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Review of Developments in Intellectual Property Law

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A Survey of the Peer to Patent Pilot Project

With the Peer to Patent project set to begin a third pilot period in October and to expand in scope,[1] the time is right to review the status of this program and to introduce our clients and readers to the Peer to Patent process, its history and its future, and its advantages, and to encourage others to get involved with this promising project. During our research for this article, we interviewed many of the people that were involved in getting the project off the ground in mid-2007,[2] and many of the people that guided the project through its second pilot period from 2008-2009.[3] Included within this elite set of patent professionals is Manny Schecter, Chief Patent Counsel at IBM,[4] Curt Rose, Director of Patents at Hewlett-Packard,[5] Scott Asmus, Patent Counsel at General Electric,[6] Matt Rainey, Vice President and Patent Counsel at Intellectual Ventures,[7] Adam Avrunin, Chief Patent Counsel at Red Hat,[8] and Mark Webbink, ex-Senior Vice President and Deputy General Counsel at Red Hat and now Executive Director at the Center for Patent Innovations at New York Law School (NYLS).[9] We hope you find this information useful and enlightening, and hope it convinces at least some to get involved with the project, and, as Thomas Jefferson put it, help "contribute[e] to a public good."[10]

Background and Current Status of the Peer to Patent Project

There has been an enormous amount of debate over the last several years about a perceived decrease in the quality of patents issuing from the U.S. Patent & Trademark Office (USPTO), and consequently whether or not the agency is

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Free, But Not Without Risk: Open Source Licensing in the Wake of *Jacobsen v. Katzer*

Introduction

Sam is the chief technology officer of a small software vendor. At the request of his customers, he kicks off a new project to redesign and upgrade his company's flagship product. During the design phase, one of his engineers suggests that several person-years of effort can be saved by incorporating a large software module from a popular "open source" program. After crunching numbers and finding that the savings add up to nearly half a million dollars, Sam green-lights use of the module. What Sam does not realize, however, is that although his decision saves time and improves his bottom line, it may also put his company at risk of a lawsuit for copyright infringement or breach of contract.

Closed and Open Source Software

Computers execute programs that are compilations of instructions and data in binary format.[1] In the early days of computing, software developers would write programs either directly in binary format or in assembly language, which can then be converted into binary format. However, due to its intricate nature, developing software in assembly language or binary format is time consuming and error prone. Over time, software developers found it more efficient to write programs in high-level languages, and then translate, or compile, their high-level language programs to binary format. High-level languages express programs in source code that, in some cases, resembles English, though in a rigid and logical fashion. Thus, a high-level language is typically easier to write and read than assembly language or binary format, and nearly all modern computer programming is carried out in high-level languages.

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fulfilling its mandate under the Constitution of promoting the progress of science and the useful arts.[11] Currently, the USPTO is struggling to deal with an overwhelming backlog of over 1.2 million pending patent applications.[12] For the patents the USPTO does issue, there is a perceived decrease in quality caused, at least in part, by the number of undeservedly broad claims and by the number of findings of invalidity during patent reexamination and litigation. In patent cases that went to trial in 2009, nearly half of the challenges to patent validity, approximately 43%, were successful[13] and over half of the validity challenges based on obviousness grounds were successful.[14] The expense of litigating suspect patents, according to IBM's Manny Schecter, "drains our economy of at least hundreds of millions of dollars per year."[15] USPTO Director David Kappos has also recently commented on how the growing patent backlog stifles job growth and the development of new businesses and products.[16] Any effort to examine more applications and trim the backlog, however, needs to be balanced with initiatives to ensure the issuance of higher-quality patents.

The Peer to Patent program was developed to address both of these seemingly countervailing problems, by improving both the quality and efficiency of patent examination by sourcing the shared knowledge of the global technical community,[17] or "crowdsourcing."[18] Specifically, the Peer to Patent program's aim is to involve third party experts residing outside of the USPTO in the search for, and submission of, prior art references.

Examiners at the USPTO typically have around 20 hours to examine patent applications.[19] In this limited time the examiners must digest the new material in the application, research the prior art, and draft an office action on the merits of the application. This short time frame makes it difficult to perform a thorough search for relevant prior art. Examiners are further constrained in that their research, for reasons outside the scope of this paper, is generally limited to internal databases that focus primarily on patents and patent applications, at the expense of non-patent literature (NPL). Furthermore, and as noted by Mark Webbink, even NPL literature that examiners do somehow find and cite is not indexed, subjected to optical character recognition (OCR'd), or tagged in any meaningful way so as to allow future searchers or other examiners to find the previously-located NPL art.[20] Additionally, for new technologies, such as software and business methods, there is not a significant amount of patent prior art in the internal databases, and as a result, the resources that the examiner can rely upon to reject an improperly broad claim are sparse, even if the claim is drawn to something well-known in the industry.

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Any effort to examine more applications and trim the backlog, however, needs to be balanced with initiatives to ensure the issuance of higher-quality patents.

The Peer to Patent project was set up to address this lack of prior art resources by using the Internet and social networking tools to provide those in the relevant technical community an opportunity to examine the application and offer not only what they think is relevant prior art, but also their commentary on how the relevant art could be applied to the claims, what elements of the claims are known in the art, and what elements of the claims are potentially new, all before the USPTO examiner even begins reviewing the application.[21] This allows the public to recommend NPL such as articles, conference presentations, web pages, products sold in the marketplace, newsgroup (*e.g.* Usenet) postings, or even publicly available or open source software code that the examiner would likely be unable to find in his or her own limited search.[22]

Although many solely attribute Beth Noveck of New York Law School with developing the Peer to Patent project, the project actually originated as a close collaboration between Noveck, IBM, and the USPTO, directed to improving the quality of examination of software patents filed with the USPTO.[23] Schecter[24] drove the corporate involvement and sponsorship for the project. Corporate involvement was critical in the early stages of the Peer to Patent project as the project was entirely funded by corporate sponsorship and foundation grants during the first two pilot periods from 2007-2009.[25] Noveck provided leadership for the project and also provided law students to help in their spare time,[26] and USPTO Technology Center Director Jack Harvey offered up his technology center (2100 - Computer Architecture, Software, & Information Security) and his time for the project.[27] Schecter stated that one reason Technology Center 2100 was chosen was because the open source software community is more skeptical about patents than are inventors in other technology areas, and thus the Peer to Patent project provided the open source community with an opportunity to get involved and do something about the perceived lack of patent quality in the software arts.[28] Additionally, Schecter stated that the open source community was already quite familiar with using collaborative online tools, and thus were a natural starting point for a project that relied heavily on collaborative tools.[29]

At the time of that initial collaboration between Noveck, IBM, and the USPTO, and

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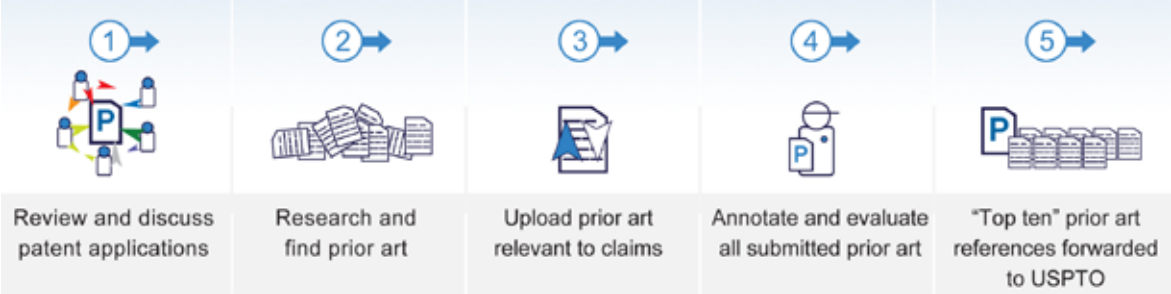

as it remains today, the only avenue for a third party to submit art against a pending United States Patent Application (outside of the Peer to Patent project) was to comply with the rules set forth in 37 C.F.R. § 1.99 governing third-party submissions. In short, § 1.99 requires that a third-party submitter wishing to submit art to the USPTO include "(1) the fee set forth in § 1.17(p),[30] (2) a list of the patents or publications submitted for consideration by the Office, including the date of publication of each patent or publication, (3) a copy of each listed patent or publication in written form or at least the pertinent portions, and (4) an English language translation of all the necessary and pertinent parts of any non-English language patent or publication in written form relied upon."[31] Furthermore, the submission must be "served upon the applicant in accordance with § 1.248," "shall not include any explanation of the patents or publications, or any other information," and must be filed "within two months from the date of publication of the application (§ 1.215(a)) or prior to the mailing of a notice of allowance (§ 1.311), whichever is earlier."[32] A submission that "does not comply with the requirements of this section will not be entered."[33]

As an alternative to the burdensome requirements of 37 C.F.R. § 1.99, the Peer to Patent project, launched in 2007, provided a platform by which any member of the public could submit relevant art along with commentary and analysis, free of charge, and without serving the applicant as required by the § 1.99. After the June 15, 2007 launch date, the project actively began soliciting public participation in the project.[34] During the first and second pilot programs, only applications falling within Technology Centers 2100 (Computer Architecture, Software, & Information Security) and 3600 (Business Methods) could participate in the program.[35] During the third pilot period, starting in October 2010, the program is expected to start accepting applications in the telecommunications, bioinformatics, and biotechnology fields.[36]

Applicants volunteering to participate in the program must file a consent form with the USPTO, after which their application is published on the Peer to Patent website for four months.[37] As an incentive for applicants to participate in the Peer to Patent program, applications submitted to the program are allowed to jump to the front of the USPTO queue.[38] Advantageously, this can be done without meeting the requirements for expediting prosecution of applications under 37 C.F.R. § 1.102,[39] and without conducting a pre-examination search or providing an accelerated examination support document, as required by the Accelerated Examination program.[40] While Schecter stated that the "make special" designation was not a factor in IBM's decision to participate in the project, he indicated his belief that universities, startups, and small inventors would find this incentive particularly attractive.[41] Scott Asmus of GE, on the other hand, stated that he felt the current 2-3 year cycle to a first office action was a serious hindrance, and jumping to the front of the queue was a great way to speed up the prosecution of important cases.[42] As noted by Webbink, the ability to jump to the front of the queue is expected to be retained in the third pilot period.[43]

The figure above[44] illustrates the general process that an application goes through in the Peer to Patent project after publication on the Peer to Patent website. First, registered peer reviewers review and discuss the disclosure and claims of the submitted application. Second, the reviewers can research and find prior art on their own, including art they may already have on hand. Third, the reviewers can upload art they believe may be relevant to the pending claims. Fourth, the reviewers can annotate the claims relative to the uploaded prior art, rank the quality of their own uploaded art relative to the claims, and rank the quality of art uploaded by others. Fifth and finally, the top ten rated prior art references are forwarded to the USPTO in an IDS drafted and submitted by the Peer to Patent program itself.[45]

The Peer to Patent platform utilizes several features borrowed from social networking architectures to solicit third party experts to find, submit, and rate prior art references during the review period. While any interested party is capable of signing up and reviewing applications, each individual can also share any application with his or her colleagues by entering one or more email addresses into a form provided on the website.[46] Reviewers can also "tag" applications with relevant claim terms (that perhaps are relevant or related to the application, but may not exist in the drafter's technical description of the

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invention) in order to improve future reviewers' ability to find relevant documents and to provide alternative key words for other reviewers (and perhaps the examiner) to use when conducting future searches.[47] Once a piece of prior art is uploaded, all other users can rank the submission for relevance and quality.[48] This method of "crowdsourcing" ensures that the submitted prior art is appropriate by relying on the collective intelligence and experience of a plurality of interested parties having expertise in the particular technology field, mitigating the effects of improper submissions resulting from those who do not understand the scope of the application's claims or the scope of the submitted prior art.

Importantly, reviewers can also describe *why* they feel a particular prior art reference is relevant to the application, by marking up the reference and/or the claims of the application. This method of mark-up ensures that the examiner spends his or her time on the most relevant portions of the submitted prior art, and does not waste his or her time on those portions of the claims shown to disclose no useful advance in the art.

All of these above-noted features stand in stark contrast to the current statutory basis for third-party art submissions, in which parties are allocated a small window in which to submit art, are required to pay a fee, and can not provide any annotations regarding the claims or the prior art, thus forcing the examiner to spend additional time reviewing the reference and comparing it to the pending claims of the application.[49]

The second pilot program ended in July 2009, and the USPTO has since been in a review period during which the agency's newly appointed chief economist is analyzing groups of applications to gain insight into the effects of the third-party contributions of prior art references and commentary.[50] Preliminary results, however, indicate some clear benefits of Peer to Patent.

Most importantly, the third-party reviewers were able to assist the examiners by providing relevant art and, presumably, ensuring that a higher quality patent would result from the examination process. Near the end of the two-year pilot program, sixty-six applications that had undergone Peer to Patent review had received their first office action.[51] Of these office actions, nearly 30% included a rejection that used prior art submitted and reviewed by the Peer to Patent reviewers as a primary reference for the rejections.[52] These numbers show a noteworthy contribution to the examination process and the quality of the reviewed prior art. The Peer to Patent reviewers made especially salient contributions when submitting NPL. About 36% of the art submitted by Peer to Patent reviewers was NPL, and over 60% of the reviewer-submitted prior art that was cited by examiners was NPL.[53] As noted by Curt Rose of HP, examiners can use the NPL provided by reviewers itself as the basis for a future rejection, or as a springboard to new NPL, perhaps via citations in the submitted NPL or via the discovery of new and/or related search terms from the NPL.[54] Schecter, Rose, and Asmus each indicated that applications they submitted to the Peer to Patent website received one or more office actions in which the examiner relied upon art cited from the Peer to Patent project as a primary reference.[55] This data illustrates that peer reviewers can contribute to both the quality and efficiency of the patent examination process.

The Future of Peer to Patent

As mentioned above, the Peer to Patent project will continue in the U.S. with a third pilot program starting in October 2010 and continuing into 2011.[56] Schecter, Rose, and Asmus, based on their positive experiences in the first and second pilots, have already indicated that they will continue to participate in the third pilot by submitting additional applications for their respective organizations.[57] During the third pilot program, the USPTO has indicated that they will, for the first time, begin providing a significant portion of the operating expenses for the project.[58]

Similar projects are being considered in Australia and Japan after successful pilot projects in these countries.[59] The UK continues to be interested in starting its own version of the Peer to Patent project as soon as financial resources become available.[60]

Webbink, meanwhile, has stated that work has recently been completed on reconfiguring the Peer to Patent website to support multiple platforms.[61] This multi-platform capability will allow the Peer to Patent website to be viewed in various jurisdictions across the globe in a user's native language, and will allow a user in a particular jurisdiction to limit application search results to that jurisdiction, or to expand the scope of any search across multiple jurisdictions.[62] Assuming that related-application information is loaded into the Peer to Patent platform, this capability should provide for additional "work-sharing" opportunities across multiple patent-granting jurisdictions. For example, art submitted by a scientist at IBM against a U.S. application could be used by the U.S. examiner during prosecution in the U.S. and also shared with a corresponding European examiner at the European Patent Office reviewing a European counterpart application to the U.S. application. The localization capability should also help extend what Rose describes as an "interesting result" of non-U.S.-based scientists submitting art against pending U.S. applications in the U.S. Peer to Patent system (and non-AU-based scientists submitting art against pending AU applications in the AU Peer to Patent System) despite the limited geographic reach of any issuing U.S. or AU patent.[63]

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Taking a longer view, Schecter, Rose, Asmus, Webbink, and Adam Avrunin of Red Hat all indicated a desire to eventually extend the Peer to Patent system into an international platform that every patent-granting entity can hook into, and that would become an integral part of the PCT patent application process, open to third-party prior-art submitters from around the globe.[64]

Room to Grow – Additional Features for Peer to Patent

Most people involved in the Peer to Patent project have viewed it, thus far, as a success. As with any project, however, there are a number of ways in which it can be further improved. For example, scaling the system up to accepting hundreds, if not thousands, of applications raises a problem of how to efficiently locate applications that are of importance to a particular organization or researcher. While the Peer to Patent project already provides a search capability, a "save search" capability would be useful, and could help in scaling up the project to a larger number of applications. For example, a researcher or organization particularly interested in patents related to magnetoresistive non-volatile random access memories could set up a "saved search," that would send a notice to the respective researcher or organization every time an application is submitted to the Peer to Patent project that matches these key words. In response to receiving the notice, the researcher or organization could review the application to see if it is related to, or of interest with respect to, the technology with which the researcher or organization is involved.

Additionally, increasing the number of annotations provided by reviewers that link each element in the submitted art to each claim element of the application could be useful. The Peer to Patent system already permits reviewers to annotate claims respective to submitted prior art, but doesn't currently require it. In fact, in surveying examiners involved in reviewing applications that were subjected to Peer to Patent review, Webbink stated that the examiners appreciated any annotations provided by submitters, and found them extremely valuable and useful in reviewing the art submitted and in conducting their own additional searches.[65] In light of this, Matt Rainey of Intellectual Ventures has suggested taking the project one step further by requiring prior art submitters to map a passage and/or figure in the submitted art to each claim element in the application in order to demonstrate specifically how the references anticipate or make the claims obvious before the submission is accepted by the Peer to Patent system, which would ensure that every examiner is similarly aided with these useful claim annotations.[66] Doing so would provide improved information and utility to the examiner while at the same time minimizing the potential for bad faith "dumping" of prior art on pending patent applications submitted for peer review.[67]

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The Peer to Patent platform utilizes several features borrowed from social networking architectures to solicit third party experts to find, submit, and rate prior art references.

Ideas for increasing expert participation in the project include providing small monetary remuneration to reviewers, increasing marketing to and/or solicitation of expert reviewers, soliciting law firm involvement in the project, and taking the project out of its self-imposed pilot status.

Providing additional incentives to reviewers may be one way to increase participation. Schecter, Asmus, and Rose all stated that it was sometimes difficult to get their organization's engineers and scientists to spend time reviewing and submitting art for the project in their spare time.[68] Schecter stated that he would entertain any idea for increasing participation in the project and improving patent examination in the process, including providing additional incentives (although not necessarily monetary incentives).[69] For example, IBM already provides some non-monetary incentives for its scientists, such as featuring successful prior art submissions on its internal website.[70]

Providing monetary incentives, though, may be one way to tilt the equation in favor of the project and get scientists and engineers that are already quite busy with their day jobs, and life outside of work, to become more involved in the project. If the patent community is truly interested in patent quality, perhaps now is the time for the community to put its money where its collective mouth is, and provide a financial incentive for those that are in the best position to have access to the most material and most relevant art, and to provide them a persuasive incentive to involve themselves in the patent granting process.

Rose isn't so sure that providing financial remuneration is a good idea, and in any case, doesn't believe that tangible awards are necessary.[71] Rose pointed to the amount of content already on the Internet that was generated without any tangible award; he believes that adding a tangible remuneration to the process would only complicate matters.[72]

On the topic of increasing participation, both Schecter and Asmus lamented the lack of law firm participation in the project, either via submission of applications to the project or via prior art submissions against pending applications. Both stated that law firm

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participation is one area where they would like to see improvement in the third pilot. Although Asmus recognized the difficulty in getting traditionally conservative engineers and attorneys to adapt to the changes in the prosecution process required by the Peer to Patent project, he argued that we are all harmed by a weak patent system, and that it is our duty make the United States patent system the best that we can, and thus he encouraged outside counsel to participate in the project.[73] To the extent that law firms avoid participation in the project for fears of imparting any willfulness charges against their client, the Peer to Patent steering committee published a memorandum regarding willfulness on their website.[74] The memorandum concludes that a peer-reviewer is unlikely to be held liable for willful infringement merely by participating in the Peer to Patent project.[75]

Asmus also noted that the mere designation of the Peer to Patent project as a pilot program may be harming the level of participation.[76] The USPTO, by picking up a portion of the cost of the Peer to Patent pilot during the forthcoming third pilot period, has taken an important first step in exiting pilot status, and may be indicating that it is nearing a point at which it will integrate the peer review program as a standard (although perhaps voluntary) application process for one or more technology centers, such as software. Asmus believes that once the project exits pilot status, and patent software vendors such as Computer Packages, Inc. integrate the administrative details of the project into their products, participation in the project will increase.[77] Asmus compared the beginnings of the Peer to Patent project to the beginnings of the electronic filing system (EFS) at the USPTO.[78] Although the thought of not using EFS now seems a distant memory to most practicing patent attorneys, the adoption rate at the time the EFS was first introduced was quite low. There is no reason to believe that the Peer to Patent system won't go through a similar growth expansion once it exits pilot status.

Another useful feature that could be added is a synonym database of related technical terms. As noted earlier, the Peer to Patent project website already allows users to "tag" applications with relevant technical terms or synonyms relative to terms used in the application, in order to improve the ability to conduct better searches on the technology and improve the ability to find the application being tagged in a future search. However, this process is not automatic and relies upon manual human review.[79] Rainey has pushed for the inclusion of a database of related technical terms (*e.g.*, a "technology thesaurus") that automatically tags an application with related terms.[80] Such a database would allow for particular applications drafted by, for example, a non-technical attorney (or perhaps using alternative and/or non-standard language) to show up in searches for a particular technology for which the applications would not otherwise appear. For example, an application directed to an "emissive display" may be automatically tagged with the terms "plasma," "SED," "LED," "polymeric," and/or "electroluminescence." In this way, even though the application never uses the term "plasma," a search by a scientist for the term "plasma" may turn up the application within its search results whereas, without the automatic tagging, it would not have. Reviewers would then still have the ability to manually add or subtract tags, or to edit the automatically added tags, when reviewing the application in more detail.

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Most people involved in the Peer to Patent project have viewed it, thus far, as a success. As with any project, however, there are a number of ways in which it can be further improved.

This tagging process would be particularly beneficial for international or foreign patent applications filed in the U.S. after translation from a non-English language. The descriptions of the technology in these applications are likely to use terms substantially different than those in general use in the U.S. and other English-speaking nations. Automatic tagging of those applications with alternate word-forms could substantially increase the reviewers' ability to find the application and to search for relevant prior art. Furthermore, if the tags are retained in the electronic file history of the patent, the tags could help to increase the pool of available prior art for future applications and for future searches by third parties and by examiners.

Additionally, and especially relevant to classes of patents such as software and business methods where prior art is not as well documented, the Peer to Patent system should provide customized links to allow a reviewer to submit what he or she views as an important patent to popular technical community websites such as (at least in the software realm) acm.org and slashdot.org. These types of technical community websites have shown a particular acumen for finding relevant and material prior art for software patents.[81] Additional community-based websites could be identified for business methods, biotechnology, telecommunications, and other classes of patents, and an appropriate list of links provided based on the detected or tagged underlying technology in the application. In this manner, if a reviewer identifies a particularly important or broad patent application on Peer to Patent, the reviewer could submit the application for enhanced review by a larger pool of experts

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via the linked technical community websites. Additionally, if a particular patent application bridges two or more technologies, an expert in one of the technologies who is reviewing the application could request the involvement of experts in the other technologies to aid in the identification of prior art or common knowledge.

Finally, the Peer to Patent project could be expanded beyond initial examination. More specifically, and in order to continue the work of preventing the assertion of improper patents, the Peer to Patent system could be expanded into the realm of post-issuance review and re-examination. While this has been somewhat implemented via the NYLS's post-issue.org website,[82] post-issue.org does not post all issued patents and does not allow third-party reviewers to submit prior art against any issued patent. Rather, the website currently requires reviewers to "request" that a particular issued patent be added to the website, and after which time third-party users are allowed to submit art against it.

The Peer to Patent project would be more useful if, after an application issues as a patent, the webpage for that application was updated to show the issued claims and the prosecution history and allowed posting of prior art on that now-issued patent. Any member of the public should then be allowed to submit prior art under the same terms as during the Peer to Patent examination process. Under this proposal, however, no action is taken, and no submitted prior art is officially considered, until the patent is litigated or a re-examination ordered. In the case of re-examination, the law could be further changed to require that the examiner review not only art submitted in a traditional re-examination request under 37 C.F.R. § 1.501, but also any citations made on the corresponding post-issuance Peer to Patent website. Of course, the same submission rules as before could be applied, such that if more than 10 references have been posted, only the top 10 are forwarded to the examiner during re-examination.

Providing for such a post-issuance continuous review process would further advance the goals of the Peer to Patent project. That is, it would improve the public's perception of patent quality, reduce the tax on the public caused by non-inventive patents, and reduce litigation costs. Even if no litigation or re-examination is initiated, if material prior art is already posted on a particular patent's Peer to Patent webpage, the patent owner may be more cautious in asserting the patent.

Some of these changes will require a change in the law. However, as Congress is currently interested in reviewing the patent process and is considering instituting various forms of post-grant review, now may be the best time to achieve such changes. These changes to post-examination review arguably solve many of the problems that Congress is looking to address, without substantially limiting the rights of inventors under the Constitution, and without substantially impeding the strong knowledge-based economy that has developed in the United States.

Conclusion

As the Peer to Patent project begins its third pilot period, it enjoys a limited record of success in the software and business method classes, during which it has been shown that community review can bring valuable prior art to light that otherwise would have been unknown to the examiner during examination of the application.[83] Beginning in October 2010, we will discover whether the same successes can be applied to the more traditional classes of telecommunications and biotechnology. Indeed, this third pilot program may determine whether the Peer to Patent program becomes a permanent part of prosecution practice before the USPTO, or whether it fades away and will be remembered for its idealistic attempt to integrate the scientific and engineering communities in the patent review and granting process.

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27. Curt Rose, Dir. of Patents, Hewlett-Packard, Peer to Patent: An Applicant's Adventure (May 2008), http://www.aipla.org/Content/ContentGroups/Speaker_Papers/Spring_Meeting/200812/RoseC-paper.pdf.
28. Schecter, *supra* note 4.
29. *Id.*
30. $180 as of the time of writing. Fee Schedule, U.S. Patent & Trademark Office (Oct. 2, 2008), http://www.uspto.gov/web/offices/ac/qs/ope/fee2009september15.htm.
31. 37 C.F.R. § 1.99(b)(1)-(4) (2009).
32. *Id.* § 1.99(c)-(e).
33. *Id.* § 1.99(e).
34. *Id.*
35. Peer to Patent, Peer-to-Patent Applicant Guidelines, at 1, http://dotank.nyls.edu/communitypatent/docs/info/P2P_Applicant_Guideline.pdf (last visited July 30, 2010) [hereinafter Applicant Guidelines].
36. Webbink, Asmus, *supra* note 1.
37. Applicant Guidelines, *supra* note 36, at 1.
38. Kappos, *supra* note 17.
39. 37 C.F.R. § 1.102 (2009).
40. The full requirements for the Accelerated Examination program are provided in the Federal Register, 71 Fed. Reg. 36,323 (June 26, 2006).
41. Schecter, *supra* note 4.
42. Asmus, *supra* note 6.
43. Webbink, *supra* note 1.
44. This image appears on the Peer to Patent website, Peer to Patent, http://www.peertopatent.org/ (last visited Aug. 24, 2010). Use of this image is governed by the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 license. *See* http://creativecommons.org/licenses/by-nc-sa/3.0/us (last visited Aug. 24, 2010). This image has been reproduced with the permission of Peer to Patent.
45. U.S. Patent & Trademark Office, Applicant's Consent to Third-Party Comments in Published Applications and Consent to Pilot Participation, http://www.uspto.gov/web/patents/peerpriorartpilot/consent.pdf (last visited July 30, 2010).
46. *See* Peer to Patent, *supra* note 45.
47. Noveck, *supra* note 22, at 146.
48. *See* Peer to Patent, *supra* note 45.
49. 37 C.F.R. § 1.99 (2009).
50. Kappos, *supra* note 17.
51. Anniversary Report, *supra* note 2, at 23.
52. *Id.*
53. *Id.* at 24.
54. Rose, *supra* note 5.
55. Schecter, *supra* note 4; Rose, *supra* note 5; Asmus, *supra* note 6.
56. Webbink, Asmus, *supra* note 1.
57. Schecter, *supra* note 4; Rose, *supra* note 5; Asmus, *supra* note 6.
58. Webbink, *supra* note 1.
59. Anniversary Report, *supra* note 2, at 28. *See generally* Peer-to-Patent Australia, http://www.peertopatent.org.au/ (last visited Aug. 24, 2010).
60. Webbink, *supra* note 1.
61. *Id.*
62. *Id.*
63. Rose, *supra* note 5.
64. Schecter, *supra* note 4; Rose, *supra* note 5; Asmus, *supra* note 6; Webbink, *supra* note 1; Avrunin, *supra* note 8.
65. Webbink, *supra* note 1.
66. Rainey, *supra* note 7.
67. *Id.*
68. Schecter, *supra* note 4; Rose, *supra* note 5; Asmus, *supra* note 6.
69. Schecter, *supra* note 4.
70. *Id.*
71. Rose, *supra* note 5.
72. *Id.*
73. Asmus, *supra* note 6.
74. Memorandum from Yeen C. Tham, Student Research Fellow, N.Y. Law Sch., Willful Infringement (Sept. 11, 2006), http://dotank.nyls.edu/communitypatent/willfulinfringement.pdf.
75. *Id.*
76. Asmus, *supra* note 6.
77. *Id.*
78. *Id.*
79. Noveck, *supra* note 22, at 146.
80. Rainey, *supra* note 7.
81. *See*, for example, the discussion of Creative patent number 6,928,433, asserted against Apple in 2006. Slashdot, Creative Sues Apple (May 16, 2006), http://apple.slashdot.org/story/06/05/16/0414226/Creative-Sues-Apple.
82. *See* Post Issue Peer to Patent, http://www.post-issue.org/ (last visited July 30, 2010).
83. Avrunin, *supra* note 8.

Daniel R. Bestor prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement and patentability analyses, patent application preparation and prosecution, and litigation matters in the electrical and computer engineering fields. Mr. Bestor has experience with due diligence and freedom to operate investigations, validity and infringement investigations, licensing negotiations, and settlement conferences.

bestor@mbhb.com

Eric Hamp was a 2010 summer clerk at MBHB. Mr. Hamp will graduate from the Northwestern University School of Law in 2011.

Free, But Not Without Risk: Open Source Licensing in the Wake of *Jacobsen v. Katzer*

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Most computer users are familiar with closed software. These programs are distributed only in binary format. Examples include Microsoft Windows®, Oracle's® databases, Adobe's® Portable Document Format (PDF) Reader, and so on. By using a closed source model, software providers protect their source code, thereby making it more difficult for other individuals and organizations to misappropriate the intellectual property associated with the source code.

However, alternative business models have grown around the concept of releasing software in an open source format—essentially making a program's high level language source code available for free. These business models typically do not focus on the sale of the software per se. Instead, open source software vendors derive revenue from support and maintenance contracts, customization, and optional closed source modules. Nevertheless, some open source software is released to build a reputation or just for fun.

Over the course of the last twenty years, the user base of open source software has evolved from computer professionals, academics, and hobbyists to the general public. Today, open source software can be found on Internet servers, desktop PCs, household appliances, and cell phones. The scope of this software varies from simple applications, to web browsers, to entire operating systems. Examples of popular open source software include the Firefox® web browser and the Linux® operating system.

While the vast majority of open source software is freely available for individuals to download and use, some is licensed under strict and rather counterintuitive terms. In particular, a popular form of free software license is the "copyleft" license. A play off of the word "copyright," a copyleft license requires that reproductions, adaptations, and redistributions of the software be licensed under the same terms as the original license to the open source software.[2] Thus, even though this open source software is distributed for free, the terms of its license could prevent a party from charging for any reproductions, adaptations, and redistributions, or making these reproductions, adaptations, or redistributions proprietary and non-free.[3] Nonetheless, given the wealth of stable, useful open source software that is readily available, software vendors often package, incorporate, adapt, or sell open source software with their own products.[4]

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The owner of the copyright to open source software may choose to enforce any applicable open source license, and penalties range from copyright infringement to breach of contract damages.

Enforcement of Open Source Licenses

The owner of the copyright to open source software may choose to enforce any applicable open source license, and penalties range from copyright infringement to breach of contract damages. To date, the Federal Circuit has rendered just one opinion on the enforceability of open source software licenses. Two years ago, in *Jacobsen v. Katzer*, the Federal Circuit found that open source licenses with terms or conditions that limit the scope of the copyright granted to the public can be enforced in copyright actions.[5] The Federal Circuit also held that if the limitations are instead covenants between the licensor and licensee, they can be enforced with contract law.[6] This decision potentially places downstream users of open source software at risk for violating a copyright license and subject to associated damages, or, at best, liable for breach of contract unless these users conform to the terms of the software's license. If the software is supposed to be "free" to use and is explicitly licensed for public use, how can one be guilty of copyright infringement? The facts from *Jacobsen* provide insight.

Robert Jacobsen managed the collaborative open source project DecoderPro, which allows model railroad hobbyists to program chips that control model trains.[7] Jacobsen's group placed copies of the DecoderPro software on a public open source repository for free downloading.[8] Along with the software, Jacobsen also distributed its copyleft license.[9] This license granted any user of DecoderPro the right to copy, modify, and distribute the software "provided that [the user] insert a prominent notice in each changed file stating how and when [the user] changed that file, and provided that [the user] do at least ONE of the following:" (1) place the user's modifications in the public domain or make them freely available, (2) use the modified files only within the user's organization, (3) rename any non-standard executables derived from the modified source code to not conflict with the standard executables, document the changes between the standard and non-standard executables, and refer to where one can find the standard versions, or (4) make other arrangements with the copyright holder.[10]

Essentially, this license required anyone modifying or distributing DecoderPro source code to publish their modifications or make these modifications available to the public. In this way, a user of the modified source code would be able to determine what parts were created by the copyright holder and what parts were contributed by other parties.[11] Matthew Katzer, chief executive officer of Kamind Associates, Inc. (hereinafter "Katzer"), developed a competing commercial soft-

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Free, But Not Without Risk: Open Source Licensing in the Wake of *Jacobsen v. Katzer*

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ware product that performed essentially the same functions as DecoderPro.[12] Katzer admitted that he or individuals in his employ used portions of DecoderPro in this competing product without complying with the terms of the DecoderPro license.[13] Jacobsen sued Katzer for copyright infringement and moved for a preliminary injunction to prevent Katzer from continuing the alleged infringement.[14] Katzer contended that the software's non-exclusive, public license prevented Jacobsen from suing for copyright infringement.[15]

The District Court for the Northern District of California held that Jacobsen's copyright on the DecoderPro software was "intentionally broad" and permitted the incorporation of the software into commercial products.[16] Further, the District Court found that Katzer's doing so without including a prominent notice of attribution (in violation of the software's license) did not give rise to a copyright claim because the terms of the license did not limit its scope.[17] Instead, the District Court viewed the terms as independent covenants between the parties.[18] As such, violation of these terms could only be adjudicated under contract law.[19] On these grounds, the District Court denied Jacobsen's motion,[20] and Jacobsen appealed to the Federal Circuit.[21]

Applying Ninth Circuit law, the Federal Circuit agreed with the District Court that the case turned on whether the terms of the DecoderPro license were conditions of that license or covenants independent from the scope of the license.[22] The Federal Circuit looked to previous cases where the Ninth Circuit had ruled that when a copyright holder grants a nonexclusive license to copyrighted material, the copyright holder waives his right to sue the licensee for copyright infringement, but can sue the licensee for breach of contract.[23] However, if the non-exclusive license is limited in scope and the licensee acts outside the scope, the copyright holder can sue for copyright infringement.[24] The Federal Circuit also considered whether the free availability of Jacobsen's source code removed it from the purview of copyright law.[25] In other words, the Federal Circuit determined the issue to be whether Jacobsen could give away his software to the public for free, yet still bring a copyright claim if a member of the public used the software in a way that failed to conform to the terms of the license.

The parties did not dispute that Jacobsen was the holder of a copyright over DecoderPro.[26] Katzer also admitted that portions of DecoderPro were copied, modified, and distributed as part of the competing product, the Decoder Commander software.[27] Thus, Jacobsen had established a *prima facie* case of copyright infringement.[28] To prevail on the preliminary injunction for copyright infringement, Jacobsen had to successfully argue that the DecoderPro license terms acted as conditions to limit the scope of the license, and that the use by Katzer was outside the scope of the license.[29]

Addressing this issue, the Federal Circuit found that the language of the DecoderPro license explicitly created conditions rather than contractual covenants.[30] For example, the terms of the license granted rights to copy, modify, and distribute DecoderPro *provided that* the license's conditions were met, and, under California contract law, the phrase "provided that" typically indicates a condition.[31] Further, the Federal Circuit concluded that these conditions enabled Jacobsen to control the distribution of the software so that he could obtain an economic benefit from its use, and that a preliminary injunction was a proper way of enforcing Jacobsen's rights, even if Jacobsen could not prove any specific monetary damages.[32,33] Accordingly, By allowing programmers to maintain some degree of downstream control over their programs, the programmers' potential economic gains are protected.

Thus, the Federal Circuit found that the conditions of an open source license can be enforced via actions for copyright infringement even though the software is given away for free. While Katzer conceded that his organization did not comply with the conditions of the DecoderPro license, there were no factual findings on the likelihood of success on the merits in proving that Katzer violated the conditions, and thus, the case was remanded to do so.[34]

Conclusion

Jacobsen v. Katzer granted copyright holders of open source software the right to control modification and distribution of such software. In light of this case, what could Sam do to protect his organization from the risk of a lawsuit? First, Sam has to determine what license (if any) applies to the open source software that he has used. Then, Sam, or his attorney, should carefully read the license to understand its terms. Finally, Sam should find ways to conform to these terms.

If Sam's company is incorporating a large module of an open source project, he should make sure that his programmers document all of the changes they make to this module so that his company will be able to comply with terms of commonly used open source licensing terms. It may be prudent for Sam's programmers to only make minimal changes to incorporated open source modules, and instead place the more substantial changes in other modules that can remain closed in order to limit the modifications that could potentially be described or disclosed to the public.

Endnotes

1. Binary format consists only of zeros and ones.
2. *See, e.g.*, *What is Copyleft?*, Free Software Found., http://www.gnu.org/copyleft/copyleft.html (last visited August 25, 2010). One of the most popular forms of copyleft is the GNU Public License (GPL).

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3. The concept of open source extends to creative work beyond just software. For example, MIT has placed over 1900 of its courses online for free under an open source style of license. *See Privacy and Terms of Use*, MIT Open Courseware, http://ocw.mit.edu/terms (last visited August 25, 2010). Additionally, most of the content in the free online encyclopedia Wikipedia also is available under a similar open source license. *See Trademarks and Copyrights*, Wikipedia, http://en.wikipedia.org/wiki/Wikipedia:About#Trademarks_and_copyrights (last visited August 25, 2010).

4. A well-known example of open source software being used commercially is the use of Linux® by Cisco® in their Linksys® brand of wireless routers. In order to comply with the copyleft terms of the Linux® license, Cisco® makes their modifications to this source code available to the public. *See GPL Code Center*, Cisco, http://homesupport.cisco.com/en-us/gplcodecenter (last visited August 25, 2010).

5. 535 F.3d 1373, 1380 (Fed. Cir. 2008).

6. *Id.*

7. *Id.* at 1376.

8. *Id.*

9. *Id.*

10. *Id.* at 1380.

11. *Id.* at 1379.

12. *Id.* at 1376; *see also Jacobsen v. Katzer*, No. C 06-01905 JSW, 2007 U.S. Dist. LEXIS 63568, at *2 (N.D. Cal. Aug. 17, 2007).

13. *Jacobsen*, 535 F.3d at 1379.

14. *Id.* at 1376. Until recently in the Ninth Circuit, a party moving for a preliminary injunction needed to establish "either '(1) a combination of probable success on the merits and the possibility of irreparable harm; or (2) that serious questions are raised and the balance of hardships tips in its favor.'" *Faith Ctr. Church Evangelistic Ministries v. Glover,* 480 F.3d 891, 906 (9th Cir. 2007). In previous copyright cases, the Ninth Circuit had found that establishing a "reasonable likelihood of success on the merits raises a presumption of irreparable harm." *See, e.g., LGS Architects, Inc. v. Concordia Homes of Nev.*, 434 F.3d 1150, 1155-56 (9th Cir. 2006). Thus, Jacobsen may have brought a copyright claim rather than a contract claim because of the Ninth Circuit's (formerly) low bar for granting a preliminary injunction in copyright cases. However, in a recent non-copyright case, the Supreme Court held that the Ninth Circuit's *possibility* of irreparable harm standard was too lenient and should be replaced with a *probability* of irreparable harm standard. *Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 375 (2008) ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction."). Some courts, including the district court conducting further proceedings in *Jacobsen v. Katzer*, have interpreted this holding to mean that the Supreme Court has overruled the Ninth Circuit's presumption of irreparable harm in copyright cases. *Jacobsen v. Katzer*, No. C 06-01905 JSW, 2009 U.S. Dist. LEXIS 1615, at *22-23 (N.D. Cal. Jan. 5, 2009). However, the Ninth Circuit has continued to apply the presumption of irreparable harm in at least some cases. *See, e.g., Marlyn Nutraceuticals, Inc. v. Mucos Pharma, GmbH & Co.*, 571 F.3d 873, 877 (9th Cir. 2009).

15. *Jacobsen*, 535 F.3d at 1379.

16. *Id.* at 1376.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.* at 1373. Jacobsen was able to appeal to the Federal Circuit, instead of the Ninth Circuit, because Jacobsen's claims against Katzer included a request for a declaratory judgment that Jacobsen did not infringe on a patent issued to Katzer, and that the patent was invalid. *Id.* at 1377. Thus, the Federal Circuit had jurisdiction under 28 U.S.C. § 1295.

22. *Jacobsen*, 535 F.3d at 1380.

23. *Sun Microsys., Inc. v. Microsoft Corp.*, 188 F.3d 1115, 1121 (9th Cir. 1999).

24. *S.O.S., Inc. v. Payday, Inc.*, 886 F.2d 1081, 1087 (9th Cir. 1989).

25. *Jacobsen*, 535 F.3d at 1380-81.

26. *Id.* at 1379.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.* at 1381.

31. *Id.* The Federal Circuit looked to California contract law because the case originated in California.

32. *Id.* at 1381-82.

33. The Federal Circuit found that open source licensing can lead to substantial economic benefits. *Id.* at 1379. In particular, programmers can increase the market share of their closed source programs by giving away parts of these programs as free, open source components. *Id.* Source code contributions from the public may serve to improve the quality of the closed source programs. *Id.* Additionally, the programmers may be able to increase their reputations while doing so. *Id.* Thus, in the Federal Circuit's view, the distribution of the open source software was based on economic motives, even if the associated economic gain was not immediate. *Id. See also Gilliam v. American Broadcasting Companies, Inc.*, 538 F.2d 14, 24 (2d Cir. 1976) ("American copyright law, as presently written, does not recognize moral rights or provide a cause of action for their violation, since the law seeks to vindicate the economic, rather than the personal, rights of authors."). However, authors of copyrighted works may find relief in unfair competition or contract law when their works are mutilated or misrepresented. *Id.*

34. *Jacobsen*, 535 F.3d at 1382-83.

Joseph A. Herndon concentrates in patent prosecution and litigation in the electrical engineering field. Mr. Herndon has technical experience in voltage and current transmission line studies, with expertise in power electronics and energy systems.

herndon@mbhb.com

Michael S. Borella, Ph.D., conducts legal research and provides technological advice in support of validity, infringement and patentability analyses, and litigation matters in the areas of computing, electrical engineering, and telecommunications in his position as law clerk at MBHB. He is the named inventor on more than sixty U.S. patent applications.

borella@mbhb.com

The Federal Circuit Decides to Reconsider Inequitable Conduct

Introduction

Two decades after the Federal Circuit termed the pleading of inequitable conduct a "plague,"[1] the problem of assertion of this affirmative defense has only metastasized. Today, it is pled not only in traditional situations, such as when a prior art reference has been intentionally withheld from the Patent Office, but also when prior art is actually before the Patent Office and expressly considered, but the applicants have made allegedly inconsistent arguments about it. A panel of the Federal Circuit faced one such non-traditional situation when rendering its decision in *TheraSense, Inc. v. Becton, Dickinson & Co*. In response to a petition for rehearing *en banc*, the entire Federal Circuit has decided to undertake a complete reconsideration of the doctrine of inequitable conduct. While briefing is not yet complete, many *amici* (both businesses and academics) have come forward to argue that the standard of proof of inequitable conduct should be raised, that the scope of the defense should be limited, or that the potential remedies for the defense should be broadened.

Existing Law on Inequitable Conduct

The doctrine of inequitable conduct arises indirectly from three Supreme Court cases involving actual "fraud on the Patent Office" – payoffs for witness silence to avoid detrimental testimony, fabrication of witness statements, and subornation of perjury.[2] The Federal Circuit translated those cases, and the 1952 amendments to the Patent Act (which categorized the pleading of "unenforceability" as a defense), into the modern doctrine of inequitable conduct.[3] Under this doctrine, more than just traditional fraud can render a patent unenforceable: a failure to disclose material information or a material misrepresentation can do so as well. The Patent Office then established regulations that set forth certain parameters for practitioners to comply with their duty of disclosure to the Patent Office and thereby avoid a finding of inequitable conduct.[4]

Under the original, and broadest, version of the Patent Office's regulations, an applicant is required to disclose any information that a "reasonable examiner" would consider material to the patentability of a claim.[5] Individuals, rather than companies, bear the burden of disclosure: any person "associated with the filing or prosecution of a patent application," which includes inventors, prosecuting patent attorneys and agents, and anyone else substantively involved in the prosecution of the patent, is required to disclose material information. Most commonly, inequitable conduct has been found when an inventor or prosecuting attorney has intentionally withheld material prior art from the Patent Office. Inequitable conduct requires "two elements, materiality and intent, [that] must be proven by clear and convincing evidence"; "'gross negligence' does not of itself justify an inference of intent to deceive."[6]

However, inequitable conduct has also been found in many non-traditional contexts, and with little or no showing of deceptive intent. Material information has been found to include non-prior art references, Patent Office decisions in applications prosecuted in parallel, and even allowance of similar claims in related applications.[7] Federal Circuit decisions have been even looser with the required showing of intent. Indeed, the Federal Circuit has indicated that deceptive intent can be inferred – with no evidence of intentional deception – if (1) highly material information is withheld, (2) the applicant knew of the information and knew or should have known of the materiality, and (3) the applicant does not provide a credible explanation for the withholding.[8]

The *TheraSense* Panel Opinion

The *TheraSense* case presents one of the non-traditional situations in which the relevant prior art was before the Patent Office, yet the courts still found inequitable conduct because of the applicant's characterization of the art.[9] The material information that was withheld in that case was attorney argument regarding the scope of the claims of a foreign counterpart to a prior art reference that was before the Patent Office. The underlying prior art reference was unquestionably before the Patent Office, and even the Federal Circuit panel was split over the interpretation of the arguments in the foreign patent office; nonetheless, the majority of the panel found inequitable conduct in what is described as not a close case.

In *TheraSense*, Abbott's[10] patent application claimed a strip sensor system used to measure the amount of glucose in blood or interstitial fluids. The test strips used in the system did not require a membrane to slow the diffusion of glucose to the electrode or to prevent red blood cells from fouling the electrode. The Patent Office repeatedly rejected the claims of the application as either anticipated or obvious, including rejections based on another patent held by Abbott, U.S. Patent No. 4,545,382 ("the '382 patent"). The '382 patent claimed a test strip where a membrane was "optional, but preferable" when testing *live* blood (*i.e.*, *in vivo*). To argue over the '382 patent, Abbott asserted that a person having ordinary skill in the art at the time of the application would have understood the "optional, but preferable" language as still requiring a protective membrane when testing *whole* blood (*i.e.*, *in vitro*).

In support of its position, Abbott submitted a declaration from its Director of Research and Development asserting that the understanding in the field of the '382 patent was that a membrane was necessary for testing whole blood. Abbott's patent prosecution counsel relied on the declaration to argue that a person skilled in the art "would not, especially in view of the working examples, have read the 'optional, but preferable' language [in the '382 patent] as a technical teaching but rather as mere patent phraseol-

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ogy" in relation to whole blood. The patent examiner was convinced, and issued the patent-in-suit.

The Federal Circuit found that the statements characterizing the '382 patent were inconsistent with arguments made in briefs that were filed in revocation proceedings regarding the European counterpart to the '382 patent, but not provided to the U.S. Patent Office. Seeking to overcome a German reference cited in the European revocation proceedings, Abbott argued that "the purpose of the protective membrane [set forth in the claims of the foreign counterpart], preferably to be used with in vivo measurements, is a safety measurement to prevent any course [*sic*] particles coming off during use but is not a permeability control for the substrate." Over a year later, in another brief in the European proceedings, Abbott "submitted that [the] disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor."

The *TheraSense* Federal Circuit panel majority concluded that the European briefs were highly material for two reasons. First, it found that the arguments made to the European Patent Office (EPO) clearly contradicted those made to the U.S. Patent Office in construing the prior art to the patent-in-suit. Second, the EPO briefs were directed toward explaining why a membrane was preferential when testing live blood, suggesting that the problems associated with testing blood *in vivo* (*i.e.*, live blood) were not present when testing blood *in vitro* (*e.g.*, whole blood). As a result, the majority concluded that it was known in the field that a membrane was not necessary to accurately measure glucose levels in some whole blood samples. Therefore, although the briefs included only attorney argument (that was interpreted as contrary to other attorney argument), the Federal Circuit found the briefs including those arguments represented material information that had to be disclosed to the Patent Office as contradictory to assertions made by Abbott in support of the patent-in-suit.

Regarding the element of intent, the majority focused on two findings made by the district court: that both Abbott's attorney and expert failed to provide a credible reason for not disclosing the EPO briefs, and their explanations for failing to disclose "were so incredible that they suggested intent to deceive." The majority found it unnecessary to disturb the lower court's conclusion that neither witness was credible in light of the standard of review. Additionally, an inventor of both the '382 patent and the patent-in-suit provided testimony that contradicted Abbott's position regarding the necessity of a membrane. The majority reasoned that the use of a different expert in making the declaration evinced an intent to deceive. Therefore, the majority concluded that both Abbott's expert and counsel intentionally withheld material information from the Patent Office and affirmed the district court's holding of unenforceability due to inequitable conduct.

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In selecting the broad questions raised *en banc* in the *TheraSense* case, the Federal Circuit has indicated its intent to reconsider inequitable conduct at a fundamental level.

Judge Linn dissented from the panel's inequitable conduct finding. In analyzing the materiality of the EPO briefs, he gave a more deferential reading to the explanation of the "optional, but preferable" language of the patent. Noting that the claim contested before the EPO was not directed exclusively to testing live blood, he reasoned that the briefs highlighted the need for membranes in certain situations, as in testing live blood, but not in others, such as when testing interstitial fluid. Therefore, he saw Abbott's position in prosecuting the patent-in-suit as being consistent with the representations made to the EPO. Judge Linn also concluded that the panel was incorrect in presuming intent to deceive because it was plausible that both the attorney and expert *subjectively* believed it was unnecessary to disclose the briefs to the Patent Office. He further discredited the majority's reliance on the inventor's testimony, as it was reasonable to believe that neither the attorney nor the expert was aware of the inventor's understanding of either the '382 patent or the level of skill in the art. Therefore, Judge Linn concluded neither witness had the requisite level of subjective intent necessary to support a finding of inequitable conduct.

Questions for Rehearing *En Banc*

The Federal Circuit granted Abbott's petition for rehearing *en banc*, indicating that it intended to reconsider key issues related to inequitable conduct. The Court identified six questions of general importance:

1. Should the materiality-intent balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should the Patent Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?

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5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.[11]

Briefing of the Issues

To date, Abbott and a number of *amici* have filed briefs regarding the Court's six issues. Abbott argues that the Federal Circuit should return to a strict reading of the *Kingsdown* case and require a showing of specific intent to deceive. Abbott further argues that inequitable conduct should render a patent unenforceable only when the patent would not have issued absent any misconduct. Abbott also argues that the Federal Circuit should abandon the "sliding scale" that allows balancing of a strong showing of materiality against a weak showing of intent because it dilutes both the materiality and intent requirements.

The *amici* have also generally argued that the standards for a finding of inequitable conduct should be raised. The Patent Office suggests narrowing the standard for inequitable conduct to a violation of existing Rule 56, not a failure to comply with the "reasonable examiner" materiality standard. It also suggests that a specific intent to deceive should be required, and should be the single most reasonable inference from the facts. PhRMA (the Pharmaceutical Research and Manufacturers of America) suggests limiting inequitable conduct to acts that allow the issuance of at least one invalid claim and advocates for consideration of intent separately from the materiality of a reference. The American Bar Association and numerous other *amici* suggest that the standard be aligned with traditional fraud considerations and require that at least one invalid claim have been issued due to the deceptive conduct. In the most extreme position, Acacia suggests abandoning the defense of inequitable conduct altogether. However, Apotex, a generic drug manufacturer, suggests retention of the current standards and tests for inequitable conduct.

Numerous *amici* have also suggested abandoning the all or nothing approach of unenforceability. Specifically, they argue that equity should allow a broad spectrum of remedies for inequitable conduct, including a reversal of the presumption of validity and other equitable remedies. These *amici* suggest that allowing the court to determine the remedy for inequitable conduct would allow it greater flexibility, which would not only be more consistent with other equitable remedies but also allow greater punishment for more culpable behavior.

Conclusion

In selecting the broad questions raised *en banc* in the *TheraSense* case, the Federal Circuit has indicated its intent to reconsider inequitable conduct at a fundamental level. The majority of the *amici* have suggested a heightened standard for inequitable conduct – at least returning the standard of the last *en banc* Federal Circuit case on inequitable conduct, *Kingsdown* – that would narrow the defense to clear and convincing showings of both materiality and intent. Given that inequitable conduct itself is an extension of the Supreme Court's precedent, it would be sensible to follow the *amici*'s advice and narrow the application of the doctrine.

Endnotes

1. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).
2. *Precision Instr. Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 807-08, 814-15 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250 (1944); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933).
3. 35 U.S.C. § 288; *J.P. Stevens Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984).
4. 37 C.F.R. § 1.56.
5. The Federal Circuit has continued to apply the "reasonable examiner" standard for disclosure even though the Patent Office has adopted a narrower standard which suggests that information is material only if "it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim" or "refutes, or is inconsistent with, a position the applicant takes in opposing an argument of unpatentability relied on by the Office, or [in] asserting an argument of patentability." *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006)
6. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 876 (Fed. Cir. 1988) (*en banc*).
7. *See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69 (Fed. Cir. 2003); *McKesson Info. Sol'ns, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 924 (Fed. Cir. 2007).
8. *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).
9. *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289 (Fed. Cir. 2010), *rehearing en banc granted, opinion vacated by* 2010 WL 1655391.
10. TheraSense became Abbott Diabetes Care, Inc. after the filing of the patent application. For simplicity's sake, TheraSense, its predecessors-in-interest, and its successors will all be referred to as "Abbott."
11. *Therasense rehearing en banc granted, opinion vacated by* 2010 WL 1655391.

Joshua R. Rich has more than a decade of experience as successful trial and appellate counsel in complex litigation involving all aspects of intellectual property, as well as other commercial matters. His experience has involved such diverse technologies as pharmaceuticals, biotechnology, medical devices, telecommunications, computer code, and graphical user interfaces. Mr. Rich is accomplished in all facets of trial and appellate litigation, ranging from trademark and copyright seizures and obtaining preliminary injunctions against patent infringement to jury trials, appeals, and certiorari petitions.

rich@mbhb.com

John M. Schafer was a 2010 summer clerk at MBHB. Mr. Schafer will graduate from the Michigan State University College of Law in 2011.

Citation by IDS: So What if I Didn't?

Introduction

Though neither desirable nor recommended, a patent may issue from an application that in its specification mentions a reference that was not, during prosecution, separately cited in an Information Disclosure Statement (IDS).[1] Upon realizing that this has happened, what is the patentee[2] to think? To do? Should they do anything?[3] Should they immediately seek reissue? How comfortable should they feel doing nothing?

In our view, the crucial question around which these scattered worries are dancing is this: what, if anything, does a patentee "get" for that mention of the reference[4] in the specification, with respect to (1) any statutory (*i.e.*, § 282[5]) presumption of validity over that reference and (2) any increased or decreased likelihood of becoming the next victim of the "plague"[6] of inequitable conduct?

For at least the reason that we do not believe that a complete, definitive answer to this question currently exists, we do not write today to offer one. Instead, and hopefully still usefully, we seek to provide an analytical structure to patentees finding themselves in this situation, to help them determine their level of comfort with the option of leaving well enough alone, and in the event that it becomes necessary, to arm them with the best arguments and authority we have been able to craft and identify to aid in their attempt to establish that the mention of the reference in the specification does in fact get them something.

With that, we turn in substance to our analysis, which we have found to be most usefully separated into three scenarios, treated below in descending order of the level of comfort we would expect an average patentee to have with each.

Scenario 1:
Reference Cited by the Examiner

Our first—and for the patentee the most comfortable—scenario is that, although the specification does mention a reference that was not separately cited in an IDS, the Examiner cited that very reference during prosecution. As stated, this is the best case for the patentee, and of course the best case within the best case is that the Examiner applied the reference to the claims under § 102[7] and/or § 103[8], though a citation by the Examiner of the reference as pertinent but less relevant than the art that was applied to the claims would seem nearly—if not exactly—as beneficial to the patentee, as to both validity and inequitable conduct.

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So what does a patentee really "get" for mentioning a reference in the specification?

First, we think it quite clear that in this scenario the patent would enjoy the strongest presumption of validity that § 282 has to offer, over the entirety of the reference, just as if the reference had been cited in an IDS.[9] In particular, making no distinction between applicant-submitted and Examiner-located prior art, the Federal Circuit stated in *Al-Site Corp. v. VSI Intern., Inc.*[10] that "[t]he [§ 282] presumption of validity . . . carries with it a presumption that the Examiner did his duty and knew what claims he was allowing. Therefore, the challenger's burden is especially difficult when the prior art was before the [Examiner]."[11]

That statement by the Federal Circuit in *Al-Site* is consistent with the language the court used some fifteen years earlier in the seminal case of *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*,[12] where the court stated that, "[when relying only on] prior art [that] was considered by the [examiner, the party challenging validity] has the added burden of overcoming the deference that is due [a] qualified government agency presumed to have properly done its job . . . ."[13]

And without more, we do not think that a patentee faced with this scenario should stay up nights worrying about inequitable conduct, since at least the first of the two primary prongs of the currently applicable formulation of the test[14] for inequitable conduct—namely (1) withholding a material[15] reference (2) with an intent to deceive the PTO—is impossible to establish when that reference was cited by the Examiner.[16]

In particular with respect to that first prong, the Federal Circuit stated in *Scripps Clinic & Research Foundation v. Genentech, Inc.*[17] that "[w]hen a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it cannot be deemed to have been withheld from the examiner."[18] This is consistent with Rule 56, which states in pertinent part that "[t]he duty to disclose . . . is deemed to be satisfied if all information known to be material . . . was cited by the Office or submitted to the Office [in an IDS]."[19] With respect to the second prong, authority is scarce, but one district court has opined that, without more, "the plain fact that [a reference] was cited . . . in [a] patent application [is] evidence of good faith,"[20] further crippling any charge of inequitable conduct.

Scenario 2:
Reference Not Cited by the Examiner, but Incorporated by Reference

Our second—and for the patentee the second-most comfortable—scenario is that the specification mentions a reference that, was not separately cited in an IDS, and was not cited by the Examiner, but was incorporated by reference[21] into the specification. As stated, within our tripartite structure, we would expect a patentee faced with this

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second scenario to feel less comfortable than one faced with the first scenario, as described above.

Our analysis of this second scenario involves a bit of construction, having near its foundation the PTO's directive in 37 C.F.R. § 1.104 that, upon "taking up an application for examination . . . , the examiner shall make a thorough study thereof . . . " Perhaps surprisingly, this construction arrives at a position of reasonable comfort for the patentee with respect to both presumed validity over the entire[22] reference, and the unlikeliness of a finding of inequitable conduct.

And though they may be a bit less convincingly supported by controlling authority than our conclusions as to the first scenario, our conclusions as to the second are essentially that the patentee deserves—but likely would be less likely to actually get—the same benefits as the patentee in our first scenario, and as such should be in the same position as if they had in fact cited the reference in an IDS (or if, as explained above, the Examiner had cited the reference).

We pause briefly here to point out that we have arrived at these conclusions notwithstanding the PTO's myriad of rulemaking attempts[23] to establish as law (or at least as an amalgam of what sounds like law) the proposition that the almighty IDS is the exclusive vehicle by which an applicant can make an Examiner aware of a reference and—by virtue of such disclosure—become entitled to consideration of the reference, paving the way for (1) a § 282 presumption of validity over the reference, and (2) as to inequitable conduct, securing at least one if not both of (a) a finding that the reference cannot be deemed withheld and (b) a finding that without more there can be no inference of an intent to deceive.

In addition to the litany of citations referenced in the endnote of the preceding paragraph, MPEP § 609.05(a) directly addresses the overarching fact pattern on which this article is focused, stating that, "[i]f information [is] listed in the specification rather than in a separate paper . . . , the information need not be considered by the examiner, in which case, the examiner should notify applicant in the next Office action that the information has not been considered."[24]

Need not, you say? Is that really correct where the listed reference was itself incorporated by reference? To proceed towards an answer, we now begin the above-mentioned construction of our analysis of this scenario with a point that was made in connection with the first: that the Examiner is presumed to have done his job properly.[25]

This of course begs the question: when an application incorporates by reference a reference not separately cited in an IDS, what exactly is the job that the Examiner is presumed to have properly done?

For starters, as noted above, 37 C.F.R. § 1.104 states that, upon "taking up an application for examination . . . , the examiner shall make a thorough study thereof . . . ." That is, the Examiner is supposed to begin the examination by reviewing the application in its entirety before moving on to searching the prior art.[26] The next brick in the wall is that the reference that our exemplary specification incorporates by reference is considered by law to be part of the application as filed, just as if the incorporated reference had been fully replicated in the specification.[27]

Thus, we believe that a court could (and we think should) hold that a reference that is incorporated by reference into the specification of an application has—at least constructively—passed before the eyes of the Examiner, and thus that the patent is entitled to a presumption of validity[28] over that reference, a position that is only buttressed by the Examiner being empowered to request from the applicant a copy of the incorporated reference.[29] And we would point out, with special emphasis on the above-quoted assertion in the MPEP that information listed in a specification "need not be considered by the examiner," that it is well accepted that the MPEP does not carry with it the force and effect of law.[30]

We feel that this conclusion—that a patent in this scenario would be entitled to a presumption of validity over the incorporated reference—could be solidly based on one or both of the following rationales: (1) that the art was before the Examiner, who is presumed to do his job,[31] a job that includes making a "thorough study" of the filed application,[32] of which the incorporated reference is a part[33] and (2) that courts have applied this presumption with respect to references in situations that could only fairly be characterized as less compelling, such as the reference (a) being mentioned in (but not incorporated by reference into) the specification,[34] (b) having its relevant subject matter described in the specification as prior art without even identifying the reference by patent number,[35] and (c) being in the class or subclass searched by the Examiner.[36,37]

We also observe that this scenario would seem to implicate MPEP § 707.05(b), which explains that, while "MPEP § 609 sets forth guidelines for applicants, their attorneys and agents who desire to submit prior art for consideration by the [PTO, such submitted] citations will not in any way . . . relieve examiners of [their obligation to cite] other pertinent prior art of which they may be aware."[38] We would think it difficult to establish that an Examiner was not aware of an incorporated reference, which is among the materials they are instructed to review before even starting to search the prior art. It seems fair to conclude, then, that because we are assuming materiality (which

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would seem to subsume pertinence), that the issued patent would be presumed valid over a reference that the Examiner had an independent obligation to cite, but did not.

Turning now to inequitable conduct in connection with our second scenario, the news is again positive. While standing by our prior statement that your average patentee would be less comfortable with our second scenario than with our first, the second scenario does carry with it the possibility that a court could adopt an analysis similar to ours above, and thereby determine that the applicant actually disclosed the incorporated reference to the Examiner in its entirety, and therefore that it could not possibly be established that the reference had been withheld. Such a court may then not even deem it necessary to assess whether there was an intent to deceive.

This seems a tad optimistic, and it is our view that most courts would instead use the intent-to-deceive prong to dismiss the charge of inequitable conduct. And, in fact, several have done exactly that.[39] So while courts may be likely to avoid syllogistically finding that the patentee satisfied the disclosure prong, they would seem perhaps just as likely to scoff at the notion that a patentee who not only disclosed a reference in the specification, but also fully incorporated that reference into the specification, was somehow trying to hide something.[40] Indeed, the incorporating page of the specification would make for a nice trial exhibit.

Scenario 3:
Reference Not Cited by the Examiner, and Not Incorporated by Reference

Our third scenario—and for the patentee the least comfortable of the three—is that the specification mentions a reference that was not separately cited in an IDS, was not cited by the Examiner, and was not incorporated by reference into the specification. Three strikes and you're out? Not so much.

Still presumed to have done their job properly, including making a thorough study of the application, it would seem that in this scenario the Examiner could be presumed to be aware of the mention of the reference, as well as of any description of it that was also included in the specification. And as noted above, several decisions[41] apply a presumption of validity based on the mere disclosure of a reference in the specification.

As such, it would seem that the patentee in this scenario should receive a presumption of validity over at least what is written about the reference in the specification, and likely over the reference in its entirety. Based on the above-cited cases applying the presumption on mere presence of a reference in the class or subclass searched by the Examiner,[42] it seems reasonable to assume that the full presumption would apply in this third scenario as well.[43]

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Absent a particular reason for concern, the best option will quite often be to do nothing at all.

With respect to inequitable conduct, it would seem that the analysis of this scenario would in most cases be nearly the same as that of the second. With the specification mentioning the reference at issue, a court would seem in most instances to have their choice of deeming the reference not withheld, finding no intent to deceive, or both. The one significant exception would seem to be where what is written in the specification about the reference is misleading in some important way, perhaps highlighting something other than its most relevant teaching, perhaps characterizing it in a way that discourages the Examiner from reviewing the rest of it, etc. In other words, this scenario is highly fact-intensive; in the words of one district court, while "the plain fact that [a reference] was cited . . . in [a] patent application [is] evidence of good faith, [the citation being done in a] deceptive and misleading manner [could evidence] an intent to deceive the PTO."[44]

Conclusion

With the three scenarios now having been broken down and assessed, we think it worthwhile to pause and appreciate that, perhaps somewhat unexpectedly, having a patent that mentions a reference that was not separately cited in an IDS during prosecution is not necessarily a reason to panic, and that often this will have no negative consequences whatsoever. Thus, absent a particular reason for concern, such as finding oneself in the third scenario with a description of the reference in the specification that leaves something to be desired, the best option will quite often be to do nothing at all, rather than, *e.g.*, rushing to file a reissue application.

We can think of and have identified no upside, however, to the fact that the mentioned reference was not separately cited in an IDS, and thus we are reminded of the age-old advice that an ounce of prevention is worth a pound of cure. To that end, we emphasize the importance of reviewing the specification of any application you are about to file, and any pending application you take over, to make sure that any references mentioned in the specification are, or have already been, separately cited in an IDS.

Also, you might consider revising the description of your standard 3-months-after-filing IDS reminder—or, perhaps better, the description of a separate, specifically-created-for-this-purpose IDS reminder—to make

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reference to reviewing the specification for potential citations. And of course don't ignore these reminders.

And should you identify that the specification of a still-pending application does mention a reference that has not yet been separately cited in an IDS, it seems to us that the safe and prudent course of action will almost always be to file an IDS to remedy this situation, even if that means filing an RCE in a case already on allowance, or even one about to issue.

In other words, if you can still do something about it, do something about it.

Endnotes

1. We note that the Patent Office (PTO) points out in § 609.04(a)-(b) of the most-recent revision (8th ed., rev. 8, July 2010) of its *Manual of Patent Examining Procedure* (MPEP) that citing a reference in a paper separate from the specification, so long as that paper satisfies both 37 C.F.R. § 1.97 (as to timing) and § 1.98 (as to content), is tantamount to correctly using an official PTO form (such as a PTO-1449 or the newer PTO/SB/08a and 08b forms). For simplicity of presentation, however, we summarily refer to the various options that each satisfy both § 1.97 and § 1.98 as citing a reference "in an IDS."
2. Again for simplicity of presentation, we summarily refer to the patent-controlling entity (*e.g.*, patentee, assignee, exclusive licensee, etc.) as the "patentee."
3. We recommend at least reading the rest of this article.
4. Of course this could arise with respect to multiple references, and indeed if the number of references is sufficiently high that may change the analysis significantly, perhaps even dispositively, but yet again for simplicity of presentation, we write today with respect to one-reference examples. These are of the most interest to us, as they would seem to take the "burying the examiner" "what ifs" off the table, and isolate the threshold conditional inquiry, or base case—*i.e.*, if a patentee gets no benefit whatsoever in the one-reference example, that would seem to obviate further analysis.
5. *See* 35 U.S.C. § 282 ("A patent shall be presumed valid[, and t]he burden of establishing invalidity . . . shall rest on the party asserting such invalidity.").
6. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988), where Judge Markey, the former (and first) chief judge of the Federal Circuit, approvingly cited the "one final word" added by Senior Circuit Judge Nichols to the decision earlier that same year in *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), namely that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague."
7. 35 U.S.C. § 102.
8. *Id.* at § 103.
9. *See, e.g., Al-Site Corp. v. VSI Int'l., Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999).
10. 174 F.3d 1308 (Fed. Cir. 1999).
11. *Id.* at 1323 (internal citations omitted).
12. 725 F.2d 1350 (Fed. Cir. 1984).
13. *Id.* at 1359.
14. *See, e.g., Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 972 (Fed. Cir. 2010) *together with Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (The party asserting the affirmative defense of inequitable conduct must establish by clear and convincing evidence that any (1) alleged failure to disclose, or misrepresentation regarding, material information (2) was made with an intent to deceive the PTO.).
15. We assume for purposes of this article that the reference mentioned in the specification is material, and we note that divining the proper standard of materiality in connection with the defense of inequitable conduct is both (1) outside the scope of this article and (2) among the subjects of the Federal Circuit's upcoming *en banc* review of *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289 (Fed. Cir. 2010), *rehearing en banc granted, opinion vacated by* 2010 WL 1655391, *1 (Fed. Cir. 2010) (requesting in pertinent part that the parties brief the following issues: "What is the proper standard for materiality? What role should the [PTO]'s rules play in defining materiality?").

For more on this case, see the article by Joshua R. Rich and John M. Schafer at page 12 of this edition of *snippets*.

For a recent and interesting analysis of that issue, touching on principles and disciplines such as separation of powers and administrative law, see David Hricik and Seth Trimble, *Congratulations on Your Hallucinations: Why the PTO's 1992 Amendment to § 1.56 is Irrelevant to Inequitable Conduct*, 38:1 AIPLA Q.J. 1 (2010). While that article is certainly interesting in its own right, it seems that, to the extent the authors' conclusions are correct, they would bear on the subject of the present article as well, and would suggest that the PTO is in fact powerless to determine what does and does not satisfy a failure-to-disclose element of a test for inequitable conduct, and is similarly powerless to determine when a reference has (or has not) been "before" or "considered by" an Examiner in connection with assessing the § 282 presumption of validity, and instead can only determine such things to the extent of the reach of its own rules, which bear not on the validity and enforceability of patents but instead on the enrollment and discipline of attorneys and agents registered to practice before it.

For a case that disagrees with this viewpoint, and concludes instead that an intent to deceive the PTO "might" indeed be inferable in the context of inequitable conduct when an experienced patent attorney handles a pending application in a manner that he knows or should know will not result in consideration by the Examiner of one or more (sort-of) cited references, see *Ortho Diagnostic Systems Inc. v. Miles Inc.*, 865 F. Supp. 1073, 1081-82 (S.D.N.Y. 1994) (where certain references were first cited in an amendment filed under 37 C.F.R. § 1.312 (*i.e.*, after the close of prosecution on the merits), where that amendment was not compliant with the requirements to have references considered at that late stage of prosecution, and where the Examiner then notified the applicant that the references would not be considered, providing an opportunity—of which the applicant did not avail itself—to ensure consideration by, *e.g.*, filing a continuation application.); *see also* MPEP § 2001.04 ("The Office does not believe that courts should, or will, find violations of the duty of disclosure because of unintentional noncompliance with 37 CFR 1.97 and 1.98. If the noncompliance is intentional, however, the applicant will have assumed the risk that the failure to submit the information in a manner that will result in its being considered by the examiner may be held to be a violation.").

All of this may be largely academic, however, in that applicants, agents, and attorneys are typically far more focused on avoiding findings of inequitable conduct than they are on avoiding disciplinary action by the PTO, believing (quite reasonably) that succeeding in the former will obviate the latter. More to the point, it is generally accepted—perhaps now a bit provisionally due to the possibility of a contradictory *en banc* decision in *Therasense*—that (1) satisfaction of the 37 C.F.R. § 1.56 duty

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of candor is not a safe harbor against a finding of inequitable conduct but that (2) the converse is not true—*i.e.*, conduct that would not support a finding of inequitable conduct would almost (if not) never run afoul of Rule 56. For a photo-negative statement of the same principle, see *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1237 n.11 (Fed. Cir. 2008) ("Although all misstatements or admissions that satisfy Rule 56 are considered material, the converse is not true: [a] misstatement or admission can be material for the purposes of showing inequitable conduct even if it does not meet the standard for Rule 56 . . . .").

16. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991).

17. 927 F. 2d 1565 (Fed. Cir. 1991).

18. *Id.* at 1582.

19. 37 C.F.R. § 1.56(a).

20. *IDEC Pharm. v. Corixa Corp.*, 2003 WL 24147449, *18 (S.D. Cal. 2003), *vacated on other grounds by* 2004 U.S. Dist. LEXIS 23859.

21. We assume for purposes of this article that any incorporation by reference was done properly, the best practices for and pitfalls of incorporation by reference being outside the scope of this article.

22. We further assume that any incorporation by reference was done with respect to the entirety of the incorporated reference, leaving to our third scenario the pesky issue of selectivity by an applicant with regard to the contents of a given reference.

23. Taken together, the pertinent sections of the C.F.R. and the MPEP relate nearly without exception to explaining seemingly *ad infinitum* that (1) citation by way of an IDS that complies with both 37 C.F.R. § 1.97 and § 1.98 is sufficient to satisfy an applicant's Rule 56 duty to disclose, and entitles the applicant to consideration by the Examiner of the IDS and that (2) a submitted IDS that does not comply with both § 1.97 and § 1.98 will not be considered by the Examiner, but will instead just be placed in the file. *See* 37 C.F.R. § 1.56(a) ("The duty to disclose . . . is deemed to be satisfied if all information known to be material . . . was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97 [and] 1.98."); MPEP § 609 ("37 CFR 1.97 [and 1.98] provide a mechanism by which patent applicants may comply with the duty of disclosure provided in 37 CFR 1.56." (emphasis added)); MPEP § 609 ("Once the minimum requirements of 37 CFR 1.97 and 37 CFR 1.98 are met, the examiner has an obligation to consider the information."); 37 C.F.R. § 1.97(i) ("[if an IDS] does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office."), MPEP § 609, 609.05(a); MPEP § 609 ("In order to have information considered by the Office during the pendency of a patent application, an [IDS] must be (1) in compliance with the content requirements of 37 CFR 1.98, and (2) filed in accordance with the procedural requirements of 37 CFR 1.97."); MPEP § 609.04(a) ("An [IDS] must comply with the provisions of 37 CFR 1.98 as to content for the information listed in the IDS to be considered by the Office."); *but see* MPEP § 2001.04 ("The Office does not believe that courts should, or will, find violations of the duty of disclosure because of unintentional noncompliance with 37 CFR 1.97 and 1.98. If the noncompliance is intentional, however, the applicant will have assumed the risk that the failure to submit the information in a manner that will result in its being considered by the examiner may be held to be a violation.").

24. MPEP § 609.05(a) (emphasis added). This section includes form paragraph 6.49.06, entitled "Information Disclosure Statement Not Considered, References Listed in Specification," for Examiners to use to provide the required notice to applicants when the Examiners have identified an instance of this situation and have decided not to consider the information listed in the specification, as the MPEP says they "need not." This paragraph reads:

> The listing of references in the specification is not a proper [IDS]. 37 CFR 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and MPEP § 609.04(a), subsection I. states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

It would seem to be a fair inference when an applicant (1) mentioned a reference in the specification and (2) did not receive the notice required by § 609.05(a), that although the Examiner "need not" have (but obviously was free to) consider that reference, the Examiner did in fact consider it.

25. *See, e.g., Al-Site*, 174 F.3d at 1323; *Am. Hoist*, 725 F.2d at 1359; *E.I. du Pont de Nemours & Co. v. Berkley & Co., Inc.*, 620 F.2d 1247, 1266 (8th Cir. 1980) ("The statutory presumption of validity flows from a congressional assumption that the PTO properly performs its administrative functions." (citations omitted)).

26. *See* MPEP § 704.01 ("After reading the specification and claims, the examiner searches the prior art. [. . .] The invention should be thoroughly understood before a search is undertaken." (emphasis added)).

27. *See, e.g.*, 37 C.F.R. § 1.57(f) ("material incorporated by reference [may be amended] into the specification or drawings of an application . . . ."); *see also Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F. 3d 1272, 1282 (Fed. Cir. 2000) ("Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." (citations omitted)); *S. Clay Prods., Inc. v. United Catalysts, Inc.*, 43 Fed. Appx. 379, 387 (Fed. Cir. 2002) (Mayer, J., dissenting) ("We have held that incorporating material by reference is the same as if the information were included directly in the host document." (*citing In re Lund*, 376 F.2d 982, 989 (CCPA 1967))); *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001).

28. *See Al-Site*, 174 F.3d at 1323; *Am. Hoist*, 725 F.2d at 1359.

29. *See* 37 C.F.R. § 1.57(e) ("The examiner may require the applicant to supply a copy of the material incorporated by reference."); *see also* MPEP § 608.01(p) ("The examiner may require a copy of the incorporated material to review and to understand what is being incorporated or to put the description of the material in its proper context.").

30. *See, e.g., Regents of Univ. of N.M v. Knight*, 321 F.3d 1111, 1121 (Fed. Cir. 2003) ("The MPEP sets forth PTO procedures; it is not a statement of law," *citing Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995) ("While the MPEP does not have the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith.")).

31. *See, e.g., Al-Site*, 174 F.3d at 1323; *Am. Hoist*, 725 F.2d at 1359.

32. *See* 37 C.F.R. § 1.104.

33. *See supra*, n.27.

34. *See, e.g., Ind. Mills & Mfg. v. Dorel Indus. Inc.*, 458 F. Supp. 2d 890, 931 (S.D. Ind. 2006) ("Despite the fact that the examiner failed to list them in the appropriate sections of the prosecution history, the Court presumes that the examiner considered [two U.S. Patents] because those references were clearly cited in the specification."); *Polaroid Corp. v. Eastman Kodak Co.*, 641 F. Supp. 828, 833 (D. Mass. 1986) ("prior art described in the specification [ ] is expected to be considered by the Examiner." (citations omitted)); *Penda Corp. v. United States*, 29 Fed. Cl. 533, 561 (Fed. Cl. 1993) ("The examiner did consider [a particular patent], inasmuch as it is one of the references cited in the

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specification of the patent at issue."). *Compare Am. Cyanamid Co. v. U.S. Surgical Corp.*, 833 F. Supp. 92, 105 (D. Conn. 1992) (Examiner not presumed to have considered prior art for purposes of double-patenting where prior art was cited in Applicant's specification).

35. *See Gould v. Gen. Photonics Corp.*, 534 F. Supp. 399, 403 (N.D. Cal. 1982) (reference deemed considered by Examiner as prior art in issuing patent-in-suit due to specification discussing same subject matter as pertinent disclosure of reference).

36. *See, e.g., E.I. du Pont de Nemours & Co. v. Berkley & Co., Inc.*, 620 F. 2d 1247, 1267 (8th Cir. 1980) ("[T]he examiner's search record is *prima facie* evidence that he considered all the references classified in the classes and subclasses searched and that he left uncited [sic] those he regarded as less relevant than those cited.") (citations omitted)); *Polaroid Corp. v. Eastman Kodak Co.*, 641 F. Supp. 828, 833 (D. Mass. 1986) ("Polaroid has fulfilled its obligation to the Patent Office where the patent in suit is in the class of patents that was cited." (citations omitted)).

37. Interestingly, though perhaps not immediately intuitive, it would appear that, while the fact that a reference is in the same class or subclass that was searched by the Examiner has been deemed sufficient to earn the patent-in-suit the § 282 presumption of validity over that reference, that same fact is not at all helpful in trying to defeat a charge of inequitable conduct. This makes sense to us, however, for at least the reason that the particular classification of a given reference has absolutely nothing to do with any conduct on the part of the applicant, agent, attorney, etc.—*i.e.*, any "individual associated with the filing and prosecution of [the] application [that issued as the patent-in-suit]." *See* 37 C.F.R. § 1.56(a). In the recent and insightfully simple and crystallizing words of Judge Joan Ericksen of the District of Minnesota, "it is whether a reference was disclosed, not whether it was considered, that is relevant to inequitable conduct." *Am. Med. Sys., Inc. v. Laser Peripherals, LLC*, 2010 WL 1957479, at *29 n.25 (D. Minn. May 13, 2010).

Thus, while constructive consideration can provide a bit of a "Get Out of Jail Free" card to a patentee in the context of the presumption of validity, no such card appears available in the context of inequitable conduct. For support for this latter proposition, *see, e.g., Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984), *overruled on other grounds by Kingsdown*, 863 F.2d at 876 (Fed. Cir. 1988) ("It cannot be presumed, where fraud or other egregious conduct is alleged, that the PTO considered prior art of particular relevance if it was not cited."); *see also FMC Corp. v. Hennessy Industries, Inc.*, 836 F.2d 521, 526 (Fed. Cir. 1987), *citing Driscoll*, 731 F.2d at 885 (evidence establishing only that the examiner made "a generalized search" of the class and subclass that contained the omitted reference was not, in and of itself, sufficient to consider the patentee's duty of candor to have been met); *but see Avco Corp. v. PPG Indus., Inc.*, 867 F. Supp. 84, 88 n.3 (D. Mass. 1994) ("[finding] that the . . . examiner knew about [a particular] patent [in the prior art, on the basis that there was no evidence contrary to the evidence establishing that the examiner actually searched a set of] categories and subcategories [that] would have revealed the [particular] patent[, relying on Federal Rule of Evidence 301 in initially adopting] the presumption that the patent categories listed by the . . . examiner are presumed to have been reviewed.").

38. MPEP § 707.05(b) (emphasis added).

39. *See Am. Med. Sys., Inc. v. Laser Peripherals, LLC*, 2010 WL 1957479, at *29 (D. Minn. May 13, 2010) ("The [patent-in-suit] incorporated by reference [a certain] application, which discloses [a certain figure] and the related description. Such incorporation is inconsistent with any intent to deceive." (citations omitted)); *Grantley Patent Holdings, Ltd. v. Clear Channel Communications, Inc.*, 540 F. Supp. 2d 724, 732 (E.D. Tex. 2008) ("[T]he fact that [the inventor] explicitly incorporated [a certain] publication by reference into the . . . specification is inconsistent with any intent to deceive.").

40. While not central to our analysis, we note that there may also be some headway that could be made using the line of cases standing for the proposition that, when a reference was considered by the Examiner, no intent to deceive can be inferred from mere attorney argument (not involving material misrepresentations, but rather just the characterizations of a zealous advocate). *See, e.g., Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009) ("While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct[, the court therefore seeing] little basis to find deceptive intent in the routine back and forth between examiner and applicant[, and the court further recognizing] that the Patent Act gives the examiner the discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record." (citations omitted)). The parallel here of course rests on the assumption that the court would deem the reference to have been actually considered by the Examiner, but could be useful to the extent that an accused infringer targets any characterization of the incorporated reference in the specification as evidencing an intent to deceive.

41. *See supra*, n.34.

42. *See supra*, n.36-37.

43. We arrive at this assumption even while mindful that, when explaining (albeit clearly in dicta) why the Supreme Court in KSR did not need to (and in fact did not) "reach the question [of whether the fact that a reference at issue as to validity was not before the Examiner] during the prosecution of [the patent-in-suit] voids the [§ 282] presumption of validity given to issued patents," Justice Kennedy wrote that "[the unanimous Court] nevertheless [thought] it appropriate to note that [, in that circumstance,] the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished." *See KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 426, 127 S.Ct. 1727, 1745 (2007). As we also assert in the article proper, we think that a reference that is mentioned in the specification is "before the Examiner" as much as—if not more so than—a reference that, for example, happens to be in the class or subclass searched by the Examiner.

44. *See IDEC Pharm. v. Corixa Corp.*, 2003 WL 24147449, at *18 (S.D. Cal. Oct. 14, 2003), *vacated on other grounds by* 2004 U.S. Dist LEXIS 23859.

Daniel P. Williams concentrates his practice in obtaining patent protection for clients in the areas of telecommunications, computer hardware and software, networks, and Internet applications. He has experience in intellectual property litigation, including patent and trade secret litigation. Mr. Williams is also the inventor of U.S. Patent No. 7,130,664.

williamsd@mbhb.com

Alan W. Krantz prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement, and patentability analyses, patent application preparation and prosecution, and litigation matters in the computing field.

krantz@mbhb.com

McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive
Chicago, Illinois 60606-6709

312 913 0001 phone
312 913 0002 fax
www.mbhb.com
snippets@mbhb.com

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Partners
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Michael H. Baniak
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Paul H. Berghoff
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Christina L. Brown
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Marcus J. Thymian
Paul S. Tully, Ph.D.
Thomas E. Wettermann
Andrew W. Williams, Ph.D.
Daniel P. Williams
Donald L. Zuhn, Jr., Ph.D.

Of Counsel
Denis A. Berntsen
Sandra B. Weiss

Associates
Jeffrey P. Armstrong
Daniel R. Bestor
Y. Elaine Chang, Ph.D.
Michael D. Clifford
Sarah E. Fendrick, Ph.D.
Jori R. Fuller
Paul A. Kafadar
Sydney R. Kokjohn
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James T. Wasicak

Law Clerks
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Michael S. Borella, Ph.D.
Timothy M. Long, Ph.D.
Kwame N. Mensah, Ph.D.
Cole B. Richter

Technical Advisors
Isadora Bielsky, Ph.D.
Willy Chen
Nathaniel P. Chongsiriwatana, Ph.D.
David A. Grabelsky, Ph.D.
A. Gracie Klock
Jelena J. Libby, Ph.D.