvement in the more mature variety of biofuel technologies, therefore, it may be important to adopt an aggressive, preemptive strategy to defeat an obviousness challenge than when pursuing a patent for an improvement in the production of cellulosic ethanol.

For instance, consider a novel processing scheme for ethanol or biodiesel production. The patent application would proceed with identifying the novel aspects of the scheme (e.g., flow rates, feedstock composition, reactor temperatures, equipment configuration, etc.) based on known prior art schemes. But the discussion should not stop there. The application should also attempt to explain, in the best light possible, why such novel aspects are critical, how they relate to data generated and why such novel aspects may be inconsistent with or against the recommendations of the prior art. For example, the

application could point out that a description of a prior art process counseled against, directly or by implication, incorporating the inventor's novel aspects into the prior art process. The prior art indicated that operating under the inventor's process conditions would result in undesirable by-products or fouling of reactor components. Or the application may point out that the prior art had not recognized the importance of claimed process parameters in achieving a desired process output (e.g., conversion). This would preemptively defeat an assertion that the applicant's process would have been an obvious product of routine optimization.

Other rationale have been articulated to defeat claims of obviousness on similar grounds. In each case the objective is to demonstrate that, in the absence of the patent application to use as a guide or roadmap, the patent opponent would have stood no chance of re-constructing the invention. This aspect of the legal analysis has not changed in recent years. But what has changed are the burdens of proof. Proponents are getting the benefit of the doubt. And patent Examiners are presumed to be immune from the dangers of hindsight. In the 1990s the opposite was true. But that was then and this is now.

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1. *KSR Int'l v. Teleflex, Inc. et al,* 550 US 398 (2007).
2. *Graham v. John Deere Co. of Kansas City,* 383 US 1 (1966).
3. *Current Biology,* Vol 17 No 4, (2007).

Prometheus Laboratories Inc. v. Mayo Collaborative Services and Mayo Clinic Rochester: More on Patentable Subject Matter

Hot on the heels of the CAFC's enunciation in *In re Bilski*[1] of the machine-or-transformation test as the standard for the determination of whether a method is patentable subject matter, the court has applied this test to methods of medical treatment in *Prometheus Laboratories Inc. v. Mayo Collaborative Services and Mayo Clinic Rochester*.[2] In *Prometheus Laboratories Inc*. the CAFC reversed the District Court for the Southern District of California's finding of invalidity of US Patents 6,355,623 ('623) and 6,680,302 ('302), finding that the patent claims were directed to patentable subject matter.

Prometheus is the exclusive licensee of '623 and '302, which are directed to methods of calibrating the correct level of thiopurine drugs to be administered for the treatment of autoimmune disease, particularly gastrointestinal autoimmune disease. Specifically, 6-Mercaptopurine (6-MP) is a drug for treating inflammatory bowel disease that is broken down by the body into various metabolites including 6-methyl-mercaptopurine (6-MMP) and 6-thioguanine. Claim 1 of '623 reads:

> 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a

> need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

In an infringement suit by Prometheus, Mayo raised the defense that the patents were an attempt to patent "natural phenomena" and thus the claims were invalid.[3] The district court agreed and found the patents invalid for not being directed to patentable subject matter.

Not all discoveries are patentable. Patentable subject matter is limited by 35 USC §101 to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." The Supreme Court has interpreted the scope of 35 USC §101 broadly, stating that "Congress intended statutory subject matter to 'include anything under the sun made by man.'"[4] Certain subject matter has, however, been categorically excluded from patent coverage, specifically "laws of nature, physical phenomena, and abstract ideas,"[5] as well as "mental processes."[6] In *Bilski*, the CAFC interpreted the prior Supreme Court precedent as establishing the following test of whether a method or a process is patent eligible under 35 USC §101: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."[7] Further, CAFC stated that such machine or transformation must be central to the claim, and must be more than mere data gathering or other "insignificant extra-solution activity." According to CAFC, the machine-or-transformation test determines whether the claim covers an application of a fundamental principle or the fundamental principle itself.

The claims at issue in *Bilski* involved methods of hedging risk in commodities trading, i.e., business method claims. These claims did not recite the use of a particular machine nor the transformation of a particular article into a different state or thing, and, thus, were found to be unpatentable.

In *Prometheus*, the CAFC held the patent claims valid, finding both the administering and determining steps to be "physical transformations," which were central to the claim. When viewed as a whole, the claims were found to be "methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."[8] CAFC determined that the "administering step" is transformative. The "determining step" was also found to be transformative "by working a chemical and physical transformation on physical substances"[9] as the blood sample was manipulated during the assay for the metabolites. Further, the fact that the drug metabolizes, or transforms, into various metabolites by virtue of a natural process of the human body does not negate patentability. The CAFC pointed out that the district court erred in characterizing both the administering and determining steps as "data gathering steps." Moreover, the fact that the "wherein" clauses, which were interpreted as providing the physician a "warning," are mental steps is immaterial as the prior steps in the method are transformations.

The facts in *Prometheus* are similar to those of *Metabolite Laboratories Inc. v. Laboratory Corporation of America*.[10] The claims at issue in *Metabolite* were directed to methods of determining the level of total homocysteine, an amino acid, in the blood and "correlating" the level of homocysteine with deficiency of the vitamins cobalamin and folate. The CAFC upheld the lower court's finding of patent validity over challenges based upon indefiniteness, anticipation and obviousness raised by Laboratory Corp. Laboratory Corp. sought *certiorari* to the Supreme Court. The issue raised was whether the Metabolite patent claims met the requirement of 35 USC §101. The Supreme Court initially granted *certiorari* but then dismissed it as being "improvidently granted" in that the §101 issue had not been raised at the CAFC. Justice Breyer dissented, stating that is was clear that "[a]t most, respondents have simply

described the natural law at issue in the abstract patent language of a 'process,'" which he characterized as "no more than an instruction to read some numbers in light of medical knowledge."[11] In finding the patent at issue in *Prometheus* invalid, the district court relied heavily upon the dissent of Justice Breyer, noting that "[a]lthough… the dissent in *Lab. Corp.* does not have precedential value, the Court finds Justice's Breyer's reasoning persuasive."[12]

The public policies of providing an incentive to inventors and insuring that basic knowledge remains in the public domain are clearly in conflict.

Given the interest that the grant of *certiorari* in the *Laboratory Corp.* case generated, the fact that in *Prometheus* the issue of patentable subject matter was raised at the district court level and the recent grant of *certiorari* in *Bilski*[13], one commentator predicts that *certiorari* may be granted in *Prometheus*.[14] The public policies of providing an incentive to inventors and insuring that basic knowledge remains in the public domain are clearly in conflict. Another commentator has proposed that a workable "dividing line" might be to find those claims addressed primarily to end users as patentable subject matter.[15] Another potential dividing line might be between methods involving administration of a drug on the one hand and those involving the correlation or detection of naturally occurring substances on the other.[16]

While the issue of §101 patentable subject matter is clearly up in the air, one should draft at least some dependent claims tied to a particular machine or a specific method of detection. Thus, even if *Prometheus* is overturned, it is clear that the claims cover an application of a natural phenomenon and not the natural phenomenon itself. It is interesting to note that the inventors of the patents at issue in *Metabolite* had also developed a method to detect the levels of the deficient vitamins.[17]

A final thought to keep in mind is that, to be patentable, claims must not only meet the requisites of 35 USC §101 but also must be novel and nonobvious. As the CAFC noted in *Prometheus*, there it was only addressing the issue of whether or not the claims were directed to patentable subject matter under 35 USC §101 and not the issues of novelty and obviousness as "whether a claimed element or step in a process is novel or nonobvious… are separate requirements set forth in 35 USC §§102 and 103, respectively. *Bilski,* 545 F.3d at 958 (citing *Diehr,* 450 US at 188-91)."[18]

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1. 545 F.3d 943 (Fed. Cir. 2008).
2. No. 2008-1403, 2009 US App. Lexis 20623 (Fed. Cir., Sept. 16, 2009).
3. *Prometheus Laboratories, Inc. v. Mayo Collaborative Services and Mayo Clinic Rochester*, 86 USPQ2D (BNA) 1705, 2008 US Dist LEXIS 25062, at *14 (SD Cal, 2008).
4. *Diamond v. Diehr, 450 US 175, 182* (1980).
5. *Id.* at 309.
6. *Gottschalk v. Benson*, 409 US 63, 67 (1972).
7. *Bilski* at 954. The case was argued in front of the Supreme Court on November 9, 2009, but at this point in time the Supreme Court has not resolved whether the test for determining if a method or a process is patent eligible will stand.
8. *Prometheus*, Federal Circuit, at *23.
9. *Id.* at 27
10. 370 F.3d 1354 (Fed. Cir. 2004).
11. *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 548 US 124, 137 (2006).
12. *Prometheus*, District Court, at *25.
13. *Bilski v. Doll*, 129 S.Ct. 2735 (2009).
14. Dennis Crouch, "Patentable Subject Matter: Federal Circuit Upholds the Patentability of Drug Dosage Form," Patently-O, http://www.patentlyo.com/patent/2009/09/patentable-subject-matter-federal-circuit-upholds-patentability-of-drug-dosage-method-claim.html, September 16, 2009.
15. Kevin Emerson Collins, "An Initial Comment on *Prometheus*: The Irrelevance of Intangibility," Patently-O, http://www.patentlyo.com/patent/2009/09/an-initial-comment-on-prometheus-the-irrelevance-of-intangibility-1.html, September 17, 2009.
16. *Prometheus*, Federal Circuit, at *23, footnote 3.
17. *Metabolite* at 1358.
18. *Prometheus*, Federal Circuit, at *14-15.

What's The Use: A Look at *In re Bose Corp.* and Fraud

In the United States, trademark or service mark rights are derived from the use of a mark to identify and distinguish the mark owner's goods and/or services from those of another. An application for federal registration can be filed based on actual use of a mark or one's *bona fide* intention to use that mark. Subject to certain international considerations, a registration will not issue and may not be maintained absent actual use of a mark. All the while, from filing an application, issuance of a registration and post-registration maintenance, a trademark owner is required to attest to its *bona fide* intention to use a mark or its actual use of a mark subject to the penalties of perjury under 18 USC §1001. Indeed, at the time an intent to use application has successfully passed the opposition stage, a Notice of Allowance provides the following guidance:

> Ensure that statements made in filings to the USPTO are accurate, as inaccuracies may result in the cancellation of your trademark registration. The lack of a bona fide intention to use the mark will all goods and/or services included in an application or the lack of use on all goods and/or services for which you claimed use could jeopardize the validity of your registration, possibly resulting in its cancellation.

It is the declarations, affidavits and attestations as to the actual use of a mark that have most often formed the basis for fraud claims. In 2003 the Trademark Trial and Appeal Board (TTAB) held in *Medinol v. Neuro Vasx, Inc.* that "[a] trademark applicant commits fraud in procuring a registration when it makes material representations of fact in its declaration which it knows or show know to be false or misleading."[1] Since the *Medinol* decision, we have seen many more challenges asserting fraud and the TTAB has applied this "knew or should have known" standard to opposition and cancellation proceedings alleging fraud.

On August 31, 2009 the TTAB's reviewing court, the Court of Appeals for the Federal Circuit (CAFC), stated in *In re Bose Corp.* that the TTAB had erroneously lowered the fraud standard to a simple negligence standard by equating "should have known" of the falsity with a subjective intent and rejected the *Medinol* standard.[2] Reviewing its own prior decisions, and particularly those addressing inequitable conduct in patent cases, the CAFC explained that mere negligence is not enough to infer fraud or dishonesty.[3] Even "'gross negligence' does not of itself justify an inference of intent to deceive."[4] Rather, the CAFC confirmed that "[t]he principle that the standard for finding intent to deceive is stricter than the standard for negligence or gross negligence… applies with equal force to trademark fraud cases."[5] Reaffirming this principle, the CAFC limited the likelihood of success of a fraud claim and held that "a trademark is obtained fraudulently under the Lanham Act *only* if the applicant or registrant knowingly makes a false material representation with the intent to deceive the PTO."[6] The court cautioned that an allegation of fraud should not be taken lightly and the subjective intent to deceive is an indispensable element of the analysis. Clear and convincing evidence is required to prove such intent.

Applying this more limited standard to the particular facts of *Bose* and reversing the TTAB's decision below, the CAFC determined that there was no willful intent to deceive although the court acknowledged that Bose had made a material misrepresentation to the USPTO. The court reasoned that Bose's false misrepresentation which was made pursuant to an honest misunderstanding or inadvertence did not constitute fraud because it lacked the requisite intent. In closing, CAFC noted its agreement with the TTAB that Bose's mark was no longer in use on specific goods and, therefore, the registration would need to be restricted to reflect this commercial reality.[7] In our

view in making this closing statement and recognizing that no public purpose would be served by cancelling a registration in its entirety, the CAFC hinted at the premise that registrations should not be cancelled in whole or deemed void *ab initio*, but specific goods or services in a registration may be removed if they are no longer in use or if fraud has been found in connection with a declaration of use of such goods and/or services.

Fraud "must be 'proven to the hilt' by clear and convincing evidence" and a party asserting fraud is under a heavy burden.

Since the CAFC's decision in *In re Bose Corp.*, the TTAB has had several occasions to address this new standard. Most notably, in *Enbridge, Inc. v. Excelerate Energy Ltd. Partnership,* the TTAB denied a motion for summary judgment where it found that the opposer had failed to meet its burden of establishing that there was no genuine issue that the applicant had the intent to deceive the USPTO.[8] The TTAB stated that, "[a]t a minimum, whether applicant knowingly made either of… these representations of use with the intent to deceive the USPTO remains a genuine issue of fact to be determined at trial."[9] It also appears that the TTAB is undertaking to review the pre-*Bose* filings which allege fraud. In some instances, as indicated in *Societe Cooperative Vignerrone Des Grandes Caves Richon-Le-Zion and Zicron-Jacod Ltd. v. Albrecht-Piazza, LLC*, the TTAB is requiring that a party amend its fraud claim where its original filing now fails to state a legally sufficient claim of fraud under *Bose.*[10] In this proceeding, the TTAB also advised that pleadings must contain explicit rather than implied expressions of circumstances which constitute fraud. "Pleadings of fraud made 'on information and belief' where there is no separate indication that the pleader had actual knowledge of the facts supporting a claim of fraud" are insufficient.[11]

Most recently, in *Asian & Western Classics B.V. v. Lynne Selkow,* the TTAB issued a precedential decision where it was called upon to consider a motion for summary judgment on a fraud claim.[12] The motion had been fully briefed. However, in view of its decision in *Bose*, the TTAB reviewed the operative pleadings in the case and determined that the claim of fraud had been insufficiently pleaded. In this case, the TTAB observed insufficiencies in the pleadings where allegations based on "information and belief" were made without identifying specific facts on which the belief is reasonably based. Under Fed.R.Civ.P. 9(b) "any allegations based on 'information and belief' must be accompanied by a statement of facts upon which the belief is founded." Citing *Bose*, the TTAB also determined that a pleading before the USPTO must include an allegation of intent. "Intent" is a specific element of a fraud claim and an allegation that a declarant "should have known" a material statement was false does not make out a proper pleading and the petitioner's allegations that "registrant knew or should have known" were found to be insufficient to infer respondent's intent to commit a fraud on the USPTO. In closing, the TTAB cautioned that fraud "must be 'proven to the hilt' by clear and convincing evidence" and stated that a party asserting fraud is under a heavy burden. Considering the factual question of intent in a fraud claim, the TTAB also advise that such a claim was "particularly unsuited to disposition on summary judgment."

While we certainly do caution trademark applicants and registrants to continue to accurately identify those goods and services for which they have a *bona fide* intention to use a mark or for which they are making actual use of a mark, especially where a laundry list of goods and/or services is identified, it seems clear based on the CAFC's decision in *Bose* as well as the TTAB's post-*Bose* actions, that a registration, or a portion thereof, will become vulnerable to cancellation based on fraud only where there has been a clear and convincing showing that the registrant had the intent to deceive. The same is true for applications. Gone are the days where, the lesser "should have known" standard would suffice. The question remains unanswered with respect to the magnitude of evidence that will be required to demonstrate the requisite willful intent

for fraud. CAFC has recognized that subjective intent to deceive may be difficult to prove. Direct evidence of such deceptive intent is rarely available. Indirect and circumstantial evidence may be available to infer the necessary intent. It is unclear what form that evidence will take. However, what is clear, is that pleadings of fraud must be specific. Moreover, based on the TTAB's recent decision in *Enbridge*, without the proverbial smoking gun, summary judgment motions asserting fraud likely will not succeed. Even then, based on the most recent decision in *Asian & Western Classics*, the TTAB hints that summary disposition may just not be appropriate.

Alisa C. Key, of counsel, Tysons Corner

1. *Medinol v. Neuro Vasx, Inc.,* 67 USPQ2d 1205, 1209 (TTAB 2003).
2. *In re Bose Corp.,* 91 USPQ2d 1938 (Fed. Cir. 2009).
3. *Id.*
4. *Id.* (internal citations omitted).
5. *Id*.
6. *Id.* (emphasis added).
7. On October 30, 2009 further to the CAFC's directive, the TTAB issued an Order amending Bose's registration to delete "audio tape recorders and players, portable radio and cassette recorder combinations" which no longer were in use.
8. *Enbridge, Inc. v. Excelerate Energy Ltd. Partnership* (Opposition No. 91170364, October 6, 2009).
9. *Id.*
10. *See Societe Cooperative Vignerrone Des Grandes Caves Richon-Le-Zion and Zicron-Jacod Ltd. v. Albrecht-Piazza, LLC,* (Opposition No. 91190040, September 20, 2009).
11. *Id.*
12. *See Asian & Western Classics B.V. v. Lynne Selkow,* (Cancellation No. 92048821, October 22, 2009).

Trade Secrets in the Board Room: Director or Observer?

When an investor takes a significant equity position in a company, the investor may be able to appoint one or more representatives to the company's board of directors. Although appointing a director secures the investor's right to vote in board decisions, this position comes with complex fiduciary duties and, consequently, greater potential liability for the investor.

Alternatively, and particularly in those cases where an investor's board position may not give it the power to control or block board actions, an investor may wish to appoint an observer who is contractually entitled to attend and participate in board meetings, but cannot vote on board actions. While an observer would obviously have less influence on board decisions, the absence of the fiduciary duties of a director may reduce the investor's overall exposure to potential liability and therefore be an attractive trade-off. An investor may be able to further limit its potential risk by including contractual provisions in a board observer agreement that would obligate the company to limit the observer's exposure to trade secrets and other proprietary information.

Director

Advantages

An individual who assumes a position on the board of directors has the right to attend and vote in all board meetings. Directors also have the authority to exclude observers, advisors and other non-director participants from board meetings when it is in the company's best interest to do so, when there is a potential conflict of interest or to otherwise protect privileged or proprietary information such as trade secrets. Having a representative on the board of directors allows an investor to monitor the

company more closely, and participate in the direction of the company.

Disadvantages

A director assumes significant responsibility regarding control and oversight of the company and has fiduciary duties both to the company on whose board he or she is serving, and to the company's shareholders. Courts have consistently held that directors owe fiduciary duties to *all* shareholders of the company, which includes the holders of common stock as well as the class of stock that the investor-director holds.[1] As a result, the potential costs of litigation arising from a breach of fiduciary duty create a sizable risk for investors with individuals appointed to the board of directors.

Appointing an observer rather than a director allows investors to avoid the complex fiduciary obligations that directors owe to the corporation and all of its shareholders.

A director faces the challenge of diligently remembering each of his or her fiduciary duties and taking them into account in all of the actions he or she may take. For example, directors owe a duty of care to the corporation on whose board they are serving, which requires that they be informed in making decisions and overseeing management. Directors also owe the corporation a duty of loyalty, requiring them to act in good faith and in the best interest of the corporation, rather than in their own interests as shareholders, if applicable. Directors must not use their position of trust and confidence to further private interests because the law requires an undivided loyalty to the corporation and demands that there be no conflict between duty to the corporation and self-interest. Opportunities for conflicts of interest arising from the dual roles of investor-directors and the costs of possible litigation cause many investors to adopt a policy of not taking board seats.

A director's breach of fiduciary duty can impose severe costs on the investor. For example, in 2005 Lexar Media, Inc. sued Toshiba Corporation for misappropriation of trade secrets and breach of fiduciary duty by the director representing Toshiba, resulting in a verdict of more than US$465 million against Toshiba.[2] Toshiba had strategically invested in Lexar and obtained a seat on the board of directors. Although Toshiba would have suffered liability for the misappropriation regardless of board membership, the presence of Toshiba's representative on the board of directors contributed to Toshiba's costs in defending against the breach of fiduciary duty claim. Choosing a position as a board observer instead of a director may have avoided such substantial litigation costs, since the observer would not have been bound by a fiduciary obligation to Lexar or its shareholders.

Board Observer

Advantages

Board observers contractually have the right to attend board meetings and receive information and materials sent to the directors on the board. Furthermore, observers generally may comment on matters before the board and otherwise participate in the board's discussions. Appointing an observer rather than a director also allows investors to avoid the complex fiduciary obligations that directors owe to the corporation and all of its shareholders.

Disadvantages

The primary difference between a board director and a board observer is that an observer cannot vote during board meetings. An observer may also be excluded from meetings or may be prevented from receiving information provided to board members if the board determines that the exclusion is necessary to preserve the company's attorney-client privilege, if there is a conflict of interest or confidentiality concern or if the observer's presence would otherwise inhibit deliberations by the board.

Contractual Protections

Due to the board of directors' role in the control and oversight of the company, trade secrets and other proprietary information may be disclosed during board meetings. Through a board observer agreement, an observer typically agrees to hold in confidence and trust the information he or she receives, and not to use or disclose any confidential information learned pursuant to his or her observation rights for any purpose other than monitoring the investor's investment in the company.

Board observer agreements often expressly permit the company to exclude the observer from attending portions of meetings in which such privileged or proprietary information is discussed, or from accessing board materials that may contain such information. As an additional protection, strategic investors may wish to contractually *obligate* the company to exclude the observer from such meetings and materials, so as to avoid future disputes that may otherwise result from claims that a strategic investor had access to the company's trade secrets or other proprietary information.

The position that each investor chooses will depend upon the level of influence the investor wishes to exert on board decisions, balanced with the level of risk it is willing to assume. Investors that invest in companies strategically, rather than for purely financial reasons, should be especially cautious when deciding whether to appoint their representatives as directors or observers and, where applicable, drafting the appropriate agreements.

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1. *See, e.g., In re Trados Inc. S'holder Litig.*, 2009 Del. Ch. LEXIS 128 (Del. Ch. July 24, 2009).

2. *Lexar Media, Inc. v. Toshiba Corp.*, No. 1-02-CV-812458 (Super. Ct. Cal. 2005).

Contributor Profiles

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Alicia M. Choi focuses her practice on the areas of patent law. Her work includes preparing and prosecuting utility patent applications in the areas of electrical and computer engineering including information technology, software systems, wireless communication, medical diagnostic devices, semiconductors, analog and digital circuitry, and consumer electronics such as optical storage media and audio devices for US and international clients. Her experience also includes conducting novelty, patentability, invalidity and infringement analyses for various electrical devices and systems. Before entering the practice of law, Ms. Choi was a lead engineer for Rockwell Automation where she was involved in the integration of various programmable controllers and electronic operators.

Gloria M. Gusler, Ph.D., focuses her practice on intellectual property matters, particularly in the area of patent prosecution. Dr. Gusler's background is in chemical engineering, materials and pharmaceuticals. She has worked for clients in the areas of medical devices and drug delivery. Dr. Gusler was in-house patent counsel at a development stage pharmaceutical company where she managed the patent portfolio, directed outside counsel and advised executives on patent matters. Prior to pursuing a career in law, Dr. Gusler worked in drug development where she managed a formulations team. She has more than 10 years of experience in drug development in both large and small company environments. Dr. Gusler is an inventor on several patents, is published in peer-reviewed journals and has made podium presentations at the Annual Meeting of the Controlled Release Society.

Alisa C. Key focuses her practice on all areas of trademark law including trademark, copyright and domain name counseling as well as trademark prosecution and enforcement in US and non-US arenas. She assists clients in the clearance, acquisition and licensing of trademark, copyright and other IP rights, the management of worldwide trademark portfolios, due diligence in corporate transactions, and the design and implementation of policies and guidelines for the proper procurement, use, protection and enforcement of trademark rights. Ms. Key is experienced in actions involving trademark and trade dress infringement, rights of publicity, domain names, dilution, the seizure of counterfeit goods and unfair competition before federal and appellate courts, arbitration tribunals and the Trademark Trial and Appeal Board of the USPTO.

Michael A. Leonard focuses his practice on intellectual property matters, particularly the procurement of patents in the fields of software and electronics. He has prosecuted patents for large corporations based in the United States, Finland, Japan, Korea and Germany, procuring patents in numerous computer science and electrical engineering fields including various software technologies, mobile telecommunications, optics and circuit fabrication. Prior to law school, Mr. Leonard was a consultant and software engineer, where he developed various software applications including an embedded operating system based on the Java language and the server side component of a digital marketplace application.

Mark Lupkowski, Ph.D., focuses on providing patent-related services to clients in chemical and life sciences technologies. These services include preparation and prosecution of patents, opinion work, counseling and litigation support. Dr. Lupkowski has worked with clients in various industries including medical devices, petrochemical, semiconductor and software. He has prepared and prosecuted numerous patents in areas such as cardiovascular implants, fossil fuel processing and business methods. Dr. Lupkowski has a Ph.D. in chemical engineering and worked as an engineer for several years prior to his career as a lawyer.

James L. Reed focuses his practice on intellectual property matters including patent prosecution, counseling, litigation and intellectual property transactions in the mechanical, electrical, database and information sharing, telecommunication and networking fields. Mr. Reed has prosecuted hundreds of patent applications before the USPTO, including numerous appeals before the Board of Patent Appeals and Interferences, assisted clients with securing patents in foreign countries and managed international patent portfolios. He has also advised on the validity, enforceability and infringement of patents in order to assess risks to his clients, or evaluate assets for potential or planned mergers and acquisitions. Mr. Reed also has several years of patent litigation experience involving patents in the medical device, databases and software, LCD, golf club, RFID and children's products fields.

Beth Seals focuses her practice on life sciences and intellectual property matters. Ms. Seals has represented pharmaceutical, medical device and biotechnology companies in connection with the preparation and negotiation of US and international clinical trial agreements, consulting agreements, services agreements and related documents, in addition to providing counsel on clinical trial regulatory issues. Ms. Seals' intellectual property practice covers a broad range of US and international transactional matters in a wide variety of areas including computer technology, biotechnology and pharmaceuticals, Internet, and media and entertainment. Her experience includes providing assistance in e-commerce and Internet transactions, trademark registration and protection, and patent and software licensing.

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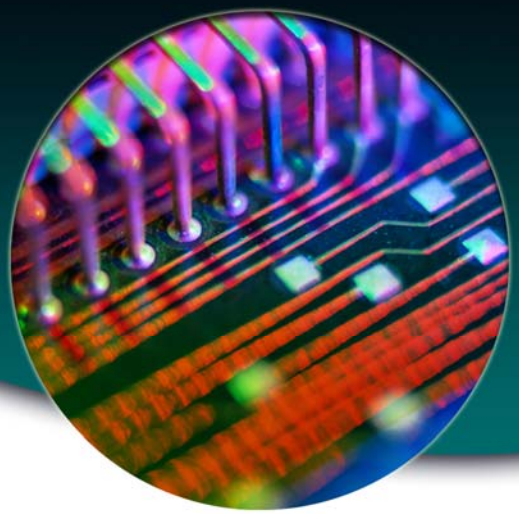

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