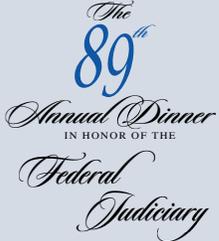


**NYIPLA<sup>®</sup>**

# Bulletin

December/January 2011

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## AMP v USPTO and the Patent-Eligibility of Isolated Nucleic Acids

by Steven Lendaris

### I. INTRODUCTION

Over the past thirty years, the United States Patent & Trademark Office (“USPTO”) has issued more than 50,000 patents claiming nucleic acid molecules. Many of these patents are directed to isolated nucleic acid molecules that have the same sequence as naturally-occurring nucleic acids. For example, nucleic acids that code for therapeutically-important proteins, e.g., insulin or erythropoietin, have been identified and subsequently patented in isolated form.

According to the USPTO, patents claiming isolated nucleic acid molecules are directed to so-called “compositions of matter,” one of the statutory categories of patent eligible subject matter defined in Section 101 of the Patent Act. Many in the biotechnology industry view the USPTO’s position as instrumental to the birth and the continued success of that industry. However, there continues to be a vocal opposition to the issuance of such patents, arguing that they are directed to natural phenomena and therefore represent patent-ineligible subject matter. In the opposition’s view, isolated nucleic acid molecules that correspond to

naturally-occurring sequences are no more eligible for patenting than the naturally-occurring elements of the periodic table. Furthermore, the opposition highlights that over the thirty years that these patents have issued, no court has explicitly addressed whether such molecules do indeed represent patent-eligible subject matter.

The Court of Appeals for the Federal Circuit is now poised to weigh in on this issue in *The Association for Molecular Pathology, et al., v. The United States Patent and Trademark Office, et al.*, No. 2010-1406. This article outlines the positions taken by the parties and *amici* during the lower court proceedings, provides a synopsis of the District Court’s decision, and outlines the arguments recently advanced before the Federal Circuit, including a description of a controversial brief filed by the Department of Justice. This article will then conclude with practical strategies that patent practitioners can use to maximize protection as this case moves forward.

### II. BACKGROUND

#### 1. The Plaintiffs File Suit

On May 12, 2009, a group of plaintiffs including non-profit

*cont. on page 3*

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Dear Fellow Members,

The New Year promises to offer many exciting programs to our members. Our monthly CLE program being held on January 26th at the Harvard Club features retired Chief Judge Paul Michel of the Federal Circuit on a panel moderated by Donna Praiss, Co-Chair of our Women in IP Law Committee. Other panelists will include Association members James Dabney and Chuck Miller. The topic for discussion is preponderant versus clear-and-convincing evidence – which standard should prevail in patent cases? The U.S. Supreme Court is currently considering this subject in the context of the *Microsoft v. i4i* case.

Kudos to Jay Anderson for his diligent efforts in planning and arranging this program. Jay is Co-Chair of our Meetings & Forums Committee, together with Rich Martinelli.

This year's cocktail reception hosted by the Young Lawyers Committee will be held on the evening of January 27th. If you know of any newer lawyers who have an interest in IP and believe that they may be interested in attending this reception, please suggest that they reach out to Sonja Keenan who is planning this event. Details are posted on the *nyipla.org* web site. Sonja is Co-Chair of the YLC Committee, together with Andrew Stein.

The 2010-2011 Association year marks the diamond anniversary of Giles S. Rich's term as NYIPLA President. We will honor the occasion with a memento of our Association's appreciation to be presented to a member of Judge Rich's family at the 89th Annual Dinner in Honor of the Federal Judiciary on March 25<sup>th</sup> at the Waldorf=Astoria. During his lifetime, Judge Rich graced the Association with his presence at some forty of the Waldorf dinners.

As a special keepsake, each attendee at this year's Judges Dinner will receive a compact disc containing a two hundred page book about Judge Rich's life published by The Federal Circuit Historical Society. Many thanks to the FCHS, and particularly its officers

Phil Swain, NYIPLA Past-President David H.T. Kane and George Hutchinson, for allowing the NYIPLA to make the CD available at the Waldorf gathering.

At our Judges Dinner, Judge Arthur Gajarsa of the Federal Circuit will receive the NYIPLA's ninth annual Outstanding Public Service award. The keynote speaker will be Judge John Gleeson of the Eastern District of New York.

April 27th marks the 27th Joint Patent Practice CLE seminar. This year's event will be held at the New York Hilton. The keynote address will be provided by Judge Gajarsa. Roughly a quarter of the presenters at the seminar will be NYIPLA members, and many others will update their IP skills in their role as attendees. If you haven't attended in past years, please consider doing so this year. If you have attended but haven't spoken, please consider volunteering to speak now.

The NYIPLA has been a proud co-sponsor of the JPP seminar since 1985, together with the Connecticut, New Jersey and Philadelphia IP associations. Here's hoping that our support of this worthwhile educational event continues long into the future.

At the NYIPLA's May annual meeting, Terri Gillis will be installed as our Association's President. Terri will be the third woman to serve in that office, following in the footsteps of Past Presidents Andrea Ryan and Marylee Jenkins. My hope is that our newly created Women in IP Law Committee will help encourage other women to serve

in similar leadership roles in the future.

For all of these reasons, 2011 promises to be a banner year for our Association. If you are already contributing to the Association's success this year, my hat goes off to you. If you are not, please make it your New Year's resolution to become active in an Association committee now. The rewards in terms of career development are certain to inure to your and the Association's benefit. The list of all NYIPLA committees and contact information for the committee chairs is on the *nyipla.org* website.

With kind regards,

Dale Carlson



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medical research and physician societies, non-profit patients' rights and advocacy organizations, as well as individual medical doctors, researchers and patients brought a declaratory-judgment action against Myriad Genetics, Inc., the Directors of the University of Utah Research Foundation and the USPTO. The plaintiffs' complaint alleged that fifteen claims selected from seven patents, all of which are owned or partly-owned by the University of Utah Research Foundation and exclusively licensed to Myriad, are directed to patent-ineligible subject matter under 35 U.S.C. § 101, and that the issuance of the claims-in-suit violated the First Amendment, the Fourteenth Amendment, and the Patent and Copyright Clause, Article I, Section 8, Clause 8.

The fifteen patent claims-in-suit are directed to diverse subject matter. A number of the claims are directed to isolated nucleic acid molecules, specifically deoxyribonucleic acid (DNA) molecules. The claimed DNA molecules have all or part of either of two particular nucleic acid sequences, known in the art as the BRCA1 and BRCA2 genes. These genes are of particular interest as certain mutations in them have been shown to correlate positively with a person's likelihood to develop breast or ovarian cancer. Other claims-in-suit are directed to methods of detecting the "normal" and "mutated" BRCA1 and BRCA2 sequences and using the result to determine the likelihood a person will develop breast or ovarian cancer. Because the method claims involve additional issues, e.g., the eligibility of claims involving mental steps, as well as the First and Fourteenth Amendment arguments advanced by the plaintiffs, this article will focus only on the isolated nucleic acid claims. However, readers are encouraged to turn to David Ryan's excellent discussion concerning the patent-eligibility of method claims involving mental steps in light of the recent decision in *Bilski v. Kappos* in the August/September 2010 edition of the NYIPLA Bulletin. (Past *Bulletins* are posted on the NYIPLA's web site – [www.nyipla.org](http://www.nyipla.org).)

The filing of the plaintiffs' complaint, as well as their subsequent briefs supporting their standing to file the declaratory judgment action and their motion for summary judgment, received broad media attention. Not surprisingly, the plaintiffs' arguments resonated with a variety of independent organizations, including the March of Dimes Foundation and the American Medical Association. These two organizations are among a number of third parties that chose to file *amicus curiae* briefs calling for the claims-in-suit to be held invalid.

As was the case with the plaintiffs' own briefs, the *amicus* filings calling for the claims-in-suit to be held invalid generally assert that the claimed isolated DNA molecules are effectively indistinguishable from naturally-occurring DNA molecules. Both the plaintiffs and these *amici* base this contention on the fact that the DNA molecules, whether isolated or not, carry the same sequence information necessary to code for the BRCA1 or BRCA2 proteins. By equating the claimed isolated DNA molecules to naturally-occurring DNA molecules based on a single property, i.e., retention of coding sequence unchanged, the plaintiffs and these *amici* argue that the claimed molecules are nothing more than natural phenomena, thus falling within the scope of subject matter judicially excluded from patent eligibility.

## 2. The Defendants Respond

In countering the plaintiffs' characterization of the claims to isolated DNA molecules as representing patent-ineligible subject matter, Myriad, the USPTO, and the *amicus* filers urging that the Court find the subject matter of the claims patent-eligible, focused the Court's attention on the differences between isolated DNA molecules and their naturally-occurring genomic counterparts. For example, the USPTO noted that

isolated and purified genes function in ways that "natural" genes cannot. For example, when genes are isolated from their natural genetic controls, they may be recombined with other polynucleotides in a way that permits researchers and pharmaceutical companies to control their expression.<sup>1</sup>

Myriad echoed that position pointing out that naturally-occurring DNA "does not have the chemical, structural, or functional properties that make isolated DNA so useful to the molecular biologist."<sup>2</sup> In addition, numerous *amicus* filers went to great lengths to educate the court on the science underlying the differences between isolated DNA and its naturally-occurring counterparts.

A second approach employed by both Myriad and the USPTO to underscore the patent-eligible nature of the claimed subject matter (i.e., isolated DNA molecules) was to clarify that the claims-in-suit were issued for novel and nonobvious isolated chemical compounds, not for the genetic information that may be carried by those chemical compounds. This approach highlighted the potentially sweeping ramifications of a finding of ineligibility in this case, as such a finding would raise doubts as to the patent-eligibility of all isolated (or purified) naturally-occurring compounds, including many vitally

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important pharmaceuticals. Furthermore, this approach attempted to clarify what the defendants saw as a fundamental misconception on the part of the plaintiffs. Specifically, both Myriad and the USPTO argued strenuously that

[c]ontrary to plaintiffs' assertions, an isolated DNA molecule is not just "information" or a manifestation of the laws of nature. An isolated DNA molecule is a chemical compound, isolated (and thus "made") by man.<sup>3</sup>

The USPTO went on to crystallize the fundamental nature of the misconception by noting that "a genetic sequence alone (e.g., a display of the genetic sequence on a computer monitor or on a piece of paper), which is information, cannot infringe a patent claiming the isolated gene, which is a chemical compound."<sup>4</sup> By highlighting the differences between naturally-occurring and isolated nucleic acids and exposing the misconception that isolated nucleic acid molecules are somehow synonymous with information, the defendants argued that the claims-in-suit were indeed directed to patent-eligible subject matter under Section 101.

### 3. The District Court Ruling

On March 29, 2010, the District Court issued its decision holding that all of the claims-in-suit were invalid as directed to patent-ineligible subject matter.<sup>5</sup> With regard to the claims to isolated DNA molecules, the District Court analyzed Supreme Court and Federal Circuit precedent and held that "purification of a product of nature, without more, cannot transform it into patentable subject matter."<sup>6</sup> Seizing upon language used in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), to craft its own test, the District Court held that "the purified product must present 'markedly different characteristics' in order to satisfy the requirements of § 101."<sup>7</sup> The Court then distinguished the claimed DNA molecules from all other isolated chemical compounds, asserting that:

[i]n light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited [ ] between native BRCA1/2 DNA and the isolated BRCA1/2 claimed in the patents-in-suit render the claimed DNA 'markedly different.'<sup>8</sup>

## NYIPLA Calendar

[www.nyipla.org](http://www.nyipla.org)

### 2011 CLE Luncheon Program

➤ Wednesday, January 26, 2011 ◀

Topic: Microsoft v. i4i

The Harvard Club

35 West 44th Street, New York, New York

Earn 1.5 NYS/NJS CLE Credits

### NYIPLA Young Lawyers Committee

#### Networking Reception

➤ Thursday, January 27, 2011 ◀

Social Bar, Grill & Lounge

795 8th Avenue, New York, NY

### JPPCLE 27th Annual Joint Patent Practice Seminar

➤ Wednesday, April 27, 2011 ◀

Hilton New York Hotel

1335 Avenue of the America, New York, NY

By finding that the information-carrying capacity of DNA represents its unique and defining characteristic, the District Court found that the claimed isolated DNA molecules could not be “markedly different” from their naturally-occurring counterparts. Being unable to identify any marked difference between the naturally-occurring nucleic acid encoding BRCA1 or BRCA2 and the claimed isolated DNA molecules, the Court determined that the claims directed to isolated DNA molecules were invalid under Section 101.<sup>9</sup>

### III. THE PENDING APPEAL AT THE FEDERAL CIRCUIT

#### 1. Myriad and Amici in Favor of Reversal

On June 16, 2010 Myriad appealed the decision of the District Court to the Federal Circuit and then, on October 22, 2010, filed its brief on the merits requesting reversal of the lower court’s decision. While Myriad and the veritable flood of *amicus* briefs filed requesting reversal of the earlier decision raised many points similar to those raised at the district court level, particularly with regard to the differences between isolated and naturally-occurring nucleic acids, the briefs did raise a number of new points.

For example, the District Court’s reliance on a finding of “marked differences” between the claimed composition and any naturally-occurring compound was questioned as an appropriate standard for compliance with Section 101. This standard was asserted as particularly problematic when combined with the reduction of the claimed compositions to their “defining characteristic.” Instead, Myriad and many of the *amicus* filers, argued that Section 101 should be interpreted broadly to confer eligibility to any man-made composition, and that the other sections of the Patent Act, e.g., Sections 102 and 103 relating to novelty and nonobviousness, respectively, could adequately police the issues raised by the plaintiffs. However, Myriad and many of the *amicus* filers also noted that even if “markedly different” was found to be the appropriate standard, isolated nucleic acid molecules would find no difficulty in satisfying that requirement of patent eligibility based on the previously identified differences.

#### 2. The Department of Justice’s Amicus Filing

Because the USPTO was not named as a defendant in connection with the statutory issues that are the focus of the instant appeal, it did not file a brief on the merits with the Federal Circuit. However, on October 29, 2010 the Department of Justice (DOJ) did file an *amicus* brief in this appeal on behalf of the U.S. Government.<sup>10</sup> This brief has

been the subject of significant media attention, not only due to the controversial nature of the case itself, but also because the brief takes a position contrary to longstanding practice of the USPTO in issuing these types of patents and to the National Institutes of Health’s practice of pursuing and obtaining these types of patents. Although the DOJ’s brief does not track the analysis of the District Court, it does agree, in certain circumstances, with the District Court’s finding that claims to isolated nucleic acid molecules represent patent-ineligible subject matter.

In contrast to the District Court’s finding that any nucleic acid capable of coding for a naturally-occurring protein represents patent-ineligible subject matter based on its information content, the position advanced in the DOJ’s *amicus* filing is far more restrained. The DOJ contends that the “touchstone for resolving this appeal” is “the distinction between products of nature and human-made inventions.”<sup>11</sup> Thus, isolated molecules that evidence the intervention of man, for example by attachment to other sequences, are considered by the DOJ to be patent-eligible subject matter, even if the molecules do ultimately encode a naturally-occurring protein. Genomic DNA, on the other hand, is asserted by the DOJ to be a product of nature and therefore represents patent-ineligible subject matter. The DOJ extends this principle to the claimed molecules by arguing that the mere isolation of all or a portion of a genomic DNA molecule, such as a portion that encodes either BRCA1 or BRCA2, would be insufficient to render that subject matter patent-eligible. This narrow interpretation of the natural phenomena exclusion would effectively eliminate the patent-eligibility of subject matter such as isolated naturally-occurring sequences, but would allow for the eligibility of subject matter that evidence some minimal amount of human engineering beyond mere isolation.

#### 3. The Plaintiffs and Amici in Favor of Affirmance

On November 30, 2010, the plaintiffs filed their brief with the Federal Circuit requesting the judgment of the District Court be affirmed. The plaintiffs’ brief, as well as the numerous *amicus* filers supporting affirmance of the lower court’s judgment, reiterated many of the same arguments advanced in the proceedings below relating to the alleged patent-ineligibility of isolated nucleic acid molecules. However, one entirely new position advanced by the plaintiffs in their brief notes that, as discussed above, the U.S. Government has expressly changed its position regarding the eligibility of isolated genomic sequences. In fact, the plaintiffs argue that based

*cont. on page 6*

on the reasoning outlined in the DOJ's brief, even claims to cDNAs would represent patent ineligible subject matter, in contrast to the DOJ's position to the contrary.

#### IV. CONCLUSION - STRATEGIES FOR THE PATENT PRACTITIONER

With the filing of the plaintiffs' brief on the merits and the subsequent *amicus* filings, briefing in the appeal is now closed and a decision from the Federal Circuit is expected later this year. However, since the law will remain unsettled until all possible appeals are exhausted, it is imperative that practitioners review their patent portfolios to ensure, whatever the ultimate outcome may be, that they have appropriately addressed the issues being raised in this case. For example, when drafting new patent applications, it is increasingly important to incorporate sufficient disclosure to support claims not only to the isolated genomic sequences, but also to engineered sequences, such as cDNA sequences and sequences present in the context of vectors. Similarly, when prosecuting pending applications, it will be important to consider hedging against the potential outcomes of this case by pursuing claims directed to the traditional isolated nucleic acid subject matter as well as claims directed specifically to engineered molecules and methods of their use.

This type of portfolio review should not end with newly drafted or pending cases. It is also important that practitioners review the issued cases in their portfolios to determine whether a reissue filing is warranted. This will become even more important if the plaintiffs in this case are successful, or even partially successful, in their bid to have isolated nucleic acid molecules that correspond to naturally-occurring sequences declared patent-ineligible subject matter. For example, a narrowing reissue application that introduces claims directed to engineered DNA molecules could be pursued in a case where broad claims to isolated nucleic acid molecules had originally issued. The timing and appropriateness of such a reissue application would have to be scrutinized in order to ensure compliance with current statutory requirements, but given the current backlog at the USPTO, it may be advantageous to have completed this analysis ahead of a potential rush of newly filed reissue applications.

**Editor's Note:** Baker Botts LLP filed *amicus* briefs on behalf of two industry organizations in the *AMP v USPTO* case (one with the District Court and one with Federal Circuit), both of which argued that claims to isolated nucleic acids should be found patent-eligible.

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#### (Footnotes)

<sup>1</sup> See USPTO's Brief in support of its Motion for Summary Judgment in *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, (S.D.N.Y.), page 23, footnote 6 (internal citation omitted).

<sup>2</sup> See Myriad's Brief in support of its Motion for Summary Judgment in *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, (S.D.N.Y.), page 8.

<sup>3</sup>*Id.* at 32.

<sup>4</sup> See USPTO's Brief in support of its Motion for Summary Judgment in *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, (S.D.N.Y.) page 22.

<sup>5</sup> See, *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 702 F.Supp.2d 181, 185 (S.D.N.Y. March 29, 2010, as amended April 5, 2010).

<sup>6</sup> *Id.* at 227.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 229.

<sup>9</sup> *Id.* at 232.

<sup>10</sup> As this brief was filed in support of neither Myriad nor the plaintiffs, the Federal Circuit rules required that it be filed prior to the plaintiffs' brief on the merits.

<sup>11</sup> See the DOJ's Brief for the United States as Amicus Curiae in Support for Neither Party for Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al., case number 2010-1406 in the U.S. Court of Appeals for the Federal Circuit, page 14.



The New York Intellectual Property Law Association Announces

*The*  
**89<sup>th</sup>**  
*Annual Dinner*  
IN HONOR OF THE  
*Federal*  
*Judiciary*

**Friday, March 25, 2011**

*Waldorf=Astoria Hotel*  
*New York City*

*Keynote Speaker*



**Honorable John Gleeson**  
*United States District Court*  
*for the Eastern District of New York*

*Outstanding Public Service*  
*Recipient*



**Honorable Arthur J. Gajarsa**  
*United States Court of Appeals*  
*for the Federal Circuit*

*Lifetime Achievement Award (posthumous)*

**Honorable Giles S. Rich**  
*On the 60th Anniversary*  
*of his NYIPLA Presidency*  
*[1950-51]*

*Please note: Reservation Forms are due by February 9, 2011*  
**More information at [www.nyipla.org](http://www.nyipla.org) or 1.201.461.6603**

## *Day of Dinner CLE Program*

**Friday, March 25, 2011**

TOPIC:

***“A View From The Bench On The Role Of The  
Expert Witness In Patent Litigation”***

*Waldorf=Astoria Hotel*  
*New York City*

Earn 2.0 NYS/NJS CLE Credits

SEPARATE REGISTRATION FROM THE DINNER

## “Cattle Call”

*Cattle call, n., a mass audition (as of actors).*

by John B. Pegram

One of my earliest solo appearances in the Southern District of New York was in the late 1960s at what we called a “cattle call.” Chief Judge Sidney Sugarman had set himself the task of reviewing all pending civil cases to get them moving. Therefore, practically every case was set for a status conference, by notice in the *Law Journal*, scheduling perhaps 20-30 cases per half day.

The SDNY had not yet adopted the “individual assignment” system, in which each case is assigned at the outset to a judge for all purposes. Instead, judges rotated through the motions part, hearing whatever civil action pretrial motions were ready to be heard that week. Cases were assigned to a judge only for trial. There was little impetus from the court to bring cases to trial and the court’s backlog was growing.

It was a warm summer day when I walked up to Foley Square from our office downtown in response to a “cattle call” notice. The conferences were noticed for the large courtroom on the main floor of the U.S. Courthouse. The courtroom was quite full of attorneys, some reading the paper, some chatting amiably, and a few arguing and then walking away in real or feigned pique. This was a familiar scene for me; similar to the motion hearing days in that courtroom. A deputy clerk appeared at the judge’s entry door every few minutes and called a case. My curiosity grew, because I had never been behind that door.

After a short conversation with the plaintiff’s attorney, a brief hello to counsel for the other defendant and a long wait, our case was called. Behind the door was a most unusual sight.

The room was approximately 20 by 20. Really, it was

*John B. Pegram is a Past President and Interim Historian of NYIPLA, and a Senior Principal of Fish & Richardson, P.C.*



intended to be a hallway, with doors on every side. The walls were covered with the standard General Services Administration paint: dark green on the lower part and light green above. A large, single incandescent bulb illuminated the space from a ceiling fixture. Judge Sugarman was seated on a long side of a rectangular table. The jacket of his blue and white striped seersucker suit hung on the back of his chair. He wore a green celluloid eyeshade. The sleeves of his shirt were rolled up and held in place by elastic garters. This was not the way we were accustomed to seeing a judge.

To the judge’s left was a law clerk and to his right was a deputy clerk, each with stacks of paper. I soon learned that some of the papers were mimeographed forms for several types of orders. The judge listened attentively to the attorneys in the case preceding ours, asked a few questions and then barked “Ninety day order.” The deputy clerk selected the form setting another status conference, filled in “90” and the caption, and the order was signed.

We were then called forward. The conference was brief. Plaintiff’s attorney said he had settled with Mr. Pegasus’s client and was ready to proceed to trial against the other party. I confirmed the settlement and requested leave to submit an order of dismissal. Dismissal was granted on the spot by a form order. The other defendant’s counsel was stunned, as he was unaware of our settlement. The judge inquired about the possibility of his client settling. The other defendant’s counsel mentioned his last royalty offer which Plaintiff’s attorney said was less than a quarter of what our client had agreed to pay and that our client had a most favored clause on a per unit basis. (Our client made much larger units). The other defendant’s counsel urged the judge to intervene. Judge Sugarman replied “I am not going to play Solomon and divide the baby. Sixty day order. If you come back, I am assigning the case for trial.”

Apparently, Judge Sugarman and his colleagues concluded that the system of motion judges and cattle call status conferences was not very effective for managing litigation. The individual assignment system was adopted shortly thereafter. ■

## Judge Rader's Remarks at NYIPLA's CLE Luncheon

by John Pegram

The Honorable Randall R. Rader, Chief Judge of the U.S. Court of Appeals for the Federal Circuit, spoke at the NYIPLA's CLE Luncheon Program on Monday, December 13, 2010. The principal topics included electronic filing, reducing discovery expense, international matters, a speech he plans to give this spring in the Eastern District of Texas, and some damages issues. Perhaps most interesting was Judge Rader's frequent connections of the role of the patent litigation system to the marketplace.

**1. State of the Federal Circuit** – The Federal Circuit is alive, well and ready to do its Constitutional duty. Within the next six to eight months, the Court will transition to the electronic docket system used by other circuits – this will permit electronic filing. Judge Rader was hoping that Judge Kathleen O'Malley will join the court soon [she was sworn in on December 27<sup>th</sup>] and that two other judicial vacancies will also soon be filled.

**2. Discovery Limits** – The Federal Circuit Advisory Council is considering a proposal by Judge Rader to limit the cost of discovery. Because of the small chance something could be missed, limiting discovery is potentially “a little bit of injustice,” which the Judge suggested was justified by the greater good of reduced discovery costs. In particular, he has suggested limiting “free” e-discovery to 5-7 search terms, beyond which the party seeking discovery would pay the cost. (No explanation was provided regarding how the Federal Circuit might impose this requirement.)

**3. International** – Most of the speech discussed implications for judicial systems of the international marketplace. Judge Rader said the judge's job is to facilitate the market and avoid conflicting results. He observed that there had been a reduction in conflicting decisions in Europe as a result of judges having met regularly. Increasingly, their patent decisions are referencing decisions of other national courts on counterpart patents and are beginning to converge.

**4. Japan** – The Federal Circuit will travel to Japan this spring for a judicial conference with the IP High Court. Judge Rader suggested

that the U.S. and Japan will both benefit from exchanges among judges and practitioners. The U.S. judges' travel expenses are being paid by the USPTO.

**5. China** – “Next, China,” said Judge Rader. Judges there are chosen among government employees and are bound by government policy. He hopes to help China appreciate the benefits of an unfettered judiciary and to persuade Chinese judges to improve the treatment of foreign litigants.

**6. E.D. Texas** – Judge Rader reported that in response to one of his comments regarding equal treatment of foreign litigants, a Shanghai judge had asked, “Is that the way they do it in the Eastern District of Texas?” Judge Rader said we have to make sure our judiciary is not embarrassed by such allegations. He used that comment as a transition to three of the six “recommendations” he plans to discuss in a speech in Marshall, Texas, possibly in March. A written version of the speech will be posted on the Federal Circuit's website.

Judge Rader also spoke of the six cases he had handled in Eastern District of Texas: one went to trial, one was settled and four were decided on summary judgment.

**7. Summary Judgment** – The first recommendation Judge Rader plans to discuss in his Texas speech is adequate use of summary judgment tools.

**8. Early Evaluation** – Not all cases are of equal value, but “How do you discover that early on?” Judge Rader's second recommendation is to inquire at an early stage into damages theories. He added that the value of inventions should also be identified early in the case and attention should be paid to that value throughout the litigation process.

**9. Damages Theories** – The wrong answer to an inquiry regarding the patentee's damages theory is to say “Microsoft makes X dollars per year and all we want is a small part.” Judge Rader noted that in both the case he tried in Marshall and the *Cornell* case in which he presided sitting by designation (*Cornell University v. HewlettPackard Co.*, 609 F.Supp.2d 279 (N.D.N.Y. 2009)), he had

*cont. on page 10*

excluded damages experts. There should be no such thing as a 25% rule of thumb which cannot possibly be relevant. He traced the “rule of thumb” doctrine to a particular set of facts in a multipatent case many years ago and said it was cited by experts who failed to do a proper regression analysis to strip out factors other than the contribution of the invention.

**10. Bright Line and Balancing Tests** – In responding to a question whether the Federal Circuit had abandoned bright line tests, Judge Rader said that the problem with a balancing test is that you never know the answer until you ask the judges and that defeats decision-making in the marketplace. There is virtue in a bright line. “Ask any CEO,” he said.

**11. Patent Legislation** – Another question asked whether Judge Rader perceived any need for patent litigation reform legislation, particularly with respect to making judges the damages “gatekeepers” after several years of failed legislation and many

topics having been addressed by the Supreme Court and Federal Circuit. He responded that the [Senate] committee took the gatekeeper proposal from the *Cornell* case, where the judge (Rader) had been a former counsel to the committee. He suggested that the gatekeeper may already be a part of the law. More generally, he suggested that a reform bill would have a lot less value now than in the past, but noted that there will be pressure from lobbyists to have some bill passed, suggesting that might be used to justify their efforts. A lot of what was in past bills, he suggested, could be jettisoned. Later, he commented “Sometimes, we don’t have to wait for Congress to act.”

**12. Amicus Briefs** – Judge Rader said that the most useful amicus briefs for him are those that give an indication of the long-term consequences in the marketplace. It is helpful when briefs refer to analogies elsewhere in the world or in our own past. “Me too” amicus briefs are not very helpful.

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## Board of Directors Meetings Reports

### Summary of the November 16, 2010 Meeting

The meeting was called to order at the offices of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., 666 Third Avenue, New York by President Dale Carlson. Theresa Gillis, Charles Hoffmann, Dorothy Auth, Susan Progoff, John Delehanty, Allan Fanucci, Walter Hanley, Ira Levy, Doreen Costa and John Moehringer were present. Alice Brennan and Jeffrey Butler participated by conference call. Also present was Feikje van Rein of Robin Rolfe Resources. Absent and excused were Mark Abate, Leora Ben-Ami and Tom Meloro.

The minutes of the October 19, 2010 meeting were approved.

Alice Brennan presented the Treasurer’s report. The Association is on better financial footing than a year ago. Overall expenses have decreased year-over-year.

The November 4<sup>th</sup> Full Day CLE program had about 135 people in attendance and it generated a profit for the Association.

The Board discussed its speaker reimbursement policy and decided to continue with past practice whereby out-of-town speakers will have their registration fee waived, NYIPLA member speakers will pay the speaker-discounted fee, and all others will pay the registration fee. The Board Liaison has been given the authority to decide any special requests. The Board passed a motion to waive speaker registration fees for CLE Luncheons.

The Past Presidents Dinner held at Oceana on November 9, 2010 was well attended.

Ira Levy reported on the preparations for the next CLE Luncheon to be held on Dec. 13, 2010, featuring Chief Judge Rader of the Federal Circuit as the luncheon speaker.

Charles Hoffmann reported on the activities of the Amicus Brief Committee. Two NYIPLA amicus briefs are currently pending. The Board considered a request for an Amicus Brief in the *Stanford v. Roche* case and has requested the Amicus Committee make a recommendation. In addition, the Board discussed filing an amicus brief in *SEB v. Montgomery Ward & Co.* The Committee is seeking volunteers to draft the brief.

In accordance with the Bylaws, Dorothy Auth read a list of new members, at which point the Board passed a motion to accept them.

Terri Gillis reported the current status of the membership renewal process. The members’ progression through membership categories (based on the years of experience) and more membership renewals have resulted in a gain in membership revenue as compared with revenue collected last year. The Board agreed that a welcome letter will be sent to all new members.

The Board Liaisons gave an update on the committees for which they have oversight. Several committees are still in the process of getting organized and arranging their first meeting while others are operating in full swing.

Dale Carlson reported that planning for the 2011 Judges' Dinner is moving forward on schedule. The Board approved holding the ticket price at the 2010 Judges Dinner pricing: *i.e.*, \$300 for members and \$495 for non-members.

Dorothy Auth noted that she plans to meet with the CLE Committee Chairs to begin planning for the Day of Dinner program. A discussion followed concluding that the topic for the program should be of particular interest to the judges in attendance.

Charles Hoffmann reported that the Annual Meeting planning has begun.

The meeting was adjourned at 2:00 p.m. The next meeting is scheduled for Tuesday, December 14<sup>th</sup>, at noon at the offices of Ropes & Gray.

### Summary of the December 14, 2010 Meeting

The meeting was called to order at the offices of Ropes & Gray, LLP, 1211 Avenue of the Americas, New York by President Dale Carlson. Theresa Gillis, Charles Hoffmann, Dorothy Auth, Mark Abate, Jeffrey Butler, Susan Progoff, John Delehanty, Allan Fanucci, Walter Hanley and John Moehringer were present. Also present were Robin Rolfe and Feikje van Rein of Robin Rolfe Resources. Absent and excused were Leora Ben-Ami, Alice Brennan, Doreen Costa, Ira Levy and Tom Meloro.

The minutes of the November 16, 2010 meeting were approved.

In Alice Brennan's absence, Terri Gillis presented the Treasurer's report. The Association continues to be on a solid financial footing.

The December 13 CLE Luncheon featuring Chief Judge Randall Rader as the keynote speaker had 65 people in attendance. The presentation was well received.

Charles Hoffmann reported on the activities of the Amicus Brief Committee. Two NYIPLA amicus briefs are currently pending. The Board discussed requests for an Amicus Brief in the following cases: *Stanford v. Roche*, *CiproUS*, *Microsoft v. i4i Partners* and *Sun v. Lily*. Several Board members recused themselves from the individual case discussions.

In accordance with the Bylaws, Dorothy Auth read a list of new members, at which point the Board passed a motion to accept them.

Terri Gillis reported that membership renewals are ahead of the renewals at this time last year.

The Board discussed the annual NYIPLA scholarship, its naming, and law schools to consider for the 2011 scholarship.

Dale Carlson reported that planning for the 2011 Judges' Dinner is moving forward on schedule. Information regarding the Dinner will be made available to the members by mid-December.

The meeting was adjourned at 2:15 p.m. The next meeting is scheduled for Tuesday, January 25<sup>th</sup>, at noon at the offices of Wiggin and Dana.

## CALL FOR NOMINATIONS 2011 NYIPLA INVENTOR OF THE YEAR AWARD

*Deadline: Friday, January 28, 2011*

We invite you to nominate an individual or group of individuals who, through their inventive talents have made a worthwhile contribution to society by promoting the progress of Science and useful Arts.

The Nomination Form for the 2011 Inventor of the Year Award can be found at:

[www.NYIPLA.org](http://www.NYIPLA.org)

For more information contact:  
Jessica L. Copeland, Hodgson Russ LLP,  
at

**1.716.848.1461**

or  
[jcopeland@hodgsonruss.com](mailto:jcopeland@hodgsonruss.com).

## 2011 NYIPLA Honorable William C. Conner Intellectual Property Law Writing Competition

*Deadline: Friday, March 11, 2011*

The Winner will receive a  
cash award of \$1500.00

The Runner-up will receive a  
cash award of \$1000.00

The competition is open to students enrolled in a J.D. or LL.M. program (day or evening). The subject matter must be directed to one of the traditional subject areas of intellectual property, *i.e.*, patents, trademarks, copyrights, trade secrets, unfair trade practices and antitrust.

[www.NYIPLA.org](http://www.NYIPLA.org)

For more information contact:  
Maren C. Perry, Leason Ellis LLP,  
at **1.914.821.9078**  
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## NEW MEMBERS

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### PLEASE NOTE

The NYIPLA's Executive Office has changed.

The new contact is

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## THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION, INC.

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### Officers of the Association 2010-2011

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 President-Elect: Theresa M. Gillis  
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 2nd Vice President: Charles R. Hoffmann  
 Treasurer: Alice C. Brennan  
 Secretary: Dorothy R. Auth

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