Nineteen Hundred and Twenty-two

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NYIPLA Proposed Comments and Recommendations to the USPTO on the USPTO's Proposed Rules Changes to Information Disclosure Statement Requirements and Other Related Matters

Submitted on September 7, 2006 to the U.S. Patent and Trademark Office from the NYIPLA, President Marylee Jenkins and The Board of Directors

The U.S. Patent and Trademark Office (the "Office") published a proposed rules package[1] on July 10, 2006 that, if adopted, will dramatically affect how patent applications are prosecuted in the United States. This memo briefly describes the substance of certain of these proposed rules changes, proposes comments for the Office to consider in evaluating whether these proposed rules should be adopted, and recommends alternatives for the Office to consider to improve the patent examination process.

INTRODUCTION

The New York Intellectual Property Law Association (the "NYIPLA") is a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property law. The Association's members include in-house attorneys working for businesses owning patents or having to deal with the patents of third-parties, as well as attorneys in private practice who represent both patent owners and accused infringers. NYIPLA members represent both plaintiffs and defendants and also regularly participate in proceedings before the Office.

The Board appreciates that the Office is trying to manage the record number of patent applications being filed each year in the Office[2] and the reported backlog, and the Board supports the Office's review of its current practices and procedures to determine ways that the Office can continue to make the patent examination process more effective and efficient. However, the Office's proposed rules represent drastic changes that will have both far reaching and comprehensive consequences.

Changes to Information Disclosure Statement Requirements

Pertinent proposed changes to the rules regarding Information Disclosure Statements can be summarized as follows:

1. Only twenty references can be cited prior to the first Office Action "on the merits" before more burdensome disclosure requirements become necessary.
2. Any English language reference having more than twenty-five pages requires detailed analysis.
3. Any foreign language reference requires detailed analysis.
4. Any reference cited after a first Office Action on the merits requires more detailed analysis.
5. Previously cited references must be reevaluated in light of changes to the claims and then appropriate comments must be filed.
6. A "safe harbor" provision is to be added to Section 1.56.

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GENERAL COMMENT

The stated purpose of the proposed rule changes is to encourage early submission of relevant information and to discourage submission of information that is unimportant or does not add something new for an Examiner to consider. The Board certainly supports such goals; however, the Board respectfully submits that the proposed changes to Sections 1.56, 1.97, and 1.98 are too far reaching and, in fact, have the unintended consequence of interfering with effective prosecution of a patent application before the Office.

While the Office's proposed rule changes apparently seek to reduce or minimize perceived burdens on Examiners resulting from untimely or extensive submissions of prior art, the Office has minimized an important concern to practitioners, namely, the consequences of being forced to provide detailed "explanations" (see proposed Section 1.98(a)(3)(iv)). The required explanations, including identification, correlation, and non-cumulative description, involve detailed analysis and legal and/or factual conclusions. Such analysis and conclusions are not only burdensome due to the extra costs to clients, but they also result in comments that could be misinterpreted at a later date, perhaps resulting in a charge of inequitable conduct. In addition, to the extent that the Office is urging applicants to cite less prior art, there is more likelihood that a practitioner's judgment will be questioned at a later time.

The Office is surely aware of the large number of reported cases where, under the present rules regarding disclosure, practitioners have been held responsible for not citing references that were believed by the practitioners to not be material. With the proposed rule changes urging that fewer references be cited and that, for ones cited, explanations be provided, more allegations of inequitable conduct are bound to follow.

The Board has the following specific comments:

Comment One: The proposed "threshold number" of twenty patents to be cited before a first Office Action is inappropriate.

The Office's comments indicate that the threshold number of twenty references that can be cited before more detailed analysis is required represents a "best" balance of the interests of the Office and the applicants. The Board submits that the Office's determination of the number "twenty", while interesting, essentially is unfair to the 15% of applicants that, according to the Office's statistics, would not be encompassed by that number.

In fact, the Board believes that there should not be any threshold number, particularly since there are certain very active technologies where large numbers of references are routinely and properly cited. However, if there must be a threshold number, the Board submits that a much higher number, such as fifty, would be a better balance of interests.

In addition, experienced patent practitioners know that there are many subject matter areas and particular clients where typically much larger numbers of references must be mentioned in an Information Disclosure Statement due to a client's extensive work in a particular area of technology. To impart a particular number as a threshold above which there will be increasingly onerous disclosure and analysis requirements is unfair and unrealistic to these situations.

Further, the detailed analysis or explanation required by the proposed rule changes for large English language documents, foreign language documents, and references above a threshold number is unduly burdensome to applicants. The costs involved in having registered patent attorneys or agents undertake a detailed analysis of such references and then submit comments to the Office will greatly increase the cost of patent prosecution, which will have a huge impact on small companies and individuals. The Board believes that this detailed analysis requirement should either be eliminated altogether or modified to require only a general designation of relevant sections of a reference, such as that provided on a PCT Search Report.

Comment Two: If there is a threshold number, the Office should not count the citation of references from a parent application against the threshold number for references cited in a continuing patent application.

As mentioned in the Office's comments, an Examiner is supposed to review references from a parent application prior to examination of a continuing patent application, i.e., a continuation or divisional patent application. However, not all of those references will necessarily be mentioned on the face of a patent to issue unless the Examiner or the applicant specifically mentions each and every such reference during prosecution of that patent. The "strength" of the statutory presumption of validity under 35 U.S.C. § 282 is directly or indirectly affected by the references specifically mentioned on the face of a patent, and therefore an applicant would prefer to see each of the previously mentioned references specifically cited. Since it would be advantageous to have all of the references from a parent patent application mentioned on the face of a patent to issue from a continuing patent application, and since this would not be a burden on the Examiner who has al-

ready reviewed the references, the Board does not believe that the references from a parent application cited during prosecution of a continuing application should be counted against the threshold number, if any.

Comment Three: The safe harbor provision does not absolve a practitioner from an allegation of inequitable conduct.

The proposed safe harbor provision of proposed Section 1.56(f) is interesting in that it inherently recognizes the concerns of practitioners regarding inequitable conduct charges, as mentioned above. However, such language is of no force or effect outside the Office and there is no certainty that a court would be guided by it. This is reflected in the commentary that:

> "… the Office is *hopeful* that a court in deciding a duty of disclosure issue will take this proposed safe harbor into account." Fed.Reg., Vol. 71, No. 131, p. 38812. (Emphasis added.)

More particularly, to the extent that a practitioner made a determination that a reference was either cumulative or non-material and didn't cite it to the Office, there is nothing in proposed Section 1.56(f) that would insulate that practitioner from a later charge to the contrary.

Inequitable conduct is almost always an issue in patent litigation, and many times the basis of a charge of inequitable conduct is the failure to cite a relevant reference during prosecution. The standards of relevance and materiality have changed over the years, and a consequence of this has been a tendency on the part of patent practitioners to avoid determining what is relevant and instead leave it up to an Examiner to make that determination. The proposed rules are incredibly troublesome in that the thrust of the determination is now being directed at the patent practitioner by virtue of a limit on the number of references that can be cited and then obligations to provide explanations, followed by an obligation to then revisit these explanations dependent upon claim changes.

Notwithstanding the language in the Federal Register, there has been a long history in the federal courts of instances where patent practitioners have been held accountable and patents have been held invalid for errors in judgment. The rule changes proposed by the Office raise the accountability of the patent practitioner to a much higher level to the extent that one can only begin to imagine the long term consequences. The Office's comments to the contrary, this is a disaster waiting to happen.

RECOMMENDATIONS

The Board does not necessarily agree that Sections 1.56, 1.97, and 1.98 need revision. However, to the extent that the Office feels it must make changes, the Board proposes the following:

1. The threshold number should be increased to at least fifty or eliminated altogether.
2. The explanation requirement of Section 1.98(a)(3)(iv) should be eliminated or modified to include only a general designation of relevant sections of a reference.
3. References cited in a parent patent application should be able to be cited in a continuing application without the references being counted against the threshold number.
4. The Office should hold public hearings on the proposed changes.

[1] See 71 Fed Reg 131, Changes to Information Disclosure Statement Requirements and Other Related Matters.

[2] In FY 2005, the Office received 384,228 Utility, Plant, and Reissue (UPR) patent applications, 25,304 Design applications, as well as 46,926 PCT applications. (Source: PTO's Performance and Accountability Report for Fiscal Year 2005).

NYIPLA CALENDAR

CLE Luncheon Program – October 25, 2006

KSR International Co. vs. Teleflex Supreme Court Case

Speakers: James Dabney, Esq., Fried, Frank, Harris, Shriver & Jacobson LLP - Petitioner's Attorney
Thomas Goldstein, Esq., Akin Gump Strauss Hauer & Feld LLP - Respondent's Attorney
John Whealan, Esq., Solicitor at the U.S. Patent and Trademark Office
Marian Underweiser, Esq., IBM In-House Counsel
Rochelle Seide, Esq., Partner, Arent Fox

SAVE THESE DATES

Friday, November 17, 2006
Fall One-Day CLE Program

Princeton-Columbia Club
(new location)
15 West 43rd Street, New York, NY
Details to follow

Friday, December 8, 2006
CLE Luncheon Program

Title to be determined
Speaker:Hon. Paul J. Luckern,
United States International
Trade Commission

May 9, 2007
23rd Annual Joint
Patent Practice Seminar

Marriott Marriot
1535 Broadway, New York, NY
Details to Frollow

Can the greater good overcome a patent in the Australian legal system?*

by James N Walsh and Robert K Cooper[1]

Rapid changes in information technology have brought the question of what should be patentable to the fore. Many new developments in commerce and industry (particularly in e-commerce) have fallen outside the traditional notions of what constitutes an invention. One of the principal issues has been whether business methods (methods of operating any aspect of a business) are proper inventions for which patents should be granted. There is now an array of views on this issue around the world.

In August 2005, Australia's Federal Court decided the case *Grant v Commissioner of Patents* (2005) AIPC 92-126. The case concerned a patent for a method by which a person could protect an asset from legal liabilities arising as a consequence of a person's occupation or business activities. The method effectively allowed individuals to avoid the full force of Australia's bankruptcy laws. Justice Branson found that the method was not patentable because it would "not add to the economic wealth of Australia or otherwise benefit Australian society as a whole". Since *Grant*, several commentators have suggested that benefit to society is a new requirement for patentability in Australia. However, the court's approach in *Grant* seems to contradict an established body of Australian cases in which the courts have been careful to leave public policy issues to Parliament.

TRADITIONAL TEST

Among other things, the *Patents Act 1990* provides that for an invention to be patentable, it must be "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies". This English statute, dating from 1623, still supplies the test used in Australia to establish whether an invention is the proper subject matter for a patent. It is separate from other requirements for patentability such as novelty and inventive step. There is no express statutory exclusion of business methods from patentability in Australia.

Section 6 of the Statute of Monopolies says that patents should only be granted to inventors of "any manner of new manufactures" provided that "they be not contrary to the law nor mischievous to the State by raising prices of commodities at home, or hurt of trade, or generally inconvenient". Courts have interpreted the statute purposively to determine whether claimed inventions are patentable subject matter.

Traditionally, schemes and plans were not considered to fall within the scope of the Statute of Monopolies and were therefore not patentable. Courts considered for a period of time whether an invention was a "vendible product" to determine whether an invention was a manner of manufacture. However, this led to difficulties in granting patents for processes claimed as inventions.

EXPANDING THE SCOPE

Australia's superior court, the High Court of Australia, redefined the "manner of Manufacture" requirement in *NRDC v Commissioner of Patents* (1959) 102 CLR 252 to accommodate processes better. The court stated:

> It is … a mistake, and a mistake likely to lead to an incorrect conclusion, to treat the question whether a given process or product is within the definition [of manner of manufacture] as if that question could be restated in the form: 'Is this a manner (or kind) of manufacture?' … The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?'.

The court then found:

> The point is that a process, to fall within the limits of patentability which the context of the Statute of Monopolies has supplied, must be one that offers some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art… - that its value to the country is in the field of economic endeavour.

The Court decided that the process in question (ridding crops of weeds) fell within the scope of the Statute of Monopolies because it involved an "artificially created state of affairs" of economic value. Since then, it has been accepted in Australia that methods, schemes and plans are now patentable subject matter to the extent that they satisfy the criteria set out in *NRDC*.

WELCOME CLARITY

The case of *Welcome Real-Time SA v Catuity Inc* (2001) 113 FCR 110 was the first in Australia to provide any real guidance on whether business methods could be patented. The case involved a method and device for operating smart cards in connection with traders' loyalty schemes. Although the respondents argued that the invention was of a type "that had never been previously held to be within the concept of 'manner of manufacture'," Justice Heerey found that the invention was patentable.

Despite this, *Welcome* does not mean that pure business methods (those that do not involve the application of science or technology) are patentable in Australia. This is because the invention before Justice Heerey involved technical components. His Honour stated:

*This article is current as of March 2006

> What is disclosed by the patent is not a business method, in the sense of a particular method or scheme for carrying on business … Rather, the patent is for a method and a device, involving components such as smart cards and POS terminals, in a business.

THE SZABO CASE

After *Welcome*, the issue of business method patents came before the Australian Patent Office (APO) in *Re Peter Szabo and Associates Pty Ltd* [2005] APO 24, which concerned an invention claimed in relation to a so-called reverse mortgage. The Hearing Officer found that the invention was not patentable, because the phrase "artificially created state of affairs" from *NRDC* required the application of science or technology in some material manner.

This approach was similar to that taken by the APO in *Re Grant* [2004] APO 11. Before the case was appealed to the Federal Court, the APO refused to grant a patent for the business method claimed because there was no "artificially created state of affairs". The invention was a method of protecting assets from legal liability and involved no discovery of a law of nature or application of technology in any way. The Hearing Officer also noted that the business method was not artificially created by the applicant because "the legislature has enacted the law in full knowledge of all its consequences".

CONTROVERSY OVER GRANT

In the decision handed down by the Federal Court in an appeal from *Re Grant*, Justice Branson affirmed the APO's decision, but for different reasons. Notably, Justice Branson found that an underlying principle governing the application of the Statute of Monopolies was that:

> [A]n invention should only enjoy the protection of a patent if the social cost of the resulting restrictions upon the use of the invention is counterbalanced by resulting social benefits.

The judge refused to confirm the reasoning by the APO in *Re Grant* and *Szabo*, while acknowledging that the principles applied by the APO in those cases may have developed into law. Instead, she considered that the benefit conferred by the invention (namely the value to financial advisers enshrined with the task of looking after their clients' assets) was not of value to the country as required by *NRDC*. She stated: "The performance of the invention will not add to the economic wealth of Australia or otherwise benefit Australian society as a whole."

Justice Branson was also persuaded to refuse the patent because the invention had the effect of insulating an asset owner from the operation of bankruptcy laws enacted to serve the public interest.

A NEW GROUND FOR REFUSAL?

Since *Grant*, several commentators have suggested that there is a new ground to refuse a patent where the claimed invention does not benefit the country as a whole. This invites a consideration of public policy, an area that the courts have traditionally left to the legislature. Cases concerning medical treatment methods in Australia (and also in New Zealand, which has similar criteria for patentable subject matter) provide useful guidance on the boundaries of public policy in this area.

Courts in Australia have not been persuaded by the policy arguments in favour of excluding methods of medical treatment of humans from patentable subject matter. When the question came before the court in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, Parliament's failure to exclude methods of medical treatment from patentability expressly was considered persuasive. Notably, Justice Wilcox stated that the issue involved "matters of ethics and social policy upon which the courts have no special expertise". The issue was left for Parliament.

New Zealand courts have taken a different approach, finding that since methods of medical treatment have traditionally been excluded from patentability at common law, it is Parliament's responsibility to provide otherwise if such methods should be patentable. It has now been recognised in *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104 that the statutory basis in New Zealand for the exclusion of methods of medical treatment is that of general inconvenience. This is a separate issue to whether an invention satisfies the "manner of manufacture" requirement, although general inconvenience also finds its statutory basis in section 6 of the Statute of Monopolies. Despite this, the ability to use general inconvenience as a ground to exclude inventions from patentability is not well supported in Australian or New Zealand law. In *Welcome*, Justice Heerey stated the following about the respondent's submissions on general inconvenience:

> [I]f an invention otherwise satisfies the requirement of s18 it can hardly be a complaint that others in the relevant field will be restricted in their trade because they cannot lawfully infringe the patent. The whole purpose of patent law is the granting of monopoly.

As a result, the APO advises in its Manual of Practice and Procedure that general inconvenience should not be treated as a separate ground for refusing to grant a patent. Likewise, the court noted in *Pfizer* that although medical treatment methods are not patentable under New Zealand law due to general inconvenience, it is difficult to conceive of any other subject matter that would fall within this scope.

Although Justice Branson did not use general in–convenience as a ground to reject the patent claimed in *Grant*, the approach she used is no different from the analysis Justice Heerey warned against in *Welcome*. Despite this, Justice Branson considered her approach to be well founded in Australian law, and applied the element of "value to the country in the field of economic

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endeavour" from *NRDC*. She considered this phrase to mean that an invention must "add to the economic wealth of Australia or otherwise benefit Australian society as a whole" in order to be patentable.

ADDING VALUE TO THE COUNTRY?

This approach ignores the context in which the relevant words appear in *NRDC*. *NRDC* progressed the law from the "vendible product" test. The focus of the court was not on inventions having to benefit the country *as a whole*, but rather on inventions being of economic value. This is demonstrated by the following statement of the court in RDC*:*

> The effect produced by the appellant's method exhibits the two essential qualities upon which 'product' and 'vendible' seem designed to insist. It is a 'product' because it consists in an artificially created state of affairs… And the significance of the product is economic: for it provides a remarkable advantage…

This demonstrates that an invention will add "value to the country" merely by having a commercial application, which was enough in *NRDC*. On this basis, Justice Branson's approach in *Grant* has no statutory basis in Australian law. By taking an approach founded in public policy, Justice Branson has created a precedent by which the APO and the courts could refuse patents for inventions that may not serve the greater good. This could make it difficult for applicants to obtain patents for any inventions (not just business methods) that do not provide a clear benefit to society or which may have the potential to prejudice certain members of the community.

The approach taken in *Grant* also appears to be unsupported in other major patent jurisdictions. The US does not appear to have any equivalent ground on which to refuse a patent. The European position is similar to that in the US on this issue, although there is an exception by which patents may be denied on the basis of "ordre public" or "morality". Having said this, inventions that are excluded on this basis seem to involve serious ethical concerns (such as human cloning) for which the Patents Act provides statutory guidance in Australia. Justice Branson may have stepped into the shoes of the legislature by considering the greater good for society when she refused the patent claimed in *Grant*.

WHAT NOW FOR BUSINESS METHOD PATENTS?

The effect of *Grant* was to introduce a greater degree of uncertainty for applicants for business method patents in Australia. In particular, it is unclear:

- whether patents will be granted for business methods not involving the application of science or technology; and
- whether the APO and courts will apply the same principles in determining whether patents should be granted for business methods.

Based on *Szabo*, it appears that the APO favours a conservative approach that has some similarity to the European "technical features" test. The European approach prevents business methods from being patentable unless they contain novel technical features. Pure business methods are not patentable. However, the Federal Court of Australia has looked favourably upon US law concerning business method patents in the past. Given that the recent US decision of *Ex parte Lundgren* Appeal No. 2003-2088 (BPAI 2005) established that pure business methods are patentable under US law, it will be interesting to see what direction Australia takes.

AN ISSUE FOR PARLIAMENT?

Although several commentators consider that *Grant* may have created a new ground on which patents may be refused in Australia, the decision is not properly based on *NRDC*. The issue before Justice Branson was not straightforward, but her approach invites courts to consider public policy in an unprecedented manner when determining whether or not to grant patents. Perhaps the facts of *Grant* would have allowed Justice Branson to rely on general inconvenience as a ground for refusing the patent, despite there being case law warning against this approach. In any case, *Grant* would best be limited strictly to the facts; namely, the refusal of a patent for an invention designed to defeat the purposes of Australia's bankruptcy laws at the expense of creditors.

[1] James Walsh is a solicitor and Robert Cooper is a partner in the Patents Group of the Melbourne office of Mallesons Stephen Jaques. This article first appeared in the March 2006 issue of Managing Intellectual Property (www.managingip.com). The authors can be reached at james.walsh@mallesons.com and robert.cooper@mallesons.com.

James N Walsh

Robert K Cooper[1]

HISTORIAN'S CORNER

"As Time Goes By - A Long and Winding Road to Patent Reform"

by Dale Carlson[1]

I'm pleased to continue as NYIPLA Historian at the behest of our new President, Marylee Jenkins. Our previous five columns have focused on patent reform, and our Association's role through the years in molding reform. This column will continue in that vein.

As the 2005-2006 legislative session draws to a close, we can be confident that the road to patent reform is marked more by twists and turns than it is by straight paths. Perhaps things have always been that way.

A prime example of a long-winding legislative path, with starts and stops along the way, can be found in the proposals behind the creation of the Court of Appeals for the Federal Circuit.

A full half-century prior to the Federal Circuit's creation in 1982, our Association voiced its opinion on the proposal to form a single court for patent appeals. A 1932 article appearing in the American Bar Association Journal begins with this opening salvo "The proposal for a Single Court of Patent Appeals has again been recently agitated and widely circulated by its sponsors. It has frequently been urged since first brought to the attention of the American Bar Association in 1898."

The 1932 ABA article (appearing at 18 A.B.A.J. 902 (1932)) documents the position of our Association on the patent court concept back then. Specifically the article notes that on "September 14, 1931, the Board of Governors of the New York Patent Law Association adopted the unanimous report of its sub-committee, which stated that it 'is convinced that the proposed bill is unsound in principle and for this reason recomments that it be not approved.'" The article goes on to say that the Board adopted this report, and was officially represented at a "Patent Section" meeting of the ABA by Richard Eyre of New York for the purpose of opposing the bill.

Dale Carlson, a partner at Wiggin & Dana, serves as the NYIPLA Historian, and as a member of the Board of Directors.

Back in 1932, our Association did not stand alone in its opposition to the patent appeals court concept. It was joined by the ABA, the Cleveland Patent Law Association, and the Committee on Patents of the Association of the Bar of the City of New York in such opposition.

Perhaps in the face of such opposition, the enactment of the Federal Circuit was a long time in materializing. Needless to say, a half-century is an unusually long time period for any proposed legislation to percolate. Nevertheless, legislative change doesn't often happen quickly, particularly when it pertains to sweeping patent reform legislation.

During 2005, sweeping reform legislation was introduced by Representative Lamar Smith in the House in the form of a "Coalition Print" dubbed "Substitute bill H.R. 2795". That bill called for, among other things, elimination of best mode. It also included a post-grant opposition procedure with a "single window" of opportunity for bringing an opposition not later than nine months after grant of a patent.

On April 5, 2006, Representative Howard Berman introduced the "Patents Depend on Quality Act of 2006" (H.R. 5096 - the "PDQ Act") into the House. The proposed PDQ Act focuses on post-grant opposition, and includes a so-called "second window" for bringing an opposition, namely within six months of an alleged infringer's receiving notice of suit.

On August 3, 2006, Senator Orrin Hatch introduced the "Patent Reform Act of 2006" (S. 3818) into the Senate. This bill also includes a second window for bringing a post-grant review proceeding. The second window is open when an opponent "establishes a substantial reason to believe that the continued existence of the challenged claim causes or is likely to cause the petitioner substantial economic harm." ■

[1] *Editor's Note: Following the author's submission of his previous Historian's Column (published in the July/August Issue), the committee chairs referenced in that column have changed. Allan Fanucci has been appointed as chair of the License to Practice Requirements, and Susan McHale McGahan has been appointed as chair of the Committee on Public and Judicial Personnel and International Relations.*

SOUTHERN DISTRICT CASE REVIEW

by Mark J. Abate and Jennifer BianRosa*

Generic Infringes Pepcid Complete

Mc Neil-PPC, Inc. v. Perrigo Co.
2006 U.S. Dist. LEXIS 51172
(July 27, 2006)
(Judge William H. Pauley III)

This patent infringement action brought under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2) involves Plaintiff McNeil's U.S. Patent No. 5,817,340 (the '340 patent) related to a solid oral dosage of aluminum hydroxide or magnesium hydroxide ("antacids"), used to neutralize acid already present in the stomach, and famotidine, which inhibits acid secretion in the stomach by interfering with histamine receptors. The combination is used to treat gastric disorders such as acid indigestion and is marketed by McNeil as Pepcid Complete. Defendant Perrigo's alleged infringing product is a generic tablet consisting of coated famotidine in one layer and magnesium hydroxide in a separate layer.

The inventors of the '340 patent learned that famotidine degrades when exposed to antacids and is rendered therapeutically ineffective. The '340 patent relates to a method for preventing famotidine degradation. In the preferred embodiment of the '340 patent famotidine granules are coated with an impermeable material that protects it from the antacids. The '340 patent lists examples where the coated famotidine granules and antacids are interspersed throughout a single layer tablet and other examples with two layer embodiments where the coated famotidine comprises one layer and antacids comprise the second layer. The specification also describes three-layer embodiments where an impermeable polymer layer separates the famotidine from the antacids in a sandwich barrier or, in the alternative, a core of antacids is encapsulated by the polymer and surrounded by the famotidine layer.

During the prosecution of the '340 patent, the Patent Office rejected McNeil's claims on the grounds of obviousness – using a coating material to prevent interaction between layers and combining histamine blockers in conjunction with antacids - were both known. The Patent Office allowed the claims after the submission of a declaration setting forth test results showing a 25-70% degradation of famotidine when uncoated and a 2% degradation when coated in a single layer tablet. Claims involving the barrier sandwich and core methods were rejected and cancelled.

The claims at issue required "mixing a therapeutically effective amount of [antacid] with a therapeutically effective amount of impermeable coated famotidine granules." The Court construed "mixing" consistent with McNeil's definition to mean "combining two or more ingredients into one mass," which encompasses both one-layer and two-layer coated granule tablets, and rejected Perrigo's construction which required that the mixture be a uniform dispersion since the specification used both one and two layer examples as variations of the preferred embodiment. The Court also rejected Perrigo's argument that the scope of the claims be limited to the single layer tablets, the subject of the test results presented during prosecution. The Court noted that there was no clear disavowal of a two layer embodiment in the prosecution history and "[t]he submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims."

Another claim required "said coated famotidine granules and the [antacids] in contact with each other, but separated by said impermeable coating on the famotidine granules." The Court construed "in contact with" to mean "a union or touching of body surfaces, a touching or meeting" and rejected Perrigo's construction that required the full therapeutic amounts of famotidine and antacids to be in contact with each other as inconsistent with its construction of "mixing." In construing the term "impermeable," the Court rejected Perrigo's argument that the granule coating be completely impermeable to the antacid. While the claim language was ambiguous, the Court noted that the inventors contemplated some interaction between the famotidine and antacid as the specification described that the combination of the "impermeable" famotidine

and antacid would still result in some degradation. Further, at the Markman hearing, Perrigo did not object to McNeil's assertion that the coating techniques identified would not result in 100% coating on each granule. The Court concluded that Perrigo's two-layer coated famotidine granule tablet infringed the '340 patent and awarded summary judgment in favor of McNeil.

The Court dismissed Perrigo's claim of invalidity of the '340 patent as obvious. While limitations of the '340 patent such as the combination of famotidine and antacid and the use of an impermeable coating appear in the prior art, the prior art did not disclose famotidine degradation. The only motivation to combine the prior art would have been to mask the taste of famotidine. The prior art also disclosed that an impermeable coating was not necessary if an unpleasant taste could be overcome by the addition of sweeteners or a flavoring agent. The commercial success of McNeil's product Pepcid Complete also weighed in favor of non-obviousness.

No Likelihood of Confusion Between 24 Hour Fitness And 24/7 Fitness

24 Hour Fitness USA, Inc. v.
24/7 Tribeca Fitness, LLC
2006 U.S. Dist. LEXIS 55547
(August 7, 2006)
(Judge Ronald L. Ellis)

Plaintiff, 24 Hour Fitness ("24 Hour") brought various trademark claims against defendant 24/7 Tribeca Fitness, LLC ("24/7"). 24 Hour is a chain of physical fitness facilities based in California. It originally operated under the mark "24 Hour Nautilus" and began using "24 Hour Fitness" in August 1996. 24 Hour has used the mark "24 Hour Fitness" continuously for over five years and owns nineteen federally registered marks containing 24 Hour Fitness and 24 Hour for health clubs and related items. 24/7 Fitness Club operates two facilities in New York City, and began to use the term "24/7" between February and April 2001.

The Court employed the test in Polaroid Corp. v. Polarad Elecs. Corp., 287 F.2d 492, 495 (2d Cir. 1961), to evaluate the likelihood of confusion between the marks. The factors to be analyzed include: "(1) the strength of the mark, (2) the degree of similarity between the two marks, (3) the competitive proximity of the products, (4) actual confusion, (5) the likelihood the plaintiff will bridge the gap, (6) the defendant's good faith in adopting its mark, (7) the quality of the defendant's products, and (8) the sophistication of the purchasers."

24 Hour's trademark was incontestable as a matter of law because it was registered and in continuous use for over five years, and therefore presumed distinctive. 24 Hour engaged in extensive advertising and promotions including display of its marks through signage and sponsorship of major sporting events. The Court noted that despite promotion and the mark's presumption of distinctiveness, it would be challenging to establish such a common phrase as inherently distinctive.

24/7 attempted to show dilution of the mark by third-party use where various hotel websites advertised a "24 hour fitness center", however the term was not used on signage or brochures, which would indicate a trademark use. The Court reasoned that third parties used the term to describe fitness services that were open all day, which weakened 24 Hour's mark. With respect to the strength of 24 Hour's mark, the Court noted that while 24 Hour's mark is relatively strong in areas with facilities, there was insufficient evidence of strength in the relevant market of New York City with only 600 members and no facilities.

Similarity of the marks weighed in favor of 24 Hour because the similarity of the marks in appearance and message created a possibility of confusion. However, the Court found no likelihood of confusion as the geographic separation and the differences between the parties' services created insufficient competitive proximity. The likelihood that 24 Hour would enter 24/7's market was a neutral factor since 24 Hour planned to co-brand with

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the basketball star Magic Johnson. The distinct celebrity association would not risk a likelihood of confusion.

Actual confusion weighed slightly in 24 Hour's favor. Evidence was presented showing that a few people entered 24/7's facility and inquired about the affiliation between 24 Hour and 24/7, and whether they were able to use their 24 Hour Fitness membership cards at a 24/7 facility. Survey evidence of actual confusion was inconclusive.

The Court found insufficient evidence for a finding that 24/7 demonstrated an intent to capitalize on the strength of 24 Hour's mark in naming their fitness club 24/7 Fitness. The Court also found no difference in the quality of the products or sophistication of the buyers.

In weighing the Polaroid factors the Court found that 24 Hour did not establish a likelihood of confusion between the two marks at issue and entered a judgment for the defendants.

Unreasonable Behavior in Copyright Action Results In Award For Costs And Fees

Baker v. Urban Outfitters, Inc.
2006 U.S. Dist. LEXIS 27429
(May 5, 2006)
(Judge Loretta A. Preska)

Plaintiff Baker, a professional photographer, pursued an unsuccessful copyright infringement action against Urban Outfitters, Inc. and Urban Outfitters Wholesale, Inc. (collectively "Urban") who inadvertently used one of Baker's photographs as an insert in plastic picture frames. Urban moved for costs and fees against Baker and his counsel.

Baker's agent informed Urban's general counsel that Urban had infringed Baker's copyright by its sale of the picture frames and inserts. Urban sold approximately 862 picture frames incorporating Baker's picture, with $3,896 in profits from the sale of the picture frames. In settlement negotiations, Baker rejected Urban's offer of more than two times its profits. After unsuccessful negotiations, Urban stopped selling the products at issue. Baker then registered the photograph with the United States Copyright Office and filed suit against Urban.

During discovery, Baker's counsel refused to produce, and cited as irrelevant, any documents relating to a prior license of Baker's photographs. Baker and his counsel represented that Baker only worked for commission and had not ever licensed a photograph. Baker later admitted in a deposition that he had licensed photographs. The Court found Baker's behavior "contumacious and disruptive" and that it had prolonged discovery.

In determining whether Urban was entitled to fees and costs the Court considered factors such as Baker's frivolousness, motivation, objective unreasonableness in the factual and legal components of the case, and the need for compensation and deterrence.

The Court found that Baker was motivated by improper considerations and attempted to maintain the suit in order to obtain a significant payment from a "deep pocket." Baker used as a justification that "the image was part of a series that cost thousands of dollars to shoot and was not one I would have licensed for a pittance." The Court cited as the most notable example of Baker's objective unreasonableness the fact that Baker and his counsel continued to demand more than $260,000 in "actual damages" when Urban's profits were shown to be worth only $3,896.

The Court found a unique need for compensation and deterrence in Baker's unreasonable pursuit of a large award which forced Urban to expend considerable resources. The court stated that an award of fees and costs was a necessary deterrence to those bringing lawsuit based on unreasonable allegations and granted Urban's motion for fees against Baker and his counsel.

No Privilege Afforded Swiss In-House Counsel Or Patent Agents

In Re Rivastigmine Patent Litigation
2006 U.S. Dist. LEXIS 54945
(August 8, 2006)
(Magistrate Judge James C. Francis IV)

In a patent infringement regarding defendants' alleged inducement of infringement of two of plaintiff Novartis's patents by seeking FDA approval to market generic versions of Exelon, a drug marketed by Novartis for the treatment of Alzheimer's type dementia, the defendants sought to compel production of documents withheld by plaintiffs on the basis of attorney-client privilege.

The categories of withheld documents included "Swiss Motion" documents requesting disclosure of communications between Swiss patent agents and their clients, Swiss in-house counsel and their clients, or European patent attorneys and their clients. Another category of documents, "Privilege Log Motion" documents, related to requests for the production of documents on the basis of alleged deficiencies in the plaintiffs' privilege log. The Privilege Log Motion documents included withheld communications related to foreign patent prosecutions, for which the plaintiffs provided a categorical log, rather than a traditional, itemized privilege log.

With respect to the Swiss Motion documents, the Court noted that communications with foreign attorneys and patent agents requires a type of choice-of-law "contacts" analysis in order to determine whether the law of the foreign country provides a privilege comparable to the

attorney/client privilege. Both plaintiffs and defendants agreed that Swiss law governed a majority of the documents involved in the Swiss Motion.

The Court held that Swiss law specifically excludes the documents at issue from the privilege and ordered production of those documents. While Swiss law provides some confidentiality protection for communications between clients and attorneys or patent agents in Switzerland, it is not comparable to the attorney-client privilege in the United States. Swiss legal professionals may be sanctioned for violating a duty of professional secrecy, but the Court distinguished secrecy obligations, a professional's ethical obligation to his client, from the attorney-client privilege, an evidentiary privilege of non-disclosure. The Swiss legal professionals involved in the communications in question were in-house attorneys and patent agents. Swiss law excludes in-house counsel from the privilege as having too great an interest in the outcome of the advice to be an objective counsel.

The Court also rejected plaintiffs' argument that a Swiss court would not order production of the documents requested since Swiss law limits the mandatory disclosure of documents in civil litigation. The Court remarked that while the "contacts" test applies to the determination of privilege with respect to Swiss legal professionals, it does not require the adoption of all Swiss discovery rules and procedures.

In deciding the Privilege Log Motion, the court found that draft patent applications, amendments, and supporting affidavits were subject to the attorney-client privilege, unless waived. With respect to plaintiffs' categorical log, the court found the categorical justifications inadequate and ordered plaintiffs to produce the corresponding documents in their entirety.

*Mark J. Abate is a partner at Morgan & Finnegan, L.L.P. and can be reached at mjabate@morganfinnegan.com. Jennifer BianRosa is an associate at Morgan & Finnegan, L.L.P. and can be reached at jbianrosa@morganfinnegan.com.

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NYIPLA/USPTO participate in the first-ever webinar on the PTO's new electronic filing system

The NYIPLA participated in its first ever joint NYIPLA/USPTO webinar on July 26, 2006. The topic of the webinar was the PTO's new web-based electronic filing system (EFS-Web) and was hosted by Brian Koma from the PTO's EFS-Web Outreach Team, with presentations by Charles Welch and Nicholas Rouvas, also from the PTO's EFS-Web Outreach Team. Peter Thurlow, Chairperson of the Meetings and Forums Committee for the NYIPLA, was also a panelist and joined in the discussion.

EFS-Web provides applicants the capability to file patent applications online using only a web-connection and PDF files. The presentation included an introduction to EFS-Web; an overview of EFS-Web and its benefits; a live demonstration; and a live Q&A session. The PTO expects that 15-20% of all submissions to the PTO by the end of this year will be done through EFS-Web, much more than the 10% they initially expected. For now, applicants are not required to use EFS-Web, but the likely trend as EFS-Web is fully implemented is to require that EFS-Web be used for all submissions to the PTO. For example, in the PTO's recent rule package, "Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination" (See FR, Vol. 71, No. 122, pgs. 36323-36327), which takes effect on August 25, 2006, the application, petition, required fees and related follow-on submissions must be filed electronically using EFS-Web.

The links to the power point presentation and recorded EFS-Web presentation are provided below.

The link to the power point presentation:
http://websurveyor.com/downloads/services/EFS-WebBriefingForNYIPLA7-26.ppt

The link to the recorded EFS-Web presentation on July 26, 2006:
http://websurveyor.com/downloads/services/7-26NYIPLATrainingedited.wrf

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http://support.webex.com/support/downloads.html?_nfpb=true&_pageLabel=DownloadsHome

Susan McGahan, Esq. at September 20, 2006 CLE Luncheon Program

Topic: U.S. Supreme Court's decision in eBay Inc. v. MercExchange, L.L.C.

On September 20, 2006, the NYIPLA hosted its monthly CLE Luncheon Program at the Harvard Club in midtown Manhattan. The topic of the meeting concerned the state of obtaining permanent or preliminary injunctive relief in patent actions in light of the U.S. Supreme Court's May 2006 decision in eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 78 U.S.P.Q. 2d 1577 (May 15, 2006). The speaker for the meeting was Susan McGahan, Esq., senior attorney in the Intellectual Property Law Group of AT&T, Inc., and former Board Member and Officer of the NYIPLA.

Ms. McGahan began her presentation by noting the pre-eBay injunction standard: a general rule elicited by the Federal Circuit that, upon a finding of infringement, courts will normally issue permanent injunctions in favor of the patentee absent exceptional circumstances. Under eBay, however, the U.S. Supreme Court rejected this "general rule," and stated that, like other non-patent cases, a patentee seeking a permanent injunction must meet the traditional four-part test. Specifically, the patentee must show: (1) that it has suffered irreparable harm; (2) that remedies available at law (e.g. damages) are inadequate; (3) that the balance of hardships weigh in favor of the patentee; and (4) that the public interest would not be disserved by a permanent injunction.

Left to Right: Peter Thurlow, Esq., Susan McGahan, Esq., Jonathan Muenkel, Esq.

Since there has been much speculation on how the eBay decision will impact a patentee's ability to obtain permanent or preliminary injunction, Ms. McGahan discussed how the Federal Circuit and District Courts have been dealing with requests for injunctions – both permanent and preliminary – since eBay. Immediately below is a list of those cases discussed:

Federal Circuit Cases

- Abbott Labs. v. Andrx Pharms., 452 F.2d 1331 (Fed. Cir. Jun. 22, 2006)
- Int'l Rectifier Corp. v. IXYS Corp., 2006 U.S. App. LEXIS 18693 (Fed. Cir. Jul. 14, 2006) (unpub.)
- Monsanto v. Scruggs, 2006 U.S. Dist. LEXIS 20914 (Fed. Cir. Aug. 16, 2006)

District Court Cases

- Z4 Technologies Inc. v. Microsoft Corp., 434 F. Supp. 2d 437 (E.D. Tex. Jun. 14, 2006)
- Finisar Corp. v. The DirectTV Group Inc., 1:05cv264 (E.D. Tex. Jul. 7, 2006)
- Paice LLC v. Toyota Motor Corp., 2006 WL 2385139 (E.D. Tex. Aug. 16, 2006)
- Christiana Indus. Inc. v. Empire Electronics Inc., 2:06cv12568 (E.D. Mich. Aug. 4, 2006)
- TiVo Inc. v. Echostar Communications Corp., 2006 WL 2398681 (E.D. Tex. Aug. 17, 2006)
- Canon Inc. v. GCC Int'l Ltd., 2006 WL 2516568 (S.D.N.Y. Aug. 29, 2006)
- Sanofi-Synthelabo v. Apotex, 2006 WL 2516486 (S.D.N.Y. Aug. 31, 2006)
- Voda v. Cordis, 2006 WL 2570614 (W.D. Okla. Sept. 5, 2006)

An analysis of the cases above reveals several trends. First, most courts post-eBay have denied requests for permanent injunctions when the patentee in question never used or licensed the patent in the past, or sold a competing product. Here, courts reason that, under the four-part test, there would be no irreparable harm by not granting a permanent injunction, nor would damages relief be inadequate under these circumstances. Second, the majority of courts concur that the eBay decision relates to permanent injunctions only, and not preliminary injunctive relief.

As an alternative to obtaining injunctive relief, Ms. McGahan addressed the idea of obtaining an exclusion order from the International Trade Commission under §337 of the Tariff Act. Here, there is no need for a patentee to show they meet the traditional four-part test. Rather, the ITC will issue an exclusion order, absent extraordinary circumstances, provided the following three conditions are met: (1) the complaining party has a valid U.S. patent; (2) the complaining party is using the patent in the U.S.; and (3) the complaining party's patent is infringed by an imported product. As to the third condition, it is important to note that the ITC cannot protect a patentee whose patent is being infringed solely by actions within the U.S. This condition is met, however, where the alleged infringing product is manufactured outside the U.S., even if it is designed, marketed and sold exclusively within the U.S.

So while the cases mentioned above may shed some light on the impact of eBay in obtaining injunctive relief in patent actions, it is likely to take further court action – specifically from the Federal Circuit – to predict with confidence where a patentee stands on this issue.

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Correspondence may be directed to the Bulletin Editor, Ashe P. Puri, Ropes & Gray LLP,
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