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Inducing Immune Infringement: The Interplay of 35 U.S.C. § 287(c) and § 271(b)

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"[I]t is important not to kill the goose that lays the golden egg, that is, the incentive for medical research."[2]

This Article explores the relationship between two patent statutes: first, the Physician's Immunity Statute, 35 U.S.C. § 287(c), which grants immunity to medical practitioners who infringe a medical method patent; and second, the inducement statute, 35 U.S.C. § 271(b), which states that a patent holder may recover from a party who "actively induces" patent infringement. In what circumstances, if any, should the medical practitioner's immunity be extended to the inducer?

Medical method patents are now regularly issued by the United States Patent and Trademark Office (USPTO).[3] While the issuance of these patents in the United States is now a foregone conclusion,[4] many countries do not issue medical method patents for public policy reasons.[5] Even within the United States, considerable controversy remains regarding the extent to which medical method patents can be enforced.[6] In response to the controversial case of *Pallin v. Singer*,[7] § 287(c) was enacted in 1997 to limit infringement actions against doctors.[8] The statutory language and legislative history of § 287(c) left open several questions, including the scope of inducement liability.

Determining if immunity extends to inducers begins with the express terms of § 287(c) and the legislative choices it represents. This Article concludes that there is indeed a conflict between § 287(c)'s language and intent, especially when considered in conjunction with § 271(b)'s policy of providing a usable remedy to infringement. To resolve this conflict, courts should carefully interpret the language of § 287(c), and limit § 271(b) in some settings, in order to give effect to the policy § 287(c) expresses.

Part I of this Article briefly lays out the legislative history and policy of § 287(c). Part II explains the statutory framework of § 287(c) and flags several questions for determining the scope of inducement liability. Part III introduces inducement liability and its importance for medical methods, including the breadth of potential liability. Finally, Part IV lays out a proposed framework

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PRESIDENT'S CORNER

As I write this column, the summer holidays are behind us and our members are busily engaged on all fronts. NYIPLA continues to undertake an impressive level of excellent work on behalf of our members and our community. Even during the summer months our Association remained remarkably active, so that many interesting programs will be held during the remainder of this year and into next year. The legislative provisions of the America Invents Act have spawned a raft of new regulations that will challenge our members in the coming years. NYIPLA members have been at the forefront as the law becomes more fully implemented, and we were fortunate to conduct two exciting programs devoted to new AIA regulations.

First, on September 20, 2012, NYIPLA hosted a CLE breakfast on AIA Implementation at the offices of Philips Corporation in Briarcliff Manor, N.Y. The program featured panelists from the U.S. Patent and Trademark Office, corporate and private practice. Especially given the success of this program, we likely will see more CLE or networking programs conducted outside of Manhattan, as we take NYIPLA "on the road" to surrounding neighborhoods. Thanks particularly to Kevin Ecker and Philips Corporation for hosting this important breakfast CLE.

The Patent Law and Practice Committee also arranged to host a USPTO Roadshow event on September 28 to discuss AIA implementation issues. Peter Thurlow, Brian Rothery, and Dorothy Auth worked very hard on this program, in conjunction with the USPTO, and by all accounts this program was a hit. These recent programs have enabled our membership to be fully updated on the latest AIA developments, and to learn directly from the USPTO about its implementation efforts. Stay tuned for further AIA programming as additional regulations are introduced next year.

On other fronts, our Young Lawyers Committee held a networking event at NYU on October 4, and our Women in IP Law Committee is organizing an event for October 24. The Meetings and Forums Committee also is hosting a CLE event during the evening on October 18. The topic is ethical issues regarding the use of social media. We hope that the evening format for these programs will be a convenient alternative to some of our lunchtime programs. Please see our website for further details on the upcoming programs.

The September/October events kicked off our fall programming, but much more is in store for the membership. I encourage you to become active in a committee to learn more about NYIPLA, meet new colleagues, and to participate in important developments in our field. NYIPLA offers you a host of opportunities, including efforts on amicus briefs, publications, membership enhancement, etc., in addition to CLE and networking events. The Board recently hosted a meeting with the Committee Chairs, and we were quite impressed with the energy of all the committees. My thanks to our Immediate Past President, Terri Gillis, for her efforts to support our committees and also to all the committee chairs and members for their commitment to NYIPLA. Please call me or any Board member if you would like to learn more.

Finally, I would like to welcome our newest Board members: Denise Loring of Ropes & Gray LLP; Rich Parke of Frommer Lawrence & Haug LLP; and Wanli Wu of Cantor Colburn LLP. Thanks also to Leora Ben-Ami of Kirkland & Ellis LLP for agreeing to serve as NYIPLA Secretary this year. We all benefit greatly from the enthusiasm and dedication of these volunteers.

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for courts to determine when an inducer should be held liable for infringement of a medical method patent.

I. The Physician's Immunity Statute

Section 287(c) lays out a complicated framework for immunizing medical practitioners from patent infringement suits. To date, § 287(c) has not been successfully invoked as a defense.[9]

A. Legislative History

In 1996, Congress added § 287(c) to the patent statute through an appropriations rider.[10] The so-called "Physician's Immunity Statute" immunizes a medical practitioner or related health care entity from damages, injunctive relief, and attorney fees in a patent infringement suit for performance of a medical activity on a body. 35 U.S.C. § 287 is entitled, "Limitation on damages and other remedies; marking and notice." The main part of the Physician's Immunity Statute, 35 U.S.C. § 287(c)(1),[11] states:

> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

The Physician's Immunity Statute was enacted at the behest of the American Medical Association (AMA) and various other advocacy groups in response to several concerns, including the perceived threat that medical method patents would have on open discourse in the medical field.[12] Although the USPTO had been granting medical method patents for several years, the first lawsuit against a doctor for infringing a medical method patent in 1994 spurred the AMA's legislative efforts to amend the Patent Act.[13]

The case, *Pallin v. Singer*, involved both direct and induced infringement claims by one ophthalmologist, Dr. Pallin, against another competing ophthalmologist, Dr. Singer. Dr. Pallin held a patent on a method of performing a sutureless cataract surgery.[14] Dr. Singer both performed the surgery, constituting direct infringement, and taught other ocular surgeons the surgery technique, constituting induced infringement.[15] Even though the case was later dismissed by a consent order invalidating the claims and enjoining Dr. Pallin from enforcing his patent, [16] the potential liability of doctors and other medical professionals led Congress to begin investigating ways to stop medical method suits.

The AMA, joined by several other medical associations, first attempted to pass legislation that would have prevented the USPTO from issuing medical method patents by placing medical methods outside the reach of § 101.[17] These groups argued that medical method patents harm the health care system in several ways. First, the AMA argued that patents would restrict peer review of medical procedures and the sharing of information for fear of infringement lawsuits. Second, the costs of licensing, litigation, and searching patents would restrict patient access to the best care. Third, the AMA worried that allowing litigation over medical methods would breach patient confidentiality. Finally, the AMA contended that medical method patents were not a necessary incentive for doctors and other health care researchers to create new methods of treatment.[18] This approach was strongly opposed by the biotechnology and pharmaceutical industry. These groups worried that the AMA's proposal to amend § 101 would prevent them from obtaining patent protection and securing funding for their research.[19]

In response to these competing concerns, Senator Bill Frist (R-TN), a doctor, proposed an amendment to § 271 that would have stated that it was not an act of infringement to use or induce certain people to perform patented medical methods.[20] This bill was criticized for severely limiting the exclusionary powers of a patent.[21] Furthermore, the Frist amendment was accused of discriminating both on the basis of the technology of the patent and the identity of the infringer.[22]

These two early approaches of excluding medical methods from issuance or infringement were quickly abandoned. In their place, H.R. 3610 proposed to immunize some infringements of medical method patents. H.R. 3610 was sent to the Senate as a conference agreement, meaning that it could not be amended and was only subject to an up or down vote.[23] The bill did not pass through the judiciary committee nor was any hearing held on its exact terms, despite including language that was not present in any previous bill. Nevertheless, the bill was passed by the Senate by a vote of 84-15 and was signed by the President later that evening.[24]

According to a letter written by Senator Orrin Hatch (R-UT), there were too many unresolved issues to "sweep" the legislation into an end-of-the-session omnibus appropriations bill.[25] In particular, Senator Hatch objected to the amendment on procedural grounds because the proposal was never the subject of hearings or amendments in either the House or Senate. Senator Hatch also objected to the legislation because of its potential to set undesirable precedent for United States trade policy.[26]

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Inducement liability is just one of many questions left open by the text of the bill and its legislative history. None of the legislative history of § 287(c) or its prior bills addresses the question of whether immunity should extend to an inducer.

B. Policy Behind the Statute

The AMA's original opposition to the issuance of medical method patents, and later its support for the Physician's Immunity Statute, is based on its concerns regarding the effects that medical method patents might have on the medical profession. Several of these concerns about a medical practitioner's direct liability also apply to the liability of an inducer.

1. Free and Open Disclosure in the Medical Profession

The Hippocratic Oath requires doctors to share information.[27] The AMA Code of Medical Ethics also requires sharing of medical knowledge and public disclosure of a physician's knowledge and research.[28] By immunizing both direct and induced infringement on the part of the medical practitioner and the related health care entity, the Physician's Immunity Statute allows medical practitioners to share information freely without fear of liability.[29] However, non-licensed researchers do not fall within the protection of § 287(c).[30]

2. Access to New Advances in Health Care for Patients

An important driving force behind § 287(c) is the fear that patients will not be able to have adequate access to new developments in medical technology without immunizing those who develop or disseminate information regarding new treatments.[31] Because simply providing instructions or advertising a method of use is considered conduct constituting "active inducement,"[32] the potential liability for insurers, instructors, textbook authors, and authors of scholarly papers would sharply limit the spread of information.

Additionally, it can be very difficult to determine whether something is patented, or if claimed in a patent, whether the patent is valid and enforceable. The difficulty of determining what is patented can lead to over-deterrence, and therefore discussion of procedures that are in fact in the public domain would also be chilled through inducement liability.[33]

3. Costs to Health Care

Today, health care costs are a source of frequent public ire.[34] If inducers were held liable for patent infringement, health care costs could go up in a number of ways. Insurance against inducement liability, acquiring licenses for patented technologies, and even reliance on older, more expensive technology would all increase the costs of patient care.[35] Presumably these costs would be passed onto patients.

4. Peer Review of Medical Procedures

Under the prospect theory of patents[36] we assume that the inventor should have control of the invention and its future development. In medical practice, however, a group-development model of medical care dominates, which emphasizes peer-reviewed procedures. The importance of peer-review and discussion to the group-development model has led to concerns over the possibility of patent law having a chilling effect on discourse. This was one of the primary motivators behind enacting the Physician's Immunity Statute.[37]

5. Patient Confidentiality

The AMA was also concerned that infringement suits would force doctors to breach patient confidentiality.[38] In order to be held liable for either induced or direct infringement, the patentee must prove that actual infringement took place. This would require a patentee to prove that the method was performed by the medical practitioner or that a patient infringed the method.[39] Thus, the AMA worried that the patentee could force the doctor to disclose confidential information during the discovery phase of an infringement suit. The concern really only supports a non-infringement statute, rather than an immunized infringement statute, since to invoke § 287(c) in the first place the medical practitioner's activity must "constitute an infringement."[40]

II. The Statutory Framework of § 287(c)

Section 287(c) lays out a multipart framework for determining if a medical practitioner is immune from liability. In order to qualify for immunity,[41] the infringement must be: (1) a "medical practitioner's"[42] performance of a (2) "medical activity"[43] (3) on a "body."[44] Then, the various liability provisions[45] of the Patent Act will not apply against the medical practitioner or a "related health care entity."[46]

A. Immunity from infringing . . .

As a preliminary matter, § 287(c) must be interpreted as creating an exception to liability, rather than an exception to infringing behavior. If practicing a medical method patent is not an infringement, then no one can be liable for inducement, since inducement requires an actual, direct infringement. If the statute is creating only an immunity, then inducement could still occur despite a lack of liability attaching to the direct infringer. This question can be answered

by looking at both the express terms of the statute and the legislative history of § 287(c). Both support the view that the statute creates an immunity to infringement liability.

First, the language of the statute states that the performance of a medical activity "constitutes an infringement," either a direct infringement or an induced infringement, and then states that the remedies provisions of the Patent Act will not apply against the medical practitioner.[47] Additionally, § 287 is titled "Limitation on damages and other remedies." On a plain meaning basis, this supports the view that the statute recognizes a statutory infringement, but then immunizes it from legal remedies.

Second, § 271(e)(1), also known as the clinical trial exemption, creates a statutory exception from infringement, stating that "it shall not be an act of infringement" to conduct research related to the development and submission of information to the FDA. This shows that Congress knew what to say if it wanted to create an exception to infringement, rather than just an immunized infringement. By choosing not to use that same language in § 287(c), § 271(e)(1) should be understood as giving a different meaning.

Finally, the legislative history of § 287(c) indicates that Congress intended an immunized infringement rather than no infringement. A prior version of § 287(c) would have created an express exception to infringement under § 271. In Senate Bill 1334, Senator Frist proposed adding a new subsection (j) to § 271 which would have stated:

> [I]t shall not be an act of infringement for a patient, physician, or other licensed health care practitioner, or a health care entity with which a physician or licensed health care practitioner is professionally affiliated, to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. . . .[48]

A number of concerns emerged about S. 1334. Seizing upon the lack of litigation among medical practitioners of patented procedures, opponents took issue with exempting a specific class of inventions and a specific profession from the patent statutes.[49] They argued that this would set a dangerous precedent under the patent laws and that it was inconsistent with the purposes of the patent system.[50]

This change in position from earlier versions of the bill indicates that § 287(c) must be interpreted as recognizing a statutory infringement, but then providing an immunity defense to the medical practitioner, or related health care entity, who infringes or induces others to infringe.

B. For a medical practitioner . . .

The first requirement for immunity under § 287(c)(1) is that a medical practitioner must carry out the infringement. Section 287(c)(2)(B) defines a "medical practitioner" as "any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity." This means that non-licensed researchers will not be immunized under § 287(c)(1). It does, however, immunize someone working under the control of a state-licensed medical practitioner.

C. Performing a medical activity . . .

The second requirement under § 287(c)(1) is for the infringing activity to be a "medical activity." Section 287(c)(2)(A) defines a "medical activity" as "the performance of a medical or surgical procedure on a body" but with three exemptions in the definition. First, it exempts patents that utilize a patented machine, manufacture, or composition of matter in performing the method. Second, it exempts patented methods of using compositions of matter (*e.g.*, pharmaceuticals), whether the drug is patented or not. Finally, it categorically exempts all processes that violate biotechnology patents from immunity.

These exemptions indicate that Congress limited the scope of the statute in response to pressures from the biotechnology, pharmaceutical, and medical device industries. By including the three specific exemptions in § 287(c)(2)(A), Congress has attempted to limit the scope of the immunity to only "pure" method claims. However, the exemptions still leave open several loopholes that could affect the patent rights of many commercialized technologies. In deciding if the immunity of the infringer should extend to the inducer, a court will have to ask if Congress intended for these exemptions to occupy the field or instead if the general purposes of the statute should prevail.

Sections 287(c)(2)(A)(i) and (ii) limit the applicability of § 287(c) to "pure" method patents – those that do not involve a *patented* machine, manufacture, or composition of matter, or patented use of *any* composition of matter.[51] This is supposed to prevent a physician from claiming immunity for using a patented medical device (*e.g.*, implanting a patented stent using a patented method). However, it is unclear if the statute applies where the device is patented but the device claims are later held invalid or unenforceable.[52]

Finally, § 287(c)(2)(A)(iii) broadly exempts all biotechnology patents from the immunity protection of the statute: clearly an intended result of biotechnology and genetics industry lobbying. Although the term "biotechnol-

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ogy patent" is not defined in the statute, the corresponding Conference Report states that it "includes a patent on a 'biotechnological process' as defined in 35 U.S.C. § 103(b), as well as a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level."[53]

D. On a body . . .

Third, in order to be immune under § 287(c)(2)(A), the medical activity must take place "on a body." Section 287(c)(2)(E) defines "body" as "a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans." This is potentially a huge loophole depending on how broadly this term is construed by the courts. Nonhuman animals used in research include patented animals such as transgenic mice.[54] Research is also performed on excised human tissues, animal tissues, human cells lines, and animal cell lines, etc. If § 287(c) is seen as immunizing research on tissue and cell lines, the statute will have a much broader scope than Congress originally contemplated.

E. And related health care entities . . .

Section 287(c)(1) immunizes both medical practitioners and related health care entities from infringement liability. Congress's rationale for immunizing related health care entities is illustrated by the facts of the *Pallin v. Singer* litigation.

Dr. Pallin sued both Dr. Singer and the clinic he was affiliated with for performing the patented sutureless cataract surgery.[55] Immunizing only Dr. Singer, and not the associated clinic, would not have stopped the *Pallin* suit. In fact, the clinic may have been a more desirable target because of its deeper pockets. The AMA feared that clinics would stop their employees from performing infringing methods in order to avoid infringement liability.[56] Immunizing the "related health care entity" was seen as necessary to effectuate the policy of the statute.

Congress's choice to expressly immunize a party aside from the medical practitioner strongly suggests that it did not intend to immunize any more parties.[57] Congress provided broad definitions of both "medical practitioners"[58] and "related health care entities."[59] It would be incongruous with the terms of the statute to extend immunity to inducers outside of those two groups.

F. But Not for Commercial Developers?

Section 287(c)(3) includes a broad exception from immunity where the infringing activities are directly related to "the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office)." Because there is no legislative history accompanying this provision, in § 287(c) as adopted or in any prior version, it is unclear what Congress intended with this provision.

One interpretation is that § 287(c)(3) is meant to direct the reader to look to § 271(e). Section 271(e), the clinical trials exemption, states that it is "not . . . an act of infringement" to conduct infringing research for the purpose of submitting information to the FDA.[60] This is a likely interpretation of § 287(c)(3) because it specifically calls out FDA-regulated activities and the "commercial development" of new technologies.

However, under a broader interpretation, § 287(c)(3) could potentially strongly limit the applicability of the immunity provision. For example, if a surgeon practices an infringing method for the purpose of improving the method and developing a device for performing the improved method, would he be liable? His performance of the patented method is "directly related" to the commercial development of a new device, but he is also involved in an effort to improve existing medical techniques and patient care. This interpretation of the statute could conflict with the goals of the statute – to protect the peer-review system of medical treatment.[61]

III. The Scope of the Inducement Problem

A. Introduction to Inducement Liability

Section 271(b) was codified in the 1952 Patent Act in order to provide an effective remedy against infringement in the case in which it is impractical or infeasible to sue the direct infringer.[62] Section 271(b) entitles the patent holder to the same relief against the inducer as against the direct infringer – the possibility of damages (including willful damages), an injunction, and attorney fees.[63] The objective of inducement liability is to give patent holders effective protection in circumstances in which the direct infringer either is not the truly culpable party or is impractical to sue. Inducement liability requires findings about the accused inducer's knowledge and intent, and some conduct which "actively induces" the infringement of a third party.[64]

The knowledge and intent requirements for inducement were recently clarified by the Supreme Court in *Global-Tech Appliances, Inc. v. SEB S.A.*[65] *Global-Tech*

holds that induced infringement under § 271(b) "requires knowledge that the induced acts constitute patent infringement."[66] Knowledge may be established through the willful blindness doctrine, but "deliberate indifference to a known risk" is insufficient.[67] Because of the knowledge and intent requirements, inducement liability is a poor vehicle to rely on for effective patent protection. However, in many cases, inducement liability is the only available avenue for effectively protecting a patent.

1. What Counts as Inducing Conduct

Section 271(b) requires "active inducement" of direct infringement. The conduct which can be relied upon to find active inducement has the potential to be very broad.[68] While the action which is inducing must be intentional, it may be "as broad as the range of actions by which one in fact causes, or urges, or encourages, or aids another to infringe a patent."[69]

Because the lower courts have found that extremely low levels of conduct may constitute active inducement (when coupled with the requisite intent and knowledge), medical device suppliers, insurers, medical instructors, and even authors of medical papers could be liable for induced infringement.

a. Providing Instructions

Provision of instructions for how to perform a medical method is extremely common. This could be found in product inserts, product demonstrations, advertisements, or even in non-commercial forms like health care training, demonstrations at conventions, medical journals, or textbooks.

In other contexts involving non-medical technologies, defendants were liable for inducing infringement based on their providing instructions to others on how to undertake a patented process or implement a patented design. Instructions included with a product have also been found sufficient to induce infringement. In *Corning Inc. v. SRU Biosystems*, the manufacturer of an infringing product was also found to have induced infringement of method claims by customers who used the product in accordance with the manufacturer's instructions.[70] In *Tristrata Technology, Inc. v. Mary Kay, Inc.*, advertisements and product inserts were found to have induced customers to practice the patented method using an unpatented product.[71]

In *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, the Federal Circuit upheld a finding of inducement liability against a party that advertised and sold a rotary saw for cutting concrete.[72] The saw, capable of multiple uses, was advertised for use in a manner that infringed the plaintiff's patent claims for a method of cutting concrete. Because at least one possible mode of use recommended and instructed by defendant's advertisements infringed on plaintiff's method claims, the defendant was found to have intentionally induced its customers' infringement.

In the medical device case of *C.R. Bard, Inc. v. U.S. Surgical Corp.*, the defendant-manufacturer was found to have induced infringement of the plaintiff's method claim although the accused product did not infringe the plaintiff's device claims.[73] The case involved a surgical hernia plug manufactured by the defendant that could be trimmed to fit the patient. Pursuant to manufacturer's instructions for reducing the plug's bulk, surgeons trimmed the "petals" of the plug during surgery. This practice supported the finding that surgeons were directly infringing the plaintiff's method claim, which called for "detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis." The court held that the manufacturer actively induced such infringement based on the manufacturer's instructions provided with the product.[74]

The Federal Circuit has also upheld inducement where the defendant published medical articles that encouraged the performance of an infringing method. In *Metabolite Labs., Inc. v. Laboratory Corp. of America Holdings*, the defendant published medical articles targeting doctors, specifically suggesting in the articles the infringing use of a patented assay to identify a vitamin deficiency.[75] The court found that

> LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements. LabCorp's articles thus promote total homocysteine assays for detecting cobalamin/folate deficiency.[76]

These cases demonstrate that the potential inducement liability for medical method patents is extremely broad, and potentially affects a number of different actors.

b. Unassembled Kits

The provider of an unassembled kit, where the kit creates an infringing device when assembled, may be liable for inducing the purchaser to create the infringing device. In a case involving a fireplace kit claimed as a device, the Federal Circuit found a manufacturer liable for induced infringement through selling a kit which included instructions for assembling the fireplace burner in an infringing combination.[77]

Even infringement of method claims may be induced through the kit or assembly theory.[78] In *nCube Corp. v.*

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Seachange Int'l, Inc., the Federal Circuit found that the defendant induced infringement of a patent for a method of providing multimedia data in networked system. The defendant sold systems without a relevant component to customers whose networks already contained their own version of relevant component. By combining the defendant's systems with pre-existing customer systems, the new, combined system infringed the patent.

Sometimes method claims are a "method of providing" a device that includes the limitations of the device and requires providing those components according to the claim limitations "for use" in a medical procedure.[79] For example, claim 11 of an external insulin pump technology patent claims:

> A method of making a delivery device for delivering an infusion medium to a user, the method comprising: providing a first housing portion . . . providing a second housing portion. . .arranging a plunger within the interior of the reservoir and moveable along an axial direction of the reservoir; supporting a slide member on the second housing portion . . . .[80]

Such claims could provide the basis for direct infringement by a medical provider who assembles the device and then uses it in the medical context. If the assembled device is not patented, then the surgeon will be immune from suit.[81] However, the manufacturer of the kit could be liable for inducement.

Overall, the potential for inducement liability on the part of manufacturers or even instructors of medical practitioners is enormous. If merely describing a patented method in a manner that encourages others to perform it constitutes conduct of "active inducement" then liability for medical method patents could be widespread.

B. Medical Methods Require Protection Against Induced Infringement

The traditional justification for the patent system is that it encourages inventors to disclose their inventions to the public in exchange for a limited monopoly.

> From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.[82]

This justification is no less true in the case of medical procedure patents. Even though "historically, surgical procedures [were] not patented," there are incentives for patenting procedures to attract investment and capital in research and development.[83] The earliest medical method patent is believed to be a patent on the method of using ether as a surgical anesthetic, granted by the USPTO in 1846.[84] By the 1960s, the USPTO routinely issued medical method patents.[85] Today there are venture-funded companies that are protected solely by medical method patents.[86] Even the AMA agrees that there is some medical technology that would not be available today without the patent incentive.[87]

Many medical method patents can be effectively protected only through inducement liability. For example, a patient may be the direct infringer of a method patent when he takes a drug to treat a specific condition.[88]

An example of this is the patent on using Rogaine to treat hair loss.[89] Rogaine the compound (Minoxidil) was already well known at the time of the patent so the compound could not be patented. Thus, the only effective protection over the discovery that Rogaine can be used to treat hair loss is a method patent. However, the patient would be the direct infringer of such a patent. To sue the patient would be both impractical (the patient may be judgment proof, difficult to find, and effective protection of the method patent would require numerous individual suits), and the patient is not the truly culpable party.

In other situations, the direct infringer of a medical method is a doctor. For example, the Acclarent patents would be infringed by a doctor performing the steps of the method using a non-patented balloon catheter and introducer assembly.[90] Suing the doctor generally presents the same difficulties as suing the patient.

In both of these situations, § 271(b) gives the patentee the only effective protection of the patented technology.

C. Possible Medical Methods Inducers

Given the broad scope of activity that has been considered inducing conduct, many activities related to medical method patents could give rise to inducement liability. Not only are many activities potentially inducing, but also many different actors.

1. Patients

A patient could be an inducer of infringement of a medical method patent. For example, a patent claiming a method of treating back pain by performing various chiropractic maneuvers on a patient's body[91] would be a "medical activity" within the terms of § 287(c). The patient, by requesting the treatment, would induce the doctor, who is the direct infringer. This could lead to an anomalous situation in which a patient who is a state-licensed medical practitioner would be immune from suit, but a "lay" patient would not be! Of course, the owner of the method patent would still have to overcome the difficulties of finding and suing individual patients to enforce the patent.

2. Insurers

Insurance companies could also induce infringement of a medical method patent. An insurance company may choose to only reimburse doctors for using a new, patented method of treatment because it is cheaper or more reliable than prior art methods. The doctor would be immune under § 287(c), but the immunity of the inducer would depend on whether or not they can qualify as a "related health care entity" under § 287(c)(2)(C). Health maintenance organizations (HMOs) are considered related health care entities, as are entities with which a doctor has a "professional affiliation."

It would be wholly counter to Congress's intentions if the immunity of an insurance company depended on the terms of its contractual relationships with its doctors. A group like Kaiser Permanente, which operates its own hospitals and labs, may be totally immune because it could readily qualify as a "related health care entity." Small insurance groups on the other hand may not, and thus could be sued for inducing infringement.

3. Device Manufacturers

Device manufacturers who provide the tools or instructions for infringement could be liable for inducing the infringing activities of doctors. As described above, merely providing instructions is considered inducing conduct.

4. Medical Articles – Authors and Publishers

Another category of potential inducers is authors and publishers of medical articles or medical training and teaching materials.[92] There is no doubt that an author who publishes a description of an improved medical technique would be shocked to find himself a defendant in a patent infringement suit for inducing infringement by doctors. This situation also leads to discriminatory results based on the licensing status of the author – a medically licensed author would be a "medical practitioner" under § 287(c)(2)(B) and therefore immune, while a non-licensed person could not avail himself of the immunity of § 287(c)(1).

IV. Resolving the Conflict Between the Statutory Language of § 287(c) With the Policy Considerations of § 287(c) and § 271(b)

The careful balance drawn by Congress in § 287(c) between the competing interests of the medical community and the device, biotech, and pharmaceutical industries is threatened by inducement liability. The question of inducement liability sets up a conflict between the major policies behind § 287(c) and with both the plain meaning of § 287(c) and traditional justifications of the patent system.

If § 287(c) is interpreted to take away inducement liability, a much broader range of conduct will be immunized than was originally contemplated in the bargain. On the other hand, to hold inducers immune would leave some technologies totally unprotected by the patent system, despite reliance on intellectual property protection for their development and financing.

This approach is consistent with earlier Supreme Court treatment of medical patent statutes. In *Eli Lilly & Co. v. Medtronic, Inc.* the Supreme Court extended § 271(e), the clinical trials exemption, to cover medical devices, not just pharmaceuticals.[93] Eli Lilly sued to enjoin Medtronic from testing and marketing of a pacemaker. Medtronic's defense rested on a broad interpretation of § 271(e)(1), which authorizes the manufacture, use, or sale of a patented article "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." The District Court of the Eastern District of Pennsylvania concluded that § 271(e)(1) does not apply to medical devices and, after a jury trial, entered judgment on verdicts for Eli Lilly. The decision was reversed by the Federal Circuit.[94]

In an opinion authored by Justice Scalia, the Supreme Court affirmed the reversal, holding that the phrase "a Federal law which regulates the manufacture, use, or sale of drugs," is ambiguous and should be read as applying to medical devices as well as drugs.[95] The court explained that the purpose of the act was to rectify two problems with limited patent terms for technology that requires extensive pre-market approval: first, the patentee loses time at the beginning of his patent while waiting for market approval; second, the public loses time at the end of the patent while waiting for a competitor to obtain market approval. Because this problem applies equally to drugs and devices, the clinical trials exception was read as applying to both drugs and devices.[96]

The Court's willingness to effectuate Congressional policy and rectify common-sense problems with the regulation of medical technology suggests that the policy of § 287(c) could be realized through a functional analysis of inducement liability rooted in the text of § 287(c).

A court will of course begin with the express terms of the statute. Section 287(c) addresses some inducement liability situations. However, other significant situations are not addressed by the statute. Because a categorical rule of immunity or no immunity in those cases would undermine the balance created by § 287(c), courts will need to determine on a case-by-case basis if the inducer is entitled to immunity. To determine if infringement

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extends to an inducer, courts should consider two things: the intent of the inducer and the primary activities of the inducing party.

A. Parties Who are Immune Under the Express Terms of § 287(c)

Section 287(c)(1) states that the activities of medical practitioners and related health care entities are immune from suits based on either direct infringement *or* induced infringement.[97] This addresses the easy cases, such as *Pallin v. Singer*, where the patentee sues both the directly infringing doctor and the inducing clinic that offers the patented procedures. Additionally, this immunizes doctors and hospitals in suits where the patient is the direct infringer and the medical practitioner and/or related health care entity is the inducer.[98]

B. Parties Who are Not Immune Under the Express Terms of § 287(c)

There are three situations where a party would not be immune from inducement liability because § 287(c)(1) itself does not apply to the medical practitioner or related health care entity. If the medical practitioner or related health care entity is not immune, then there is no basis for holding the inducer immune. These exceptions will allow for inducement liability in a substantial number of situations.

First, Section 287(c)(3) states that the protections of § 287(c)(1) do not apply to the activities of individuals which are "directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office)" and are "regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act."[99]

While the scope of subsection (3) is unclear, it at least allows for liability against companies who are developing new medical products that will require FDA approval. In those cases, § 271(e) will determine whether they are infringing and if another party may be liable inducing their activities.[100]

Second, § 287(c) does not apply to "any patent issued based on an application the earliest effective filing date of which is prior to September 30, 1996."[101] Because of this exception, some older cases may have turned out differently had § 287(c) applied. For example, in *C.R. Bard v. U.S. Surgical*, U.S. Surgical was held liable for inducing infringement of a method claim, although it did not infringe the patent's device claim. The patent was issued on an application filed in 1993, so § 287(c) did not apply.[102]

Third, § 287(c)(1) does not apply if one of the three exceptions to the definition of "medical activity" is invoked. That is, if the medical method involves the use of a patented machine, manufacture, or composition of matter; or a patented method of using any composition of matter, whether patented or not; or a biotechnology patent. This makes § 287(c) inapplicable to virtually all methods of using a drug (whether the drug is patented or not).

C. Parties Who are Not Addressed by the Express Terms of the Statute

In some cases, the express terms of the statute do not dictate whether immunity will extend to an inducer. In those situations the court should look to two considerations to determine if immunity will extend to the inducer. These considerations are an attempt to effectuate the core policies of the statute – to protect the free exchange of ideas amongst medical practitioners and allow for peer review and improvement of medical techniques. The inquiries also attempt to curb immunity to avoid an end-run around medical method patents by enterprising copycats. Finally, this inquiry will not be a great additional burden on the court because the intent and conduct of the inducer must be examined to determine if the requirements for inducement liability under § 271(b) itself are met.

1. Intent of the Inducer

The court should first consider the intent of the inducer. The main goal of this inquiry is to determine if the inducement occurred for educational or research reasons, or if the inducement was intended to produce commercial gains. While this flavor of intent inquiry is not traditionally an element of inducement liability, a court could look to the inducer's intent – based on an interpretation of the language in § 287(c)(3) – to decline to immunize conduct that is directly related to commercial development.

In some cases this intent test will be determinative. For example, where the inducer is selling a non-patented or non-infringing device with instructions to perform a patented method, the inducer will not be immune. Thus cases like *C.R. Bard v. U.S. Surgical Corp.* will come out the same way.

Where the inducer is merely an academic author without a financial stake in the inducement, the inducer should be immune. This would protect non-physician researchers, who are not medical practitioners under the statute, from liability for researching and improving medical techniques. It would also protect non-state-licensed instructors who teach infringing methods from inducement liability. This inquiry helps preserve the free flow of information and

peer review that is necessary in the medical profession for self-regulation and improved patient care.

However, this may still be a difficult analysis for the court. For example, in *Metabolite Labs*, the trial court found induced infringement on the basis of published articles in medical journals. The Metabolite patent was filed prior to the effective date of § 287(c) so immunity was not at issue in the case. In a case like that, where the inducer is publishing educational articles, but with the intention of driving business to itself, the court would have to continue on to the second inquiry and look at the other activities of the inducer to determine if immunity should be extended.

2. Primary Activities of the Inducer

If the court cannot resolve the intent question either way, the court may next look to the other activities of the inducer. If the inducer is not primarily involved in commercialization of medical technologies, but is instead primarily involved in treatment, education or research activities, the inducer should not be held liable. On the other hand, if the inducer is primarily engaged in the commercialization of medical technologies they should be held liable for inducing infringement. This inquiry is again based on the legislative intent of the statute embodied in § 287(c)(3) and in Congressional debates over precursor bills to § 287(c).

The major themes of the debate over § 287(c) were the protection of medical sharing norms versus the necessity of effective patent protection for funding development of medical products. By inquiring into the primary activities of the inducer and the inducer's intent, the courts should be able to weed out cases in which the activities of the inducer are meant to circumvent the patent bargain of public disclosure in exchange for the right to exclude.

Courts would implement this test by looking at the inducer's activities as a whole. For example, in *Metabolite Labs* inducement liability would still attach because LabCorp is a company that profits from the commercialization of medical technologies.

This two-step analysis best reflects the goal of Congress as embodied in § 287(c) – to protect the development of medical knowledge amongst practitioners without destroying the patent bargain of the inventor. Although the express terms of the statute represent only interest groups who secured exemptions to "medical activities," courts should not allow either inducers or patentees to circumvent the intended scope of § 287(c) by creating a rigid yea or nay rule in all cases of inducement.

V. Conclusion

The interaction of the Physician's Immunity Statute and inducement liability presents many complex questions that the courts will have to answer soon enough. Given the breadth of conduct that can give rise to inducement liability, it is only a matter of time before courts confront this issue. There is no clear answer to the question of extending the direct infringer's immunity to the inducer from either the text of the statute or the conflicting policies of § 287(c) and § 271(b). Instead, the court would have to rely on the legislative decisions behind § 287(c) and § 271(b) and try to balance two competing interests – the medical community's desire for open discourse over medical methods, and the patent owners ability to effectively enforce their monopoly rights.

(Endnotes)

[1] Ms. Moulton is currently a Law Clerk to the Hon. Raymond C. Clevenger, United States Court of Appeals for the Federal Circuit, for 2012-2013. She received a JD from Columbia Law School in 2012, an MS from The George Washington University in 2009, and a BAS in Biomedical Engineering from the University of Pennsylvania in 2006. This article first appeared in Vol. 13 of the *Columbia Science and Technology Law Review*, pp. 206-233 (Feb. 15, 2012), http://www.stlr.org/cite.cgi?volume=13&article=5.

[2] 142 Cong. Rec. 26,642 (1996) (letter from Sen. Orrin G. Hatch to U.S. Patent and Trademark Office Comm'r Bruce Lehman) (internal quotes omitted).

[3] *See, e.g.*, U.S. Patent No. 7,912,554 (filed Apr. 29, 2005) ("Method for treatment of aneurysms"); U.S. Patent No. 7,285,124 (filed Dec. 31, 2003) ("Single-tailed suturing method"); U.S. Patent No. 6,231,496 (filed Jul. 7, 1999) ("Medical treatment method") (claiming a method of human sterilization); U.S. Patent No. 6,383,172 (filed Apr. 2, 1999) ("Retrograde venous perfusion with isolation of cerebral circulation"); U.S. Patent No. 6,209,545 (filed Mar. 22, 1999) ("Method of recovering peripheral nerves functionality").

[4] *See Ex parte Scherer,* 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954) (ruling that medical methods cannot be held to be unpatentable subject matter, or be subject to a higher patentability standard, merely because they involve treating the human body).

[5] *See* Julie A. Burger and Justin Brunner, *A Court's Dilemma: When Patents Conflict with Public Health*, 12 Va. J. L. & Tech. 7, 32 (2007); *see also* Jasemine Chambers, *Patent Eligibility of Biotechnological Invention in the United States, Europe, and Japan: How much patent policy is public policy?*, 34 Geo. Wash. Int'l L. Rev. 223, 226-40 (2002) (surveying the U.S., European, and Japanese policy approaches to the patent eligibility of medical methods).

[6] *See, e.g., Ass'n for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, 702 F. Supp. 2d 181, 232-37 (S.D.N.Y. 2010) (ruling gene analysis method and cancer therapeutic screening method claims unpatentable subject matter), *aff'd in part & rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011) (overruling invalidation of screening method claim), *vacated by* 132

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S. Ct. 1794 (2012), *aff'd in part & rev'd in part*, 689 F.3d 1303 (Fed. Cir. Aug. 16, 2012); *Prometheus Labs. Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012); *Metabolite Labs., Inc. v. Lab. Corp. of America Holdings,* 370 F.3d 1354 (Fed. Cir. 2004), *cert. dismissed*, 548 U.S. 124 (2006).

[7] *Pallin v. Singer,* 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995) (first infringement case brought against a physician for infringing a medical method patent).

[8] *See* Leisa T. Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(c)*, 16 Tex. Intell. Prop. L.J. 299, 307 (2008).

[9] As of this writing, only one case, *Emtel, Inc. v. Lipid Labs, Inc.*, 583 F. Supp. 2d 811 (S.D. Tex. 2008), has invoked § 287(c) as a possible defense. The patent was held not infringed, so no inquiry was made into the requirements for a § 287(c) defense.

[10] Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 (1996) (codified as 35 U.S.C. § 287(c) (1999)).

[11] Subsection (c)(2) includes definitions of several terms.

[12] *See* Jeff S. Rundle, *The Physician's Immunity Statute: A Botched Operation or a Model Procedure?*, 34 J. Corp. L. 943, 945 (2009); Brett Alten, *Left to One's Devices: Congress Limits Patents on Medical Procedures*, 8 Fordham Intell. Prop. Media & Ent. L.J. 837, 862 (1998). *See generally* Eric M. Lee, *35 U.S.C. § 287(c) – The Physician Immunity Statute*, 79 J. Pat. & Trademark Off. Soc. 701, 710 (1997) (noting the arguments from the medical community in favor of § 287(c)); Fariba Sirjani & Dariush Keyhani, *35 U.S.C. § 287(c): Language Slightly Beyond Intent*, 3 Buff. Intell. Prop. L.J. 13, 25-26 (2005) (listing the lobbying groups supporting and opposing the language of § 287(c)).

[13] *Pallin v. Singer,* 36 U.S.P.Q.2d (BNA) 1050, 1050 (D. Vt. 1995).

[14] *See id.*; U.S. Patent No. 5,080,111 (filed June 28, 1990).

[15] *Pallin v. Singer*, 36 U.S.P.Q.2d at 1051.

[16] *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28, 1996).

[17] Am. Med. Ass'n, *Patenting of Medical Procedures, Reports of Council on Ethical and Judicial Affairs, House of Delegates Proceedings, 144th Annual Meeting* 200-06 (June 18-22, 1995) (hereinafter "AMA Proceedings"). *See also H.R. 1127, 104th Cong. (1995) ("LIMITATION ON ISSUANCE OF PATENTS. On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture or composition of matter may claim such technique, method, or process.").*

[18] *See* AMA Proceedings, *supra* note 17.

[19] *See, e.g., The Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the H. Judiciary Subcomm. on Courts and Intellectual Property, 104th Cong. 92 (1995) (statement of Frank Baldino, Jr., President and CEO, Cephalon, Inc.).*

[20] *See* Lee, *supra* note 12, at 706.

[21] *See* Alten, *supra* note 12, at 873.

[22] *See* Alten, *supra* note 12, at 871.

[23] *See* Alten, *supra* note 12, at 875; *see also* Appropriations Bill (H.R. 3610) Containing Patent Limitations on Medical Procedures, 52 Pat., Trademark & Copyright J. (BNA) 612 (October 3, 1996).

[24] *See* Alten, *supra* note 12, at 875.

[25] *See* 142 Cong. Rec. 26,642 (1996).

[26] *See, e.g.*, Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. Davis L. Rev. 601, 669 (2000) (suggesting that § 287(c) violates the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).).

[27] "I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow." Louis Lasagna, The Hippocratic Oath - Modern Version (1964), *available at http://ethics.ucsd.edu/journal/2006/readings/Hippocratic_Oath_Modern_Version.pdf.*

[28] American Medical Association, *Code of Medical Ethics of the American Medical Association,* § 9.08 (2008-2009 ed.).

[29] 35 U.S.C. § 287(c)(1).

[30] *Id.* § 287(c)(2)(B).

[31] *See* Lee, *supra* note 12, at 710; Rundle, *supra* note 12, at 945-46.

[32] *See infra* Part IV.A.1.

[33] *See generally* Stewart E. Sterk, *Property Rules, Liability Rules, and Uncertainty about Property Rights*, 106 Mich. L. Rev. 1285, 1331-1334 (2008) (noting that there is great uncertainty regarding the scope and existence of patent rights and that the cost of determining these rights can be prohibitively expensive).

[34] *See, e.g.*, Uwe E. Reinhardt, *Fees, Volume, and Spending at Medicare,* New York Times Economix (December 24, 2010, 6:00 AM), http://economix.blogs.nytimes.com/2010/12/24/fees-volume-and-spending-at-medicare/.

[35] *See generally* Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 Nw. J. Tech. & Intell. Prop. 280 (2010) (arguing that preventing the patenting of medical diagnostic and therapeutic methods may be a way of effectively reducing health care costs); Amy Lynn Sorrell, *Tinkering with Patents: Decisions Muddy the Waters on Legal Rights, Am. Med. News* (May 26, 2008), *http://www.ama-assn.org/amednews/2008/05/26/prsa0526.htm (arguing that enforcing sweeping medical process patents can increase health care costs and reduce health care quality).*

[36] *See generally* Mark A. Lemley, *Ex ante versus Ex Post Justifications for Intellectual Property*, 71 U. Chi. L. Rev. 129, 132-33 (2004) (citing Edmund Kitch's prospect theory of patents in *The Nature and Function of the Patent System,* 20 J. L. & Econ. 265 (1977)).

[37] *See* Lee, *supra* note 12 at 710.

[38] *Id.*

[39] *Id.* at 715.

[40] *Id.*

[41] *See* 35 U.S.C. § 287(c)(1).

[42] *Id.* § 287(c)(2)(B).

[43] *Id.* § 287(c)(2)(A).

[44] *Id.* § 287(c)(2)(E).

[45] 35 U.S.C. § 283 (injunction); 35 U.S.C. § 284 (damages); 35 U.S.C. § 285 (attorney fees).

[46] *Id.* § 287(c)(2)(C) ("[A]n entity . . . under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.").

[47] *Id.* § 287(c)(1).

[48] Medical Procedures Innovation and Affordability Act, S. 1334, 104th Cong. § 2 (1st Sess. 1995).

[49] Richard P. Burgoon, Jr., *Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c)*, 4 U. Balt. Intell. Prop. L.J. 69, 77 (1996).

[50] *See id.*

[51] This requires the court to engage in an initial inquiry into the subject matter of the method patent – such as another *Markman* hearing – to see if it is appropriate to allow a § 287(c) defense to go forward at trial.

[52] There is also no requirement that the device be patented in the United States or patented by the same or a related entity to the method patent.

[53] H.R. Rep. No. 104-863, at 854 (1996) (Conf. Rep.) (quoting 35 U.S.C. § 103(b)); Lee, *supra* note 12, at 720.

[54] *E.g.*, U.S. Patent No. 4,736,866 (filed June 22, 1984).

[55] *See Pallin v. Singer*, 36 U.S.P.Q.2d 1050, 1051 (D. Vt. 1995).

[56] *See* Lee, *supra* note 12, at 703.

[57] *Expressio unius est exclusio alterius*.

[58] 35 U.S.C. § 287(c)(2)(B) (defining a medical practitioner as "any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.").

[59] *Id*. § 287(c)(2)(C)-(D) (defining a related health care entity as "an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic," and defining a professional affiliation as "staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.").

[60] 35 U.S.C. § 271(e)(1).

[61] *See supra* Part II.B.

[62] *See* 35 U.S.C. § 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer.").

[63] 35 U.S.C. § 283 (injunction); 35 U.S.C. § 284 (damages); 35 U.S.C. § 285 (attorney fees).

[64] Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 228 (2005).

[65] *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

[66] *See id*. at 2068.

[67] *Id*.

[68] Lemley, *supra* note 64, at 229.

[69] *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 411 (5th Cir. 1963).

[70] *Corning Inc. v. SRU Biosystems*, 400 F. Supp. 2d 653, 665-66 (D. Del. 2005).

[71] *Tristrata Technology, Inc. v. Mary Kay, Inc.*, 423 F. Supp. 2d 456, 465-66 (D. Del. 2006).

[72] *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303, 1311-12 (Fed. Cir. 1998).

[73] *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 258 F. Supp. 2d 355, 361 (D. Del. 2003).

[74] *Id*.

[75] *Metabolite Labs., Inc. v. Lab. Corp. of America Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

[76] *Id*. Metabolite's patent was filed prior to the enactment of § 287(c), so the immunity could not apply. *See* U.S. Patent No. 4,940,658 (filed Nov. 20, 1986).

[77] *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1364-65 (Fed. Cir. 2006).

[78] *nCube Corp. v. Seachange Int'l, Inc.*, 436 F.3d 1317, 1325 (Fed. Cir. 2006).

[79] *See, e.g.*, U.S. Patent No. 7,736,344 (filed Nov. 22, 2006) (claim 11); U.S. Patent No. 7,678,078 (filed Oct. 21, 2008) (claim 20).

[80] U.S. Patent No. 7,736,344 (filed Nov. 22, 2006) ("Infusion Medium Delivery Device and Method with Drive Device for Driver Plunger in Reservoir").

[81] *See* 35 U.S.C. § 287(c)(2)(A) (although a medical practitioner is immune from suit for the "medical activity," that immunity does not apply to the use of a patented "machine, manufacture, or composition of matter.").

[82] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

[83] Ho, *supra* note 26, at 617.

[84] *See* U.S. Patent No. 4,848 (filed Oct. 27, 1846).

[85] *See Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954) (ruling that medical methods cannot be held to be unpatentable subject matter, or be subject to a higher patentability standard, merely because they involve treating the human body).

[86] *See, e.g., Patents: Commitment to Innovation*, Acclarent, http://www.acclarent.com/company/patents/ (last visited Dec. 8, 2011) (listing patents granted on a method of opening sinus passageways with an unpatented balloon catheter assembly).

[87] *See Am. Med. Ass'n, Council on Ethical and Judicial Affairs, Ethical Issues in the Patenting of Medical Procedures,* 53 Food & Drug L. J. 341, 348 (1998). The most commonly cited example of a procedure that may have gone undeveloped had patent protection not existed is the Surrogate Embryo Transfer (SET) procedure. The SET procedure cost over $500,000 to develop. After the NIH denied funding, a private venture capital group provided research funding for the project. The private venture group would have been unwilling to invest without the assurances against free-riding secured by a patent. *See* George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting,* 14 Hastings Cent. Rep. 25, 25-26 (1984).

[88] This example would not invoke § 287(c) because patented uses of compositions of matter are exempted from the definition of medical activities in § 287(c)(2)(A)(ii).

[89] U.S. Patent No. 4,596,812 (filed Aug. 28, 1980).

[90] *See, e.g.*, U.S. Patent No. 7,654,997 (filed Apr. 21, 2004) ("A method for enlarging an ostium of a paranasal sinus of a subject, said method comprising the steps of: placing in the subject's head a port device having a lumen through which a balloon catheter may be inserted; positioning a light emitting portion of a light emitting instrument within the paranasal sinus; emitting light from the light emitting portion of the light emitting instrument; observing the emitted light; advancing a balloon dilation catheter through the port device to a location within the ostium of paranasal sinus; and inflating a balloon of the balloon catheter to expand the ostium and modify bone that directly underlies mucosa of the ostium.").

[91] U.S. Patent No. 6,209,545 (filed Mar. 22, 1999) (claiming a method of manually massaging the nerves in the human body to restore function of the nerves. No device, other than the hands, is associated with the method).

[92] *See, e.g.*, *Metabolite Labs., Inc. v. Lab. Corp. of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004).

[93] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

[94] *Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033 (E.D. Pa. 1988), *rev'd*, 872 F.2d 402 (Fed. Cir. 1989).

[95] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. at 665-69.

[96] *Id*. at 675-78.

[97] 35 U.S.C. § 287(c)(1).

[98] However, subject to logistical constraints, the patients could be sued as direct infringers. *See* Part II.B, *supra*.

[99] 35 U.S.C. § 287(c)(3)(A)-(B), which read as follows:

> (3) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:
>
> > (A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and
> >
> > (B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

[100] *See* Carrie S. Martin, *Proving Inducement of Infringement of Method-of-use Patents in Hatch-Waxman Act Litigation: Are the Standards Realistic of the Pharmaceutical Industry?*, 32 AIPLA Q.J. 163 (2004).

[101] 35 U.S.C. § 287(c)(4).

[102] U.S. Patent No. 5,356,432 (filed Feb. 5, 1993). The patent in *Metabolite Labs* was also filed prior to the effective date of § 287(c).

Conversations with the New NYIPLA Board Members

In May 2012, three new members joined the NYIPLA Board of Directors: Wanli Wu from Cantor Colburn LLP, Denise Loring from Ropes & Gray LLP, and Richard Parke from Frommer Lawrence & Haug LLP. The *Bulletin* interviewed the new Board members to discuss their experiences with the NYIPLA.

Wanli Wu

BULLETIN: How long have you been a member of the NYIPLA?

WW: I have been involved for four to five years.

BULLETIN: Why did you first join the NYIPLA?

WW: I had the privilege to work with the senior partner of my old firm, Dale Carlson. He was a past president of the NYIPLA. He encouraged me to join.

BULLETIN: How has your NYIPLA membership benefited your law practice?

WW: My knowledge about IP law has grown by participating in the various committees.

BULLETIN: In which committees have you been involved during your membership?

WW: I have been a member of the Licensing Committee, the License to Practice Committee (also called the License to Practice Requirements Committee), and the Publications Committee, of which I was co-chair for the past two years.

BULLETIN: How did you end up on the Board?

WW: I was nominated by Dale Carlson.

BULLETIN: Why did you desire to be on the Board?

WW: I was hoping to make more of a contribution to the Association.

BULLETIN: Are you active in any other bar associations?

WW: I am a member of other associations, but not that active. I feel that the NYIPLA gives its members a better opportunity to participate. Sometimes the other bar associations feel like a closed loop.

BULLETIN: For those readers who may not know, what is the Board's role in the larger organization?

WW: The Board makes sure that the Association is financially in good shape, helps facilitate all kinds of activities that encourage the active participation of members, makes sure that it actively serves members, and makes contributions to IP law through IP amicus briefs.

BULLETIN: What is your role on the Board?

WW: I am the liaison to the Publications Committee. There is a Board member liaison for each committee.

BULLETIN: What are your goals for your time on the Board? What do you hope to accomplish?

WW: I am not exactly sure because I have not been on the Board for very long and I am still learning. But I want to do whatever I can to encourage the active participation of the members. I believe that is the key to the success of the organization.

BULLETIN: Over the longer term, what do you see as the future of the Association?

WW: The Association will have a powerful and valuable voice in matters related to patent law because the Association has a lot of excellent attorneys and practitioners. Also, I see the NYIPLA continuing to get its voice heard through amicus briefs and influencing the local patent rules in the EDNY and SDNY.

BULLETIN: Is there anything else you want to add?

WW: I just want to talk a little more about my experience with the NYIPLA. It has been fun to get involved and to learn a lot from people with different experiences and styles. It has been great getting networking opportunities and forming long-lasting friendships. The NYIPLA has given me a sense of accomplishment because I feel satisfied when I get things done such as getting the *Bulletin* published.

Denise Loring

BULLETIN: How long have you been a member of the NYIPLA?

DL: I became a member as a young associate, close to 30 years ago.

BULLETIN: Why did you first join?

DL: When I was a young associate, my firm, Fish and Neave, was very active in the NYIPLA and it encouraged all its lawyers to join and participate.

BULLETIN: How has your NYIPLA membership benefited your law practice?

DL: The Association is one of the most prestigious IP associations in the country, and the programs they have offered have been terrific. Also, the opportunity to interact with my colleagues in the Association has been a tremendous asset. In sum, the benefits have been the ability to associate with smart people and to be a part of a great association.

BULLETIN: In what committees have you been involved during your membership?

DL: My Board membership has been my first active role since joining the Association.

BULLETIN: How did you end up on the board?

DL: I got a call from Mark Abate and was invited to put my name in to be nominated.

BULLETIN: Why did you desire to be on the board?

DL: After being a member of the Association for so many years and not having the opportunity to participate, I thought it would be terrific at this stage of my career to give back to the Association.

BULLETIN: What is your role on the Board?

DL: I am the liaison to the Amicus Briefs Committee. It is a tremendous opportunity to help shape the law by participating in the drafting of amicus briefs.

BULLETIN: Are you active in any other bar associations?

DL: I am a member of the ABA and AIPLA, and I am very active in the Federal Circuit Bar Association where I participate in panel discussions at the Annual Bench and Bar Conference.

BULLETIN: How does involvement in the NYIPLA compare with your involvement in these other organizations?

DL: I am most active in the NYIPLA. I have often participated at the NYIPLA lunch conferences. I guess that's because it is closer to home and closer to what I do every day than some of the other bar associations.

BULLETIN: What are your goals for your time on the board?

DL: I have only been involved for a couple of months. But I want to help contribute to the Amicus Briefs Committee and contribute to the Association's stature and make it an organization young lawyers want to join. And going forward, I want to keep the Association doing the same good work it has been doing in the past.

BULLETIN: Over the longer term, what do you see as the future of the Association?

DL: Over the course of my career, IP has become more and more important to companies, businesses, and universities. As the value of IP increases, the value of IP lawyers increases, and the NYIPLA's value increases. Also, it is critical for young lawyers to join an organization like the NYIPLA so that they can stay involved in the legal community and because their involvement improves the organization and improves their career as lawyers.

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Richard Parke

BULLETIN: How long have you been a member of the NYIPLA?

RP: I have been a member since 1990.

BULLETIN: Why did you first join?

RP: I started my legal career at Morgan & Finnegan, which was a big supporter of the NYIPLA. In fact, my recollection is that all M&F attorneys were members and active in the Association.

BULLETIN: How has your NYIPLA membership benefited your law practice?

RP: Over the years I've attended a number of NYIPLA's CLE offerings – they are almost always on cutting-edge topics that I have found to be useful to my practice. The Association's high standing in the legal community has allowed it to attract outstanding speakers from the federal bench, the PTO, and the bar.

Also, the NYIPLA has wonderful social and networking events that allow members get to know their New York-based colleagues better, with the annual Judges Dinner being the best known of these types of functions.

BULLETIN: In which committees have you been involved during your membership?

RP: Before joining the Board, I served on the CLE Committee for three years.

BULLETIN: How did you end up on the Board?

RP: Through my work on the CLE Committee I came into contact with a number of Board members. Last year a representative asked me if I was interested in having my name put forward for election to the Board. I was honored to be considered, and said yes.

BULLETIN: Why did you desire to be on the Board?

RP: It seemed to be a natural outgrowth of my work as a co-chair of the CLE Committee, which is an incredibly active group. In fact, I am now the Board liaison to the CLE Committee, which allows me to be a conduit between the two entities. I generally take active roles in any organization I join, so being on the Board is an opportunity for me to help in managing the Association, which is one of the country's leading IP bar associations. In short, it's both a privilege and an honor to serve.

BULLETIN: Are you active in any other of the bar associations?

RP: I had been active in another IP-related bar association, but beginning with my work on the CLE Committee several years ago the NYIPLA has been my primary legal 'extracurricular activity' – there's definitely a lot going on that keeps one busy.

BULLETIN: What are your goals for your time on the Board?

RP: As I mentioned, I am the Board's liaison for the CLE Committee. My primary goals are to help strengthen our already robust CLE offerings and to increase our visibility and membership.

BULLETIN: Over the longer term, what do you see as the future of the Association?

RP: In my short time on the Board I've been impressed by the vision of my fellow members for the Association's future. We are continually looking for new ways to increase the importance and relevance of this organization to the IP bar. I think that this is critically important for younger lawyers, in particular. An essential focus of our efforts should be directed to showing them – and their firms – that NYIPLA membership is helpful to their development as attorneys, via our solid CLE, networking, and mentoring opportunities.

BULLETIN: Is there anything else you would like to add?

RP: Nothing more than to encourage everyone reading this to consider increasing their involvement in and support of this important organization and to not hesitate in sharing their ideas about what we can do better. Thank you.

Decision by U.S. Court of Appeals for the Federal Circuit in *Myriad* Remand Mirrors Reasoning in NYIPLA Amicus Brief

By Charles R. Macedo, Michael J. Kasdan, and David P. Goldberg, Amster, Rothstein & Ebenstein LLP[1]

On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") released its highly anticipated decision in *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Aug. 16, 2012) ("*Myriad IV*"), concerning the patent eligibility of isolated DNA under 35 U.S.C. § 101, on remand from the U.S. Supreme Court. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) ("*Myriad III*").

In *Myriad IV*, the Federal Circuit largely followed the rationale of its prior decision in the case. *Cf. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) ("*Myriad II*"). The *Myriad IV* majority decision reflects a reasoning similar to the positions set forth in the NYIPLA Amicus Brief filed in this case. *Compare* Brief for Amicus Curiae N.Y. Intellectual Property Law Ass'n in Support of Neither Party, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. June 15, 2012), *available at* http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/Myriad%20_2010_1406.pdf ("NYIPLA Amicus Brief"), *with Myriad IV*, No. 2010-1406 (Fed. Cir. Aug. 16, 2012). Anthony F. Lo Cicero and Charles R. Macedo of Amster, Rothstein & Ebenstein LLP and Ronald M. Daignault and Matthew B. McFarland of Robins, Kaplan, Miller & Ciresi LLP prepared the NYIPLA Amicus Brief.

Background

This case began in 2009, when a number of medical associations, doctors and patients challenged the patent eligibility of claims in seven patents held in part by Myriad Genetics, Inc. and the University of Utah Research Foundation ("Myriad"). On summary judgment at the trial court level, all of the claims were held to be patent ineligible. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office,* 702 F. Supp. 2d 181, 220-37 (S.D.N.Y. 2010) ("*Myriad I*").

In a July 29, 2011 split decision, the Federal Circuit reversed in part, finding all of the isolated DNA composition claims, as well as one method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells, to be patent eligible. *Myriad II*, 653 F.3d at 1329, 1358. *Myriad II* also found one set of method claims directed to identifying cancer-predisposing mutations by analyzing or comparing a patient's DNA sequence to a normal sequence to be patent ineligible. *Id.* at 1355-57.

Thereafter, the U.S. Supreme Court granted *certiorari*, vacated *Myriad II* and remanded the case to the Federal Circuit to be reconsidered in light of its recent decision in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). *See Myriad III*. In *Mayo*, the Supreme Court invalidated certain blood testing method claims directed towards diagnosing and treating a disease for claiming unpatentable laws of nature.

The NYIPLA Amicus Brief

The NYIPLA filed an amicus brief not supporting either party to offer its views that the Supreme Court's *Mayo* decision did not change existing patent-eligibility jurisprudence under 35 U.S.C. § 101, and that the composition claims at issue (for isolated DNA), as well as the method claim based on screening potential cancer therapies based upon changes in the growth rates of transformed cells, were patent eligible.

In pertinent part, the NYIPLA Amicus Brief argued:

> *Mayo* maintained that patent-eligibility should be defined under Section 101's four categories of statutory subject matter [*i.e.*, process, machine, manufacture, or composition of matter], and importantly, did not overturn the holding in *Diamond v. Chakrabarty* that patent eligibility be broadly construed to "include anything under the sun that is made by man," 447 U.S. 303, 309 (1980). *Mayo*, 132 S. Ct. at 1293. *Mayo* also

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> continued to limit the judicial exceptions of patent-eligible subject matter subject to the same three "fundamental principles" set forth in its prior precedent: (1) laws of nature; (2) natural phenomena; and (3) abstract ideas. *Id.*

NYIPLA Amicus Br. at 4.[2]

The NYIPLA Amicus Brief asserted that applying these principles to the claims at issue should lead the court to find that:

- Myriad's composition claims and one of its method claims fell within a statutory category of patent-eligible subject matter,
- these claims did not preempt any fundamental principles, and
- therefore, these claims were patent eligible under 35 U.S.C. § 101.

The Federal Circuit Decision

The majority decision in *Myriad IV* follows this reasoning. *See Myriad IV,* slip op. at 36-52, 59-61. Writing for the court, Judge Lourie explained that the isolated DNA in Myriad's composition claims was distinct from naturally occurring DNA:

> BRCA1 and BRCA2 in their isolated states are different molecules from DNA that exists in the body; isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.

Id. at 45. The court went on to conclude that "the challenged [composition] claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different – have a distinctive chemical structure and identity – from those found in nature." *Id.* at 44.

Of note, the court pointedly rejected plaintiffs' contention that the native and isolated DNA molecules were the same because they contained the same nucleotide sequence, holding:

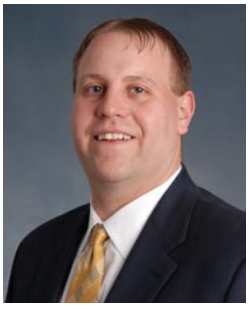
> [T]he patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material. The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact.

Id. at 48. Thus, because the isolated DNA molecules claimed did not fall within the product of nature exception, the claims were found to be patent eligible.

With respect to the method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells, the majority concluded that this claim was patent eligible because it recites a screening method based on the use of transformed, non-naturally occurring cells, and thus "includes more than the abstract mental step of looking at two numbers and 'comparing' two host cells' growth rates." *Id.* at 60. The majority also noted that the fact "that the claim also includes the steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell – patent-eligible subject matter." *Id.*

The *Myriad IV* decision indicates that the Federal Circuit is committed to maintaining the fundamentals of the patent-eligibility jurisprudence under 35 U.S.C. § 101. The decision also reminds practitioners that § 101's proper and limited role is to function as a "coarse filter" only. *See, e.g., MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1261 (Fed. Cir. 2012).

Importantly, the majority's discussion of Myriad's composition claims opens by stating this is not a case about genetic policy making,[3] nor is it about whether the claims at issue would pass muster under 35 U.S.C. §§ 102, 103 or 112. Rather, the majority's opinion is solely limited to addressing the question of patent eligibility. Nevertheless, because of the charged political context of the case, there is a possibility that this decision will lead either to an *en banc* rehearing or another grant of *certiorari* by the U.S. Supreme Court.



(Endnotes)

[1] Charles R. Macedo and Michael J. Kasdan are Partners and David P. Goldberg is an associate at Amster, Rothstein & Ebenstein LLP. Their practice specializes in intellectual property issues including litigating patent, trademark and other intellectual property disputes.

[2] The NYIPLA also submitted an amicus brief in *Mayo* that advocated similar positions to those set forth in the NYIPLA Amicus Brief in *Myriad IV*. *See* http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/MayovPrometheusNo2010-1150%20090811.pdf.

[3] "Whether its unusual status as a chemical entity that conveys genetic information warrants singular treatment under the patent laws," the majority opined, "is a policy question that we are not entitled to address." *Myriad IV*, slip op. at 49.

Mayo Collaborative Services v. Prometheus Labs., Inc., No. 10-1150
(March 20, 2012)

Issue: Patent Law – Patentability under 35 U.S.C. § 101

By Charles R. Macedo, Michael J. Kasdan and David Boag of Amster, Rothstein & Ebenstein LLP

On March 20, 2012, in a unanimous decision authored by Justice Breyer, the U.S. Supreme Court found patent claims directed to diagnosing and/or treating a disease to be an unpatentable law of nature under 35 U.S.C. § 101.

In *Mayo*, the Supreme Court reaffirmed that the principles set forth in its prior decisions in *Bilski v. Kappos*, 561 U. S. ___, 130 S. Ct. 3218 (2010); *Diamond v. Diehr*, 450 U.S. 175 (1981); *Parker v. Flook*, 437 U.S. 584 (1978); and *Gottschalk v. Benson*, 409 U.S. 63 (1972), remain in full force and effect. The Court rejected the notion of the "machine or transformation" test as a surrogate for determining whether a claim preempted an abstract idea, law of nature or natural phenomenon and instead focused on whether a claim merely seeks to preempt a law of nature (which is not patent eligible) or claims a particular application of a law of nature (which is patent eligible). In making this determination, the Court confirmed that merely adding insignificant "post-solution" or "pre-solution" activities is not sufficient to turn a claim that preempts a law of nature into a practical application of a law of nature, and thus become patent eligible. Here, the Court found that the additional steps of the claim beyond the law of nature itself added "nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field." Slip op. at 3. Thus, the Court concluded that the claims did not claim a genuine application of a law of nature.

The Court also reconfirmed that merely limiting a claim to a particular field of use – here, the medical field – is not sufficient to turn a claim that preempts a law of nature into a practical application of a law of nature, and thus become patent eligible.

The Court also rejected efforts to screen claims directed to "laws of nature" by using other portions of the Patent Act, including novelty, obviousness and definiteness inquiries, or crafting special judicial rules for particular types of inventions.

Since the Supreme Court decided *Bilski* in 2010, there have been a series of divergent opinions issuing from the U.S. Court of Appeals for the Federal Circuit on patent eligibility. It is not clear whether *Mayo* will provide any further clarity on the issue of patent-eligible subject matter.

The NYIPLA filed an amicus curiae brief in this case. *See* http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/MayovPrometheusNo2010-1150%20090811.pdf.

Caraco Pharmaceutical Labs., Ltd. v. Novo Nordisk A/S, No. 10-844
(April 17, 2012)

Issue: Hatch-Waxman Act – Counterclaims

By The Supreme Court & Appellate Practice Group of Mayer Brown LLP

The FDA is authorized to approve generic drugs only if they do not infringe the patent of a brand manufacturer. For drugs that are covered by unexpired patents, the Hatch-Waxman Amendments permit generic manufacturers to show that a proposed generic drug will not infringe the patent. One method of doing that, a "section viii statement," asserts that the generic drug will be marketed only for uses that the patent does not cover. In evaluating section viii statements, the FDA relies on "use codes" submitted by the patent holder. In *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, the Supreme Court held that a generic manufacturer may file a statutory counterclaim to force a patent holder to correct use codes that inaccurately describe the patent as covering a particular use.

The FDA approved three uses of the diabetes drug repaglinide. Novo Nordisk, respondent in the Supreme Court, held a patent, since expired, on the repaglinide chemical compound. It still holds a method-of-use patent on one of the three approved uses. Caraco, petitioner in the Supreme Court, filed a "paragraph IV certification," another method of showing non-infringement under the Hatch-Wax-

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man Amendments, which asserted that the patent was invalid or will not be infringed. Caraco later submitted a section viii statement, together with a proposed label that carved out the use described in the patent. Novo Nordisk then amended its use code to cover the other FDA-approved uses, leading the FDA to deny Caraco's application.

Novo Nordisk had also responded to the paragraph IV certification, which is an act of constructive patent infringement, by filing an infringement suit. Following the use-code amendment, Caraco counterclaimed under 21 U.S.C. § 355(j)(5)(C)(ii)(I) to force Novo Nordisk to correct the use codes, which Caraco argued were not claimed by the patent. That statutory provision states that a generic manufacturer "may assert a counterclaim seeking an order requiring the [brand manufacturer] to correct or delete the patent information [it] submitted . . . under [two statutory subsections] on the ground that the patent does not claim . . . an approved method of using the drug." Slip op. at 1-2.

The district court granted summary judgment to Caraco and issued an injunction requiring Novo Nordisk to correct the codes. A divided panel of the Federal Circuit reversed on two alternative grounds. It held that the statutory counterclaim is available only when the patent does not claim *any* FDA-approved method of use, not when it merely does not cover a particular use, and that the counterclaim provision, in any event, does not reach use codes, because they are not "patent information" submitted under the relevant statutory subsections.

In an opinion by Justice Kagan, the Supreme Court unanimously reversed. The Court first rejected Novo Nordisk's contention that "not . . . an" in the statute means "not any." *Id.* at 13. It agreed with Caraco that the phrase instead means "not a particular one," such that the statute permits a counterclaim whenever the patent does not claim a method of use for which the generic manufacturer seeks to market the drug. The Court also rejected Novo Nordisk's contention that a counterclaim is not a proper mechanism for forcing correction of use codes because they are not "patent information" that is "submitted . . . under" the relevant statutory subsections. *Id.* at 15. The Court agreed with Caraco that a use code satisfies the ordinary meaning of "patent information" and that "submitted under" should be read broadly to cover filings required, not only by the statutory subsections themselves, but also by their implementing regulations.

Justice Sotomayor wrote a concurring opinion, which highlighted the inefficiencies in the statutory scheme for correcting use codes through litigation and urged the FDA to clarify what is expected of brand manufacturers submitting the codes.

Kappos v. *Hyatt*, No. 10-1219

(April 18, 2012)

Issue: Patent Act – Introduction and Review of Evidence in Challenges to Patent Denial

By The Supreme Court & Appellate Practice Group of Mayer Brown LLP

When the United States Patent and Trademark Office ("PTO") denies an application for a patent, the applicant may seek judicial relief in two different ways. The applicant may obtain review directly in the Federal Circuit (pursuant to 35 U.S.C. § 141) or, in the alternative, the applicant may file a civil action against the PTO in federal district court (pursuant to 35 U.S.C. § 145). In *Kappos v. Hyatt*, the Supreme Court clarified both the scope of evidence that a patent applicant may proffer in a Section 145 proceeding and the appropriate standard of review. Justice Thomas authored the Court's opinion, which was unanimous.

As to the scope of the evidence, the Court concluded that "there are no limitations on a patent applicant's ability to introduce new evidence in a [Section] 145 proceeding beyond those already present in the Federal Rules of Evidence and the Federal Rules of Civil Procedure." Slip op. at 14. The Court rejected the argument of the PTO Director, Kappos, who contended that the evidence to be considered by the district court should be limited to the record before the PTO. Finding that Section 145 contained no explicit limit on the scope of evidence that may be considered, and that the predecessor statute similarly permitted applicants to adduce new evidence in a district court action, the Court declined to import "background principles of administrative law" into Section 145. *Id.* at 5-13. The Court rejected the Director's argument that permitting new evidence in Section 145 proceedings would encourage gamesmanship by applicants, finding it "unlikely" that an applicant would "intentionally undermin[e] his claims before the PTO on the speculative chance that he will gain

some advantage in the [Section] 145 proceeding." *Id*. at 14.

Next, the Court found that "if new evidence is presented on a disputed question of fact, the district court must make *de novo* factual findings that take account of both the new evidence and the administrative record before the PTO." Slip op. at 14. "[I]t makes little sense," the Court explained, "for the district court to apply a deferential standard of review to PTO factual findings that are contradicted by the new evidence." *Id*. at 6.

Because an appeal of an application denial pursuant to 35 U.S.C. § 141 is limited to "the same administrative record that was before the PTO," slip op. at 2, *Hyatt* underscores the preferability of Section 145 proceedings for applicants who wish to proffer additional materials in support of a patent application that has been rejected by the PTO.

Justice Sotomayor, joined by Justice Breyer, concurred to express her view that the Court's decision leaves intact a district court's ability to reject, on an equitable basis, evidence that was purposely suppressed from the PTO proceeding, writing that she "do[es] not understand today's decision to foreclose a district court's authority . . . to exclude evidence 'deliberately suppressed' from the PTO or otherwise withheld in bad faith." Concurrence at 3. According to Justice Sotomayor, "when a patent applicant fails to present evidence to the PTO due to ordinary negligence, a lack of foresight, or simple attorney error, the applicant should not be stopped from presenting the evidence for the first time in a [Section] 145 proceeding," but courts "retain their ordinary authority to exclude evidence from a [Section] 145 proceeding when its admission would be inconsistent with regular equity practice and procedure." *Id*. at 2-3.

The NYIPLA filed an amicus curiae brief in this case. *See* http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/KapposvHyattNo.10-1219.pdf.

Moving UP ▲ & Moving ON ➤➤➤

➤ Frankfurt Kurnit Klein & Selz, PC has added S. Gregory Boyd as a partner and as head of the firm's Interactive Entertainment Group. Prior to joining Frankfurt Kurnit, Mr. Boyd was an associate at Davis & Gilbert LLP.

➤ Peter Vogl, formerly of Jones Day, joined the Intellectual Property Group of Orrick Herrington & Sutcliffe LLP as a partner.

➤ Mark Bloomberg, formerly of Ropes & Gray LLP, joined the intellectual property practice of Zuber Lawler & Del Duca LLP as a partner.

➤ Joseph Drayton, formerly of Kaye Scholer LLP, joined the Intellectual Property Litigation group of Cooley LLP as a partner.

➤ Amr Aly, formerly of Kilpatrick Townsend & Stockton LLP, joined the Intellectual Property practice of Mayer Brown LLP as a patent litigation partner.

The Bulletin's Moving Up and Moving On feature is for the Association's members. If you have changed your firm or company, made partner, received professional recognition, or have some other significant event to share with the Association, please send it to the Bulletin editors: Mary Richardson (mrichardson@kramerlevin.com) or Robert Greenfeld (rgreenfeld@mayerbrown.com).

THURSDAY, NOVEMBER 1, 2012, 8:00 AM to 5:00 PM

One-Day Patent CLE Seminar

Keynote Speaker Honorable Mitchell Goldberg

United States District Court for the Eastern District of Pennsylvania

Judge Goldberg was appointed as a United States District Court Judge for the Eastern District of Pennsylvania on October 31, 2008. Prior to his appointment, Judge Goldberg began his legal career in the trial and appellate divisions of the Philadelphia District Attorney's Office. In 1990, he joined the firm of Cozen O'Connor, where his practice initially focused on commercial litigation, and he eventually became manager of the firm's Arson and Fraud Unit. In 1997, Judge Goldberg became an Assistant United States Attorney for the Eastern District of Pennsylvania, where he focused on white collar crime cases. Judge Goldberg began his judicial career in February 2003 with an appointment to the Bucks County Court of Common Pleas, and was elected to a ten-year term on that Court in November 2003.

Judge Goldberg's remarks will be directed to the antitrust issues that arise in patent cases involving pharmaceutical companies and "reverse payments" licensing.

Panel 1 Implementation And Effects Of The America Invents Act

Moderator William Thomashower *Schwartz & Thomashower LLP*

- **New Rules Regarding First Inventor to File** William LaMarca *United States Patent and Trademark Office*
- **Reexamination Strategy** Irene Hudson *Fish & Richardson, P.C.*
- **ADR, Judicial Recourse, and Estoppel in Post-Grant Review** Charles Miller *Dickstein Shapiro LLP*
- **Joinder** Stacey Cohen *Skadden, Arps, Slate, Meagher & Flom LLP*

Panel 2 Validity And Infringement Of Method Claims

Moderator Adda Gogoris *Merchant & Gould, P.C.*

- **Supreme Court and Federal Circuit Cases Regarding Abstract Ideas** Charles Macedo *Amster, Rothstein & Ebenstein LLP*
- **Supreme Court and Federal Circuit Cases Regarding Laws of Nature** Ronald Daignault *Robins, Kaplan, Miller & Ciresi LLP*
- ***Akamai* – Inducement of Infringement** Paul Ackerman *Dorsey & Whitney LLP*

Panel 3 Ethical Considerations In Patent Prosecution And Litigation

Moderator Wan Chieh (Jenny) Lee *King & Spalding LLP*

- **Supplemental Examination** Jonathan Ball *Greenberg Traurig, LLP*
- **PTO New Regulations on Rule 1.56** Robert Katz *Eaton & Van Winkle LLP*
- **Update on Inequitable Conduct Decisions Since Therasense** Pablo Hendler *Ropes & Gray LLP*
- **Effect of *Hyatt* on Prosecution Strategy** Jon Gordon *Frommer Lawrence & Haug LLP*

Panel 4 Issues Arising In Licensing Patents

Moderator Andy Berks *Nostrum Pharmaceuticals LLC*

- **Allocation of IP Rights in Research Agreements** Andy Berks *Nostrum Pharmaceuticals LLC*
- **Licensing with Government Agencies and Academic Institutions** Steven Hoffberg *Ostrolenk Faber LLP*
- **Admissibility of Settlement Agreements** Richard Brown *Day Pitney LLP*

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HISTORIAN'S CORNER

As Time Goes By – What Makes the NYIPLA So Special?

A quarter century ago, the Hon. Robert W. Sweet answered that question thusly: "It is rather paradoxical that in this most modern area of the law, this organization fosters the spirit, the camaraderie and the fellowship of a simpler day when lawyers rode the circuit, knew and trusted each other. Because you strengthen each other and your own branch of the profession, you strengthen all of us in the justice system."[1]

The NYIPLA's success in fostering a kindred spirit among its members has taken different forms over the years, ranging from dinner dances and golf outings to CLE programs in the form of weekend get-aways, full- and half-day programs, and luncheon seminars. The timeless Judges Dinner continues to afford us the opportunity to share the kindred spirit with others, including family, friends and, needless to say, judges.

The NYIPLA's efforts to help its members strengthen each other professionally by means of continuing legal education dates back to a time long before mandatory CLE became the order of the day. Indeed, from its founding the NYIPLA has served as a platform, an academe if you will, for educating members and the public alike in all things IP.

Through its seminars, the NYIPLA affords its members the opportunity to prepare papers and have them published, as well as the opportunity to speak before fellow members and non-members on developments in IP law. Public speaking skills and writing skills honed through NYIPLA programs serve to catalyze leadership roles for many of our members, both within the Association and within local, national, and other regional IP law associations.

We now live in an era when tweeting and instant messaging are the order of the day. Whether we're at the dinner table at home or in a booth in a fancy restaurant, cell phones are conspicuously competing with fellow diners in demanding the attention of their owners. It seems that we've become slaves to our machines.

Dale Carlson, a partner at Wiggin and Dana, is NYIPLA Historian and its Immediate Past President.

Query: Is there a place for face-to-face connectedness in our lives today? If so, one may wonder how our Association can continue to foster this connectedness so that our members can continue to appreciate and love the Association for the kindred spirit it engenders, rather than merely "like" it with the click of a button on their computer. I believe that the answer is "yes," and that it is our active members who are the key to maintaining professional growth and collegiality within our Association for the simple reason that it is the active members who exemplify the spirit of the organization.

Judge Sweet's kind words about the NYIPLA continue to ring true today. Our members strengthen each other and the IP profession as a whole through the vehicle of our Association. However, this can only be accomplished by active participation of the members in Association activities.

The NYIPLA continues to provide a fine forum for in-person gatherings, whether for CLE, networking, or Committee meetings. There is no doubt that face-to-face interactions are still the best way to ensure that we get to know and trust our fellow colleagues in the IP profession.

As NYIPLA President Tom Meloro launches the 2012-13 Association year, I encourage each of you to actively participate in our Association's Committee activities and CLE programs. Such participation is its own reward, and often provides a stepping-stone to leadership positions within and outside of the Association. There is also the satisfaction of knowing that you can help preserve the kindred spirit of the Association's founding for the foreseeable future. After all, that's what makes the NYIPLA so special.

With kind regards,
Dale Carlson

(Endnote)

[1] Excerpt from an after-dinner speech at the NYIPLA's 1988 Annual Meeting; *see* July/August 1988 *NYPTC Bulletin*, volume 28, number 6, page 4.

2012 US Bar - JPO Liaison Council Meeting

By John B. Pegram[1]

The US Bar - JPO Liaison Council met with Japan Patent Office officials on June 27, 2012 in Washington, DC. NYIPLA was represented by John B. Pegram and Raymond E. Farrell. This report summarizes the major JPO presentations. Slides presented by the JPO are posted at http://www.nyipla.org/nyipla/USBarJapanPatentOffice.asp .

Deputy Commissioner Takahashi Sakurai provided a JPO Update. The number of PCT applications filed in the JPO continued to increase, by 20% in 2011. Japanese companies are more focused on international filings and quality of cases, so domestic applications went down.

The JPO is focusing on issuing stronger, "internationally stable" patents through: harmonization, improving foreign language searching capability, cooperation on adoption of a common classification system, meeting global quality standards, and improvement of IT systems. Reduced time from examination request to first action is being achieved in the JPO through improved IT systems, increased outsourcing (especially classification and two-thirds of the searching) and a small increase in the number of Examiners. This time was down to 23 months at the end of 2011. The goal is 11 months by the end of 2013.

Mr. Sakurai explained expansion of *Matome* examination, which seeks to expedite the examination process by bringing together related applications of a company before the same examiner and by increased use of interviews. He noted that the JPO is always open to meet with U.S. users, and that firms such as IBM and Microsoft meet regularly with Examining Groups.

Tomoki Sawai, Director of the International Division, said that the JPO strongly seeks harmonization of the patent laws of developed countries, emphasizing three points:

- The sovereignty of each country should be respected by pursuing "best practices," rather than seeking compromises;
- The importance of harmonization for major countries should be recognized; and
- A bottom-up approach should be used to promote cooperation in examination.

He described several of the recent harmonization meetings including the establishment of regular meetings of the Trilateral and major European national patent offices at Tegernsee, in South Germany, and a meeting of heads of the IP5 offices in Corsica in June 2012. The Tegernsee group had agreed in April 2012 to carry out a series of studies on harmonization topics including: grace period, 18-month publication, the effect of prior applications (secret prior art) and prior user rights. The IP5 agreed at the Corsica meeting to establish a "Patent Harmonization Expert Panel" within the IP5, which is intended to engage China in such discussions.

Japan adopted an expanded grace period, effective April 1, 2012, and experienced a 50% increase in applications relying on the grace period. The JPO is willing to accept a U.S.-style grace period and is actively seeking harmonization on this issue, but Europeans appear reluctant to change, especially the German chemical industry.

A Japan-China patent offices meeting was held in October 2011. Discussion topics included the PPH (patent prosecution highway) pilot program, harmonization, machine translation, and an exchange of views on patent legislation and practices. A further meeting was held in December 2011, when the topics were trademark cooperation, misappropriated trademark application examination (Chinese companies using famous Japanese marks), and examiner exchange program.

The Asian Trilateral meeting in December 2011 was devoted to a case study of inventive step, opinions on utility model protection, harmonization matrix, a common hybrid classification (competing with CPC (cooperative patent classification)), and machine translation cooperation (CN-JP, JP-KR, CN-KR). SIPO (the Chinese State Intellectual Property Office) has been encouraging the filing of utility model applications. The JPO is very concerned about the fact that SIPO expects to receive 900,000 utility model applications a year by 2015. The Asian Trilateral will study this matter, including the possibility of requiring examination of utility models.

Tatsuya Tada, Deputy Director of Examination Standards, reported on recent revisions of JPO Examination Guidelines. Examiners are now required to explain the specific reasons and grounds for the refusal based on the claim language and description, and to indicate to the applicant how to amend in order to overcome the refusal. Mr. Tada pointed out that over 75% of the PPH applications filed in Japan from the United States are refused – at least initially – because of written description problems. Most of these refusals are due to errors in translation.

Yuichi Ito, Assistant Director of the International Division, reported on Patent Prosecution Highway (PPH) developments. In particular, he explained the PPH *Mottainai* pilot program, which seeks to increase the value of the first examination of applications with the same priority. In the regular PPH program, an office of second filing (OSF) relies on examination by the office of first filing (OFF); however, the benefits of PPH are wasted when an office other than the OFF is the first to examine an application. In the PPH *Mottainai* pilot program, any office – including the OFF – may rely on the examination results from the office that first examines the application. This pilot program was launched on July 15, 2011 among the JPO, USPTO and six national patent offices. The EPO began participating on January 29, 2012.

(Endnote)

[1] John B. Pegram is a Senior Principal at Fish & Richardson P.C., a Past President of NYIPLA and a long-time NYIPLA delegate to the JPO Liaison Council.

CLE PROGRAMS

June 28, 2012 Women in IP Law and CLE Program

"An Outside Counsel Perspective: Maximizing Opportunities To Succeed With Colleagues and Clients"

On June 28, 2012 the Women in IP Law Committee hosted a Continuing Legal Education (CLE) panel and wine tasting networking event at the offices of Goodwin Procter LLP. The panel program was titled "An Outside Counsel Perspective: Maximizing Opportunities To Succeed With Colleagues and Clients." The panel of speakers included Leora Ben-Ami, Kirkland & Ellis; Sona De, Ropes & Gray; and Marta Gross, Goodwin Procter. Jeanna Wacker from Kirkland & Ellis served as the moderator. The speakers covered a range of topics on the role of outside counsel and how to succeed. The speakers offered advice on how attorneys can market themselves, how mentoring can help a career, and how attorneys can adapt to today's changing market demands.

July 12, 2012 CLE Program

"Making and Leveraging Connections: How to Develop a Professional Network as a Young IP Lawyer"

By Jonathan Auerbach

On July 12, 2012, the Young Lawyers Committee hosted the panel, "Making and Leveraging Connections: How to Develop a Professional Network as a Young IP Lawyer" at the Princeton Club. The panel introduced summer and junior associates to the importance of networking from the perspective of partners and in-house counsel. The panelists were Terri Gillis of Mayer Brown LLP, NYIPLA Immediate Past President; Kevin Culligan of Goodwin Procter LLP; Dorothy Auth of Cadwalader, Wickersham & Taft LLP, NYIPLA Second Vice-President; Kevin C. Ecker of Philips Intellectual Property and Standards, NYIPLA Board of Directors Member; and Frank Sedlarcik of IBM. Jonathan Auerbach of Goodwin Procter LLP was the moderator. Anne Hassett of Goodwin Procter LLP, NYIPLA Board of Directors Member, also attended. The panelists gave a brief introduction of their practices and began by discussing what they would have done differently regarding networking if they were starting over again as junior associates. The panelists also discussed the importance of joining and actively participating in professional organizations and bar associations and how to develop relationships organically, rather than just for business purposes. The panelists closed by discussing how young associates should make a habit out of balancing networking and business development with their legal work so that they will be able to grow their network as they advance in their careers. The attendees posed thoughtful and relevant questions to the panel throughout. Information on NYIPLA and membership applications were distributed to all attendees. A reception followed the discussion.

July 18, 2012 CLE Program

"Hot Topics In Trademark Law"

By Pina Campagna and Kathleen McCarthy

On July 18, 2012, the NYIPLA Trademark Law and Practice Committee hosted and the NYIPLA Continuing Legal Education (CLE) Committee co-sponsored the 2012 Half-Day Trademark CLE seminar at The Princeton Club. The program is an annual event presented by the NYIPLA. This year's program was entitled "Hot Topics in Trademark Law." The Honorable Thomas P. Griesa, United States District Judge for the Southern District of New

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York, delivered the keynote address. Robert Rando, co-chair of the NYIPLA CLE Committee, introduced Judge Griesa. Judge Griesa spoke about Rule 1 of the Federal Rules of Civil Procedure, which provides that the Federal Rules "should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding." Judge Griesa expressed concern regarding the exorbitant costs of litigation and opined that the requirements that have been and continue to be added to the Federal Rules are depriving litigants of the promise of Rule 1–that every action and proceeding will receive an "inexpensive determination."

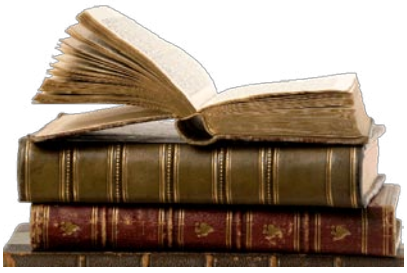
Current co-chairs of the NYIPLA Trademark Committee, Kathleen McCarthy of King & Spalding and Pina Campagna of Carter, DeLuca, Farrell & Schmidt, LLP, served as moderators. In addition, immediate past co-chair Steven Gustavson of Goodwin Procter LLP, NYIPLA Board of Directors Member Richard Parke of Frommer Lawrence & Haug LLP, and NYIPLA Board Liaison Susan Progoff of Dorsey & Whitney LLP were instrumental in developing the program agenda and securing speakers.

Linda Chan of Arent Fox LLP provided an overview of the new Generic Top-Level Domains (gTLDs), the application process, and the current protective measures available for trademark owners. Perry Viscounty of Latham & Watkins LLP discussed the implications of the recent keyword advertising case, *Rosetta Stone Ltd. v. Google, Inc.,* 676 F.3d 144 (4th Cir. Apr. 9, 2012), the first case in which a Court has opened the door to infringement suits against Google based on customer confusion and in which internet service providers could be found liable for direct and/or contributory infringement. Mr. Viscounty provided practical advice for how trademark owners can prevent the use of their trademarks as keywords. Jonathan Moskin of Foley & Lardner LLP and chairman of the NYIPLA Internet and Privacy Law Committee spoke about uses of online tracking technologies for building behavioral profiles and creating behavioral advertising and how these tracking technologies may have privacy issues. Mr. Moskin discussed FTC-initiated mechanisms and enforcement actions and legislation proposed for protecting consumer privacy.

Jane Pollack of Citigroup spoke on sports sponsorships and sponsor agreements. Specifically, Ms. Pollack spoke about the rights typically granted and excluded from sponsorship agreements, the liabilities and responsibilities of the parties, and how ambush marketing can be prevented. Howard Shire of Kenyon & Kenyon LLP discussed what is required to prove damages in trademark cases and how to do so. Mr. Shire began with the sections of the Lanham Act that govern the recovery of damages for the violation (or willful violation) of any right of the registrant of a mark and continued with a discussion of each of the principles of equity, i.e., defendant's profits, plaintiff's actual damages, and attorney fees. Pasquale Razzano of Fitzpatrick Cella Harper & Scinto provided an update on trademark dilution in the Trademark Trial and Appeal Board (TTAB) and the courts. Mr. Razzano presented recent case law that further clarified and distinguished the meaning of "famous mark" as in the *Rosetta Stone v. Google* case, the meaning of the term "association arising from the similarity" of the marks as in *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.,* 633 F.3d 1158 (9th Cir. 2011), and dilution by blurring and tarnishment. Mark Bloomberg of Ropes & Gray and co-chair of the NYIPLA CLE Committee provided the closing remarks.

The NYIPLA would again like to express its gratitude to the speakers for their time in preparing and presenting the talks on today's hot topics and to the attendees for attending the program. The NYIPLA Trademark Law and Practice Committee continues to welcome any and all comments, requests and recommendations regarding the content and timing of this annual program. In addition, the NYIPLA Trademark Law and Practice Committee will continue to accept members for the 2012-2013 year for those interested in participating.

ATTN: NYIPLA Members



If you have any NYIPLA historical records, specifically Bulletins (1967-1981), Greenbooks (prior to 1951), and Judges Dinner booklets (1973 & prior to 1971), please contact Bill Dippert at wdippert@eckertseamans.com or 1.914.286.2813.

Minutes of May 22, 2012
Meeting of The Board of Directors
The New York Intellectual Property Law Association

The Board meeting was called to order at The Princeton Club, 15 West 43rd Street, New York, NY 10036 at 5:35 pm by President Thomas Meloro. In attendance at the Board meeting were:

Thomas Meloro	Annemarie Hassett
Dorothy Auth	Charles Hoffmann
Leora Ben-Ami	Ira Levy
Jeffrey Butler	Anthony Lo Cicero
Kevin Ecker	Wanli Wu
Bruce C. Haas	Theresa Gillis
Walter Hanley	

Past Presidents in attendance included: Dale Carlson, Mark Abate, Chris Hughes, Melvin Garner, Ed Filardi, David Kane, John Pegram and Ed Vassallo.

Absent and excused from the meeting were Denise Loring, Alexandria Frisbie and Richard Parke. Feikje van Rein and Robin Rolfe were in attendance from the Association's executive office.

Tom Meloro called the meeting to order. Tom welcomed the new members to the Board and thanked the Past Presidents for their attendance.

The Board approved the Minutes of the April 18, 2012 Board meeting.

Tom Meloro made a brief statement to the Board, stating that a great deal had been accomplished in the previous year and that he hoped that the continuity on the Board would allow the Board to accomplish a great deal this year.

The Board discussed the success of the various Committees, indicating that the Committees had become very active and productive. It was noted that a large number of committee activities are already scheduled for this year. There was a discussion of the Women in IP Law Committee and its programs in particular, with Board member comments that they would try to have the women at their firms attend the newly scheduled events. The Board expressed its appreciation to Goodwin Procter for hosting the June panel discussion and wine tasting for the Women in IP Law Committee, noting that having programs with no cost to the attendees was of great advantage to the organization.

The Board then discussed an issue raised by the Amicus Briefs Committee regarding the *Myriad* case, now pending at the Court of Appeals for the Federal Circuit. Tom Meloro and Jeffrey Butler recused themselves from this discussion. The Board briefly discussed the issue presented to the Federal Circuit regarding the role of 35 USC § 101 in biotechnology applications and particularly with regard to "isolated DNA" claims. The Board approved the preparation of an amicus brief which would not take any position on the merits but would consider and discuss the implications of the various possible outcomes in the case.

The meeting was then adjourned by Tom Meloro.

Minutes of June 12, 2012
Meeting of The Board of Directors
The New York Intellectual Property Law Association

The Board meeting was called to order at the offices of Willkie Farr & Gallagher LLP, 787 Seventh Avenue, New York, NY 10019 at 12:35. In attendance at the Board meeting were:

Thomas Meloro	Bruce Haas
Charles Hoffmann	Theresa Gillis
Dorothy Auth	Walter Hanley
Anthony Lo Cicero	Denise Loring
Leora Ben-Ami	Richard Parke
Wanli Wu	

Alexandra Frisbie, Kevin Ecker, Annemarie Hassett, and Jeffrey Butler attended by telephone. Absent and excused from the meeting was Ira Levy. Feikje van Rein attended from the Association's executive office.

Tom Meloro called the meeting to order, noting that the Board had a very full agenda but would try to go through the entire agenda in the allotted time.

The Board approved the Minutes of the May 22, 2012 board meeting.

Jeffrey Butler provided a Financial Report, first reporting that the audit was continuing to progress and that it would hopefully be ready for discussion during the July meeting. Jeffrey continued that the finances of the organization were sound with approximately $1.2 million in current equity. This positive equity situation was particularly noteworthy as the expenses associated with two Judges Dinners were included in this year's expenses.

Jeffrey Butler then turned to the approval of new members. Terri Gillis moved to waive the reading of the new members' names, and the Board approved the motion. The Board noted that some new members appeared to be from outside the jurisdiction for the NYIPLA and therefore should be added as nonvoting members. The Board also noted that it appeared from the list of New Members that certain firms might be becoming more involved in the organization. It was agreed that Board members should contact individuals at these firms to encourage further participation in committees and activities of the Association. Tom Meloro moved the admittance of the new members subject to a determination whether each new member

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would be a voting member or a nonvoting member. The motion was approved by the Board.

Denise Loring then reported on behalf of the Amicus Briefs Committee. The Board discussed the very well written draft brief on the *Myriad* case circulated by the Committee. After discussion, the Board agreed that the brief should include a position on the issue of patent eligibility and favoring the continued patent eligibility of isolated DNA sequences. Tom Meloro, Jeffrey Butler and Terri Gillis were recused from discussion or voting regarding this brief. Denise also updated the Board regarding two issues which may become appropriate for Board consideration.

Annemarie Hassett raised the issue of the statement of interest and the Board agreed that the statement needed to be updated. Annemarie indicated that she would provide a draft updating the statement of interest for this amicus brief as well as for future use.

Anthony Lo Cicero and Annemarie Hassett then reported on work ongoing regarding alternative formats and rates on behalf of the CLE and Meetings and Forums Committees. Tony and Annemarie noted that a questionnaire was being sent to member firms and corporations regarding member needs for practical CLE training in areas such as trial skills. The Board considered whether the results might be published in some form and will consider this after the results are analyzed. Annemarie and Tony further noted that the Committees were looking at the Association's CLE programming broadly, recognizing that work pressures and economics limit participation in some events. Feikje noted that Ira Levy had reported that the Meetings and Forums Committee did have a meeting calendared and was discussing additional formats.

Richard Parke reported on the Trademark program on behalf of the CLE Committee. Richard noted that Judge Griesa had agreed to speak at the trademark luncheon and that the panel for the program included attorneys from law firms and at least one attorney from a corporation. The Board discussed the timing of the trademark luncheon, noting that it is reasonably close to the INTA annual meeting. While there was the view that the closeness to INTA might lessen attendance and that the Committee could consider whether there are alternatives in the future, the Board stressed the need to have programs related to all aspects of intellectual property law and considers the trademark program important for the members of the Association.

Anthony Lo Cicero next reported on the 2012 Annual Meeting. Tony mentioned and the Board agreed that having a CLE program was a very positive addition to the day. The Board also agreed that the Committee meeting format prior to the Annual meeting was useful and increased attendance at the Annual Meeting itself.

Tony then reported on the issue of the Judges Dinner Software. This software, which is being written for the Association, integrates many of the functions needed for the efficient management of the Judges Dinner. The cost of the software is approximately $20,000 and the implementation of the software will be done by Robin Rolfe Resources at no additional cost. Feikje van Rein indicated that the Association's other software was adequate and that the cost of the new software would be a one-time expense. The Board agreed that the cost was appropriate and Feikje indicated that software should be ready for use in conjunction with the 2013 Judges Dinner.

Tom Meloro then discussed Bylaw revisions. As it appears that the Bylaws may be outdated to some extent, a small group made up of Walter Hanley, Terri Gillis, Mary Lee Jenkins, Paul Bondor, and Robert Baechtold will review the Bylaws. The group will provide a report to the Board giving a general overview of the Bylaws and possible issues and then later report to the Board with specific recommendations. The Board wishes to approve any necessary changes by March, so that the changes will be ready for approval at the next annual meeting.

Terri Gillis reported on the Local Patent Rules. Terri reported that the scope and acceptance of Local Patent Rules was still open to discussion.

Tom Meloro then reported on the Association's Diversity Scholarship. Tom discussed a suggestion to have a 501(c)(3) foundation created to fund the Scholarship, noting certain fundraising and tax advantages. The Board agreed that considering the creation of a separate foundation may be advantageous.

Bruce Haas presented on behalf of the Membership Committee. Bruce led a Board discussion focused on the Association's desire to increase membership outside of Manhattan and including those in corporations. The Board discussed the possibility of having programs in locations outside Manhattan and discussed that possibility of new rate structures to encourage membership.

Wanli Wu, reporting for the Publications Committee, noted that the Committee was functioning well and that the *Bulletin* was on track for timely publication.

Kevin Ecker provided an update regarding the Inventor of the Year Committee. Kevin noted the Committee was meeting the following week and was attempting to create a set of Frequently Asked Questions to be available to possible candidates to assist with the process.

Walter Hanley reported on the Conner Writing Competition, indicating that the Committee needed to update the list of professors teaching intellectual property because the Committee solicits student articles through the professors. It was agreed that the Association's administrative office might be able to assist.

The Copyright Committee report was given by Charles Hoffmann, who noted that a June meeting was scheduled to discuss future events.

Alexandra Frisbie reported on behalf of the Corporate Committee, stating that the committee was attempting to meet shortly to discuss its future activities and that the Committee would like to work with other Committees as appropriate to include the perspective of corporate counsel.

Charles Hoffmann reported for the Internet and Privacy Law Committee, indicating that the Committee was working to increase its membership.

Dorothy Auth reported for the Patent Law and Practice Committee. The Committee was working to run a CLE program in September with the PTO. There is also a possibility of a July meeting with SIPA (Shanghai IP Administration).

Anthony Lo Cicero then reported for the Patent Litigation Committee, stating the Committee will be meeting shortly.

Speaking for the Trademark Practice Committee, Tony noted that this Committee should be meeting shortly as well.

The Website and Records Committee Report was given by Jeffrey Butler, who noted that old documents were being imaged and that the website was vastly improved but the Committee was looking at continued improvement.

Leora Ben-Ami reported for the Women in IP Law Committee, noting that Goodwin Procter was sponsoring a panel discussion and wine tasting in June.

Annemarie Hassett reported for the Young Lawyers Committee, indicating that the Committee was having a panel discussion on the development of business development goals on July 12th. The Committee is also considering mini seminars in various local law schools to discuss careers in IP with law students.

The Board determined that there was no need for an Executive Session and therefore the meeting was adjourned at 2:05 p.m.

Minutes of July 17, 2012
Meeting of The Board of Directors
The New York Intellectual Property Law Association

The Board meeting was called to order at the offices of Willkie Farr & Gallagher LLP, 787 Seventh Avenue, New York, NY 10019 at 12:30. In attendance at the Board meeting were:

Thomas Meloro	Wanli Wu
Charles Hoffmann	Bruce Haas
Dorothy Auth	Theresa Gillis
Anthony Lo Cicero	Walter Hanley
Kevin Ecker	Richard Parke

Alexandra Frisbie and Jeffrey Butler attended by telephone. Absent and excused from the meeting were Leora Ben-Ami, Ira Levy, Annemarie Hassett and Denise Loring. Feikje van Rein and Robin Rolfe attended from the association's executive office.

Tom Meloro called the meeting to order.

The Board approved the Minutes of the June 12, 2012 board meeting.

Jeffrey Butler provided a Financial Report, first reporting that the audit has been finished. Loeb & Troper submitted a first draft and Jeffrey and Feikje are in the process of reviewing the financial report and the management letter. The management letter includes recommendations for changes as to certain of the Association's policies. These recommendations need to be implemented to comply with IRS processes. Kevin Ecker requested further explanation from the auditors as to what actions are needed to be in compliance with the suggested segregation of financial duties at the Executive Office. Jeffrey presented the Annual Report of the Treasurer which shows a decline in the bank accounts as NYIPLA posted two years of Judges Dinner expenses in fiscal year 2011-2012. Overall the revenue numbers are trending downwards which needs attention from the Board and Executive Office to increase program attendance and more members.

Jeffrey Butler then turned to the approval of New Members. Jeffrey moved to waive the reading of the new members' names, and the Board approved the motion. The Board also moved to unanimously approve all of the listed new members.

Tony Lo Cicero reported that the contract with the Waldorf=Astoria has been signed and the next Judges Dinner will be on Friday, March 22, 2013. The Judges Dinner Committee met by phone and recommends that the tables in the Grand Ballroom be charged a modest premium seating fee of $350. The committee also reviewed the hospitality suite's locations and requirements, and recommends enforcing a membership requirement as well as a minimum table purchase, depending on the size and location of the hospitality suite. A new initiative will be Quiet Rooms for the convenience of guests in the satellite rooms who wish to listen to the keynote speaker. Other items that were discussed included the Towers elevator traffic and the noise level in the Grand Ballroom as well as the satellite rooms and how to encourage guests to be quiet during the keynote speech. The Board approved the Judges Dinner Committee's recommendations.

Richard Parke reported on the upcoming July Trademark program on behalf of the CLE Committee. At the time of the Board meeting, there were 42 people registered. Judge Griesa is scheduled to be the keynote speaker. Richard reported that the Committee will start planning for the November One-Day Patent Program during the summer so the program can be marketed after Labor Day.

Tom Meloro updated the Board on his initiative to set up a separate 501(c)(3) foundation as a means to collect contributions for the yearly diversity scholarship given to a worthy law school. Tom reported that the Chairs of the Diversity Scholarship Committee will present details of this proposal at the September Board meeting.

Bruce Haas reported on the Membership and Corporate Committees' proposal to offer a special corporate member rate of $150, which includes a $100 credit to an NYIPLA CLE event. Already-renewed corporate members will receive a credit towards future CLE programs. The Board approved this corporate member offer. Corporate members Alexandra Frisbie, Jeffrey Butler, and Kevin Ecker abstained from voting.

Alexandra Frisbie reported that she will help jumpstart the monthly meetings of the Corporate Committee.

Dorothy Auth, on behalf of the Patent Law Committee informed the Board that the USPTO has reached out to Peter Thurlow, co-chair of the Patent Law Committee to co-sponsor its USPTO Roadshow on September 28 at the Public Library in New York City. The Board approved a co-sponsorship and the hosting of a reception after the USPTO program. The Committee has also been working on implementing the USPTO's initiative to set up a pro-bono patenting program. Tom Meloro requested more information on this initiative.

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Terri Gillis and Dorothy Auth mentioned that the Women in IP Law program at Goodwin Procter was well attended (50 people) and received excellent feedback.

In Denise Loring's absence, Tom mentioned that there were no noteworthy developments from the Amicus Briefs Committee and the report was included in everyone's Board materials packet.

Tony Lo Cicero reported that the survey on alternative CLE formats has been sent to each identified member firm and the office has received a small number of responses. It is too early to give a comprehensive report to the Board.

Richard Parke reported that the July 12 program for Young Lawyers was well received. NYIPLA received a request from AIPLA to co-promote their young lawyers' program on August 10. The Board decided that it would be a good initiative and to send one broadcast email and to reach out to the NYIPLA Young Lawyers Committee to encourage their attendance. The Executive Office will be onsite with marketing materials.

The Board determined that there was no need for an Executive Session and therefore the meeting was adjourned at 1:57 p.m.

NEW MEMBERS

Last Name	First Name	Firm/School	E-mail Address	Tel. No.
Aisiku	Ojeiku	Brooklyn Law School	ojeiku.aisiku@brooklaw.edu	
Anderson, III	Theodore C.	Kilgore + Kilgore PLLC	tca@kilgorelaw.com	214-379-0810
Ayompe	Augustine	Benjamin N. Cardozo School of Law	ngutiman@gmail.com	
Baker	Mark Daniel	Quinn Emanuel Urquhart & Sullivan LLP	markbaker@quinnemanuel.com	212-849-7136
Bapna	Abhishek	Kenyon & Kenyon LLP	abapna@kenyon.com	212-908-6006
Bell	Rachel	Fitzpatrick, Cella, Harper & Scinto	rbell@fchs.com	
Berger	Lena	Fordham IP Institute	magdalena.berger@gmx.com	
Bongiorno	Marina		marina.bongiorno@gmail.com	
Brake	Aubrie	Florida International University	aubrieb3@gmail.com	
Brenckman	Elizabeth Eilleene	Fish & Richardson, P.C.	brenckman@fr.com	212-641-2305
Brown	Andrew	Paul, Weiss, Rifkind, Wharton & Garrison LLP	abrown@paulweiss.com	212-373-3709
Brukman	Alla	Ropes & Gray LLP	alla.brukman@ropesgray.com	212-596-9000
Burak	Robert Daniel	Amster, Rothstein & Ebenstein LLP	rburak@arelaw.com	212-336-8000
Capasso	Jessica	Amster, Rothstein & Ebenstein LLP	jcapasso@arelaw.com	212-336-8109
Cardenas-Navia	Jaime	Fitzpatrick, Cella, Harper & Scinto	jcardenas-navia@fchs.com	
Chatterjee	Neel I.	Orrick Herrington & Sutcliffe LLP	nchatterjee@orrick.com	650-614-7356
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