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In This Issue

Reverse Payment Terms In ANDA Settlement Agreements

In the wake of the Supreme Court's denial of certiorari in Cipro V the FTC and DOJ should be required either to abandon their campaign against reverse payment terms in ANDA settlements or to offer some substitute formulation which satisfies their objections <u>to PRE and to any other aspect of the "Consensus Rule" of *Tamoxifen**</u>

by David F. Ryan[1]

A. Introduction

On March 7, 2011, the Supreme Court of the United States denied a petition for certiorari which sought review of the decision of the Court of Appeals for the Second Circuit in *Cipro V.*[2] That petition represented a challenge by a number of direct purchaser antitrust treble damages plaintiffs to the twin determinations by the Second Circuit in *Cipro V* (a) that "reverse payment" terms in settlement agreements terminating ANDA infringement litigations under the Hatch-Waxman Act[3] were not presumptively unlawful, and (b) that the Court of Appeals would adhere to the rule it had announced in its *Tamoxifen* decision more than five years ago.[4]

The rule of *Tamoxifen*, sometimes referred to in this article as the "consensus rule", provides that unless at least one of three types of misconduct can be established, reverse payment terms in ANDA settlement agreements will be upheld against challenges under the antitrust laws:

> Unless and until [1] the patent is shown to have been procured by fraud, [2] or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, [3] as long as competition is restrained only within the scope of the patent [citing Cipro III][5].
>
> We further agree with the *Cipro III* court that [3] absent an extension of the monopoly beyond the patent's scope * * * * and [1] absent fraud * * * * [2] the question is whether the underlying infringement lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" [citing *PRE*][6].

466 F.2d at 213 (numerical brackets supplied). As can be seen, the consensus rule announced by the Second Circuit in Tamoxifen explicitly engrafts the Supreme Court's holding in PRE onto the controlling test.

In PRE, the Supreme Court ruled that before initiation of an intellectual property infringement lawsuit can be proscribed under the antitrust laws, a two-part test must be satisfied:

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PRESIDENT'S CORNER

March 28, 2011

Dear Fellow Members:

As you read this column, my penultimate one as NYIPLA President, our March 25th Judges' Dinner will have already occurred. For those members who were able to attend, my hope is that you had a pleasant and memorable evening.

As an aside, Past President John Pegram observed that all three federal judges honored at the Dinner have names beginning with a "G", causing him to think that I must have a penchant for the letter "G". In an "ah-ha" moment, John recalled that my wife's name begins with a "G". Good golly!

Unfortunately, some of our members were not able to attend the Dinner, for reasons of health, location or schedule. Especially for you, my Welcome Letter is reproduced below, as it appeared in the Dinner program book.

If you were unable to attend, please feel free to reach out to Feikje Van Rein at fvanrein@robinrolferesources.com to request a complimentary copy of the compact disc about Judge Rich's life that was distributed at the Dinner.

"I am most pleased to welcome you to the 89th Annual Dinner in Honor of the Federal Judiciary.

On this occasion, it is fitting to consider Samuel Taylor Coleridge's words: 'often the spirits of great events stride on before the events, and in today already walks tomorrow.' Our gathering here at the Waldorf promises to be a great event. Perhaps the spirits of the great minds of those who have graced our Association's gatherings in decades past are here beside us now. If you look around the room through your mind's eye, you may sense their presence.

Tonight, we honor one such great mind from the past, that of Judge Giles Rich. Some of you knew him personally, others may know of him, and still others may wish to learn about him. For each of you, the Association has a gift for you to read and hopefully treasure.

The gift is a CD at the back of the program book. The CD contains a journal prepared by the Federal Circuit Historical Society. The journal speaks to Judge Rich's passions, including his love of the law and his family, and his resolve to maintain a strong patent system. My short article in it discusses the NYIPLA's role in facilitating Judge Rich's career growth.

Tonight, we also honor great minds from among our living federal judges. Judge Arthur Gajarsa, of the U.S. Court of Appeals for the Federal Circuit, is the recipient of our Association's ninth annual Outstanding Public Service Award. Judge John Gleeson, of the U.S. District Court for the Eastern District on New York, is our Keynote Speaker.

All three judges can truly feel at home in our region. Judge Gajarsa launched his career as a patent examiner in the U.S. Patent Office, and later worked as a patent advisor for the Department of Defense, and as a patent agent for a Washington, D.C. IP boutique in patent litigation involving an early electronic computer.

Judge Gajarsa has ties to New York and Connecticut. He received his undergraduate degree in electrical engineering from Rensselaer Polytechnic Institute in Troy, New York. Currently, he Chairs RPI's Board of Trustees. He is a member of the Connecticut bar, and early in his career worked for an insurance company in Hartford, CT.

Judge Gleeson began his career at Cravath, Swaine and Moore in New York. Later, he became an Assistant United States Attorney in the Eastern District of New York, and eventually rose to Chief of the Criminal Division.

Judge Gleeson is co-author of the treatise *Federal Criminal Practice: A Second Circuit Handbook*, LexisNexis (10th Edition 2010). He has taught courses at Brooklyn Law School and the University of Virginia School of Law. Currently he is an Adjunct Professor at New York University School of Law where he teaches courses in Complex Federal Investigations and Sentencing.

Judge Rich started at his father's patent firm in Manhattan at the beginning of the Great Depression. Later, he taught patent courses as an Adjunct Professor at Columbia University's School of General Studies in the 1940s and 1950s.

Judge Rich was NYIPLA President in 1950-51. He co-authored the Patent Act of 1952. In his "second career" as a member of the judiciary, he went on to become the longest-lived, active federal judge in the history of our country, passing away in 1999 at age 95.

To each of these judges and their families, I say: 'Welcome home'.

To all judges present, and their families, I say: 'Thank you for joining us. You make this gathering possible.'

To my wife, Ginger, the rest of my family, friends, colleagues, and mentors, I say: 'Thank you. Your selfless support lifts me to the podium this evening.'

To all attendees, I say: 'Thank you for being here. Take hope from Mr. Coleridge's words: '...in today already walks tomorrow.'"

With kind regards,

Dale Carlson
NYIPLA President

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> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits . . . Only if challenged litigation is objectively baseless may a court examine the litigant's subjective motivation . . .This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability.

508 U.S. at 60-61 (emphasis in original). If the enforcement agencies elect to continue their campaign against reverse payment terms in ANDA settlements, they should be forced to finally come to grips with the *PRE* decision which they have already succeeded in avoiding for more than ten years.

The denial of certiorari in *Cipro V* represents the final chapter of yet another setback story in the almost unbroken chain of Court of Appeals losses which the Federal Trade Commission ("FTC") has suffered during its campaign to establish the "per se" or "presumptive" illegality of reverse payment terms in ANDA settlements.[7] The public phase of this lengthy campaign – which has involved administrative litigations, consent judgments, amicus filings and, most recently, support for legislation – celebrated its eleventh anniversary just this month.[8] The denial of certiorari in *Cipro V* is also noteworthy because, amid a wave of publicity in 2009, the Department of Justice ("DOJ") had announced that it would align itself with the FTC for the first time in *Cipro V* and seek application of a rule of presumptive illegality to ANDA reverse payment settlement agreements.[9]

The Supreme Court's denial of certiorari in *Cipro V* was proper (1) because the Second Circuit merely reiterated the consensus rule of *Tamoxifen* which it had announced more than five years ago; (2) because the petition raised no novel issues; (3) because alteration of the consensus rule might well undermine the Congressional purpose of maximizing patent challenges by generic pharmaceutical manufacturers under the Hatch-Waxman Act as well as the more general public policy objective of encouraging settlement of other types of patent litigation (at least in areas where similar asymmetries in settlement leverage are known to exist); (4) because predictions of success or failure in patent litigation are inherently uncertain and post hoc assessments of patent strength are even less reliable; (5) because lowering the bar for antitrust challenges to patent settlements inevitably would result in a chilling effect on such settlements which, in turn, might lead to the across-the-board R&D budget reductions at both generic and innovator pharmaceutical manufacturers; (6) because the antitrust enforcement authorities have never proposed any realistic alternative to the *Tamoxifen* rule; and (7) because the FTC and DOJ have both refused to confront the fact that the *Tamoxifen* rule is itself inextricably intertwined with the Supreme Court's *PRE* decision – and that, accordingly, any alteration of that rule might require that *PRE* itself be overruled or modified.[10]

As yet, there has been no indication that the denial of certiorari in *Cipro V* will lead the FTC or the DOJ to acquiesce in the consensus rule of *Tamoxifen*.[11] In any event, several high profile FTC reverse payment ANDA settlement litigations are currently pending in at least the Third and Eleventh Circuits, and it is expected that prior legislative proposals to alter the consensus rule of *Tamoxifen,* will be renewed before the current Congress.

Both of the enforcement agencies remain dissatisfied with the consensus rule of *Tamoxifen,* and, indeed, that dissatisfaction on the part of the DOJ may well have led to the belated support offered by the Antitrust Division for the FTC's fallback theory of presumptive illegality in 2009. Both of the agencies likewise appear dissatisfied with the Supreme Court's decision in *PRE* – a decision which neither agency even attempted to deal with in any appellate brief for a period of more than ten years. That ten-year period finally ended last summer with the filing of the FTC's *Watson*[12] appeal brief with the Eleventh Circuit – almost five years after the Second Circuit had incorporated the holding of *PRE* into the consensus rule of *Tamoxifen*.[13]

Apart from their short-lived and unsuccessful attempt to convince the Second Circuit to abandon the consensus rule of *Tamoxifen* in favor of the presumptively unlawful standard in *Cipro V*,[14] the enforcement agencies have never proposed any judicial substitute for the consensus rule of *Tamoxifen*. The author respectfully submits that the enforcement agencies should be required (1) to set forth with specificity for the Courts and Congress any proposals they may harbor for replacement of the consensus rule of *Tamoxifen*, (2) to identify any areas of disagreement they may have with that rule, and (3) to memorialize any objections they may have to the Supreme Court cases – most particularly *PRE* – upon which the consensus rule of *Tamoxifen* is based.

B. The First Four Certiorari Petitions in Reverse Payment Litigations

The certiorari petition in *Cipro V* represented the sixth time the Supreme Court had been asked to render a substantive ruling regarding reverse ANDA settlement payments. All six of the petitions for certiorari have now been denied by the Supreme Court, three of them (including the petition challenging *Tamoxifen*) after the views of the Solicitor General ("SG") supporting the denial of certiorari had been requested and reviewed by the Supreme Court.[15]

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1. *Andrx v. Kroger (Cardizem)*

A little more than seven years ago now, on December 29, 2003, the NYIPLA filed a brief *amicus curiae* with the United States Supreme Court supporting the grant of a petition for certorari in *Andrx v. Kroger* – a consolidated private treble damages litigation arising from the same alleged facts previously pleaded by the FTC in *In re Hoechst Marion Roussel* and the first of the six Court of Appeals reverse payment ANDA cases in which petitions for certiorari were denied by the Supreme Court.[16] The NYIPLA argued that certiorari should be granted because of "the stark contrast between" the *Cardizem* decision in which the Sixth Circuit purported to apply a per se rule of illegality[17] and the Eleventh Circuit's ruling in *Valley Drug*[18] (Br. 4-5), and to clarify "how a *per se* rule proscribing settlement payments could be accommodated with" the following four specific categories of precedents (Br. 7):

> First, because agreements settling patent litigation remain favored as a matter of public policy, the antitrust legality of their ancillary or subsidiary terms should be evaluated under the rule of reason rather than as naked horizontal restraints . . .
>
> Second, patent settlement agreements remain presumptively lawful unless and until proved to be "objectively baseless" under the standard announced in *PRE* . . .
>
> Third, because territorial and field of use market allocations represent lawful ancillary restraints in a patent license, a temporal restriction on entry can be justified *a fortiori* as representing nothing more than a promise not to infringe for all or a portion of a presumptively valid patent's remaining term . . . and
>
> Finally, a patentee's refusal to license is always justifiable as part of what the Solicitor General recently told this Court represented "the core patent right of exclusion"[19] . . .

(Br. 6)

Some months later in July 2004, the SG filed his "Brief For The United States As Amicus Curiae" in *Andrx v. Kroger* (in which the FTC joined), finding no conflict between the *Cardizem* and *Valley Drug* decisions and recommending denial of the petition for certiorari. The SG argued that although "infringement settlements

Inventor of the Year Award

Please join us at the NYIPLA Annual Meeting on May 24, 2011
when we will be honoring the
2011 Inventor of the Year Award Winner

Dr. Rajiv Laroia

Dr. Laroia will be recognized for his pioneering work at Qualcomm Flarion in the area of OFDM (Orthogonal Frequency Division Multiplexing) which is the foundation for future generation telecommunication technologies such as LTE, 4G and Wi-Fi.

We will also present an NYIPLA Young Innovators Award to a group of students, Barber et. al., for their invention made during high school relating to a curb climbing wheelchair.

precluding entry by the alleged infringer in exchange for reverse payments may raise antitrust concerns", nevertheless "such agreements are not necessarily subject to per se condemnation" (Br. III). The SG also pointed out that *Cardizem* involved "an agreement that has been construed to exclude non-infringing and potentially non-infringing products" and, accordingly, "does not squarely conflict with" *Valley Drug* (*Id*.).

2. *Valley Drug*

In *Valley Drug,* the Eleventh Circuit explicitly held that reverse payment provisions in ANDA settlements could not be characterized as per se unlawful because they secured to the patentee no more than could have been obtained by enforcement of the patent in the settled litigation. Citing the Federal Circuit's *Xerox*/*ISO* decision, the Court noted that "a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself" (344 F.3d at 1305). The Court of Appeals then quoted the late Honorable David G. Trager's decision in *Cipro II,*[20] in ruling that where settlements do not expand the temporal or subject matter scope of the patent's claims, "the exclusionary effect of the patent must be considered before making any determination as to whether the restraint is per se illegal" (*Id*. at 1306).

Based in part upon Judge Trager's "concern for the effect of settlement-restricting antitrust liability rules on the incentives for research and development" as set forth in *Cipro II* (261 F.Supp.2d at 256), the Court of Appeals went on to conclude that

> exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.

344 F.3d at 1308 (footnote omitted). When the antitrust plaintiffs petitioned to overturn this result, certiorari was again denied by the Supreme Court.

3. *Schering-Plough*

In supporting the petition for certiorari before the Supreme Court in *Andrx v. Kroger*, the NYIPLA had pointed to the then recent December 18, 2003 decision of the Commission in *Schering-Plough*[21] and argued that "the grant of certiorari would facilitate essential guidance for the FTC as well" (Br. 15-17).

On March 8, 2005, the Court of Appeals for the Eleventh Circuit set aside the decision of the Commission in *Schering-Plough* and vacated the cease and desist order. The Court chided the Commission for ignoring portions of the ALJ's decision which were pertinent under the *Valley Drug* analysis and reiterated the Court's prior holding that the antitrust analysis of a patent settlement must focus on whether any purportedly anticompetitive effects exceeded the legitimate exclusionary effects of the patent. The Court of Appeals also ruled that the required traditional rule of reason analysis could not be truncated.

The FTC conceded that it had no evidence that the generics could have entered the market on their own prior to expiration of the patent and there was no evidence that the patents were invalid or that the infringement suits against the generics were not legitimate. In addition to its discussion of *Valley Drug*, the Eleventh Circuit again drew the policy arguments supporting the importance of the right to settle as encouragement for both generic Paragraph IV validity challenges and the R&D budgets of innovators, as well as the asymmetries in settlement leverage that the structure of ANDA litigation itself imposes from Judge Trager's *Cipro II* decision, as well as from Judge Posner's decision in *Asahi Glass*.[22]

Although the FTC had supported denial of the petition for certiorari in *Andrx v. Kroger* by joining in the SG's amicus curiae brief, the shoe was on the other foot in *Schering-Plough*. There it was the FTC that filed a petition for certiorari with the Supreme Court after the Eleventh Circuit's decision had vacated the Commission's decision which had held that the reverse payment provisions violated Section 1 of the Sherman Act, 15 U.S.C. §1. When the Supreme Court again solicited the views of the SG, the Court was informed that the petition for certiorari filed by the FTC should be denied.[23] Despite the filing by the FTC of a supplemental brief addressing the SG's arguments, the FTC's petition was in fact denied.

One of the most interesting aspects of the doctrinal split between the FTC and the DOJ was illuminated by the following passage set forth in the SG's brief amicus curiae:

> The FTC's approach, however, appears to place undue weight on the parties' subjective views of the strength of the claims as reflected in the settlement agreement, as opposed to a more objective assessment of the claims based on evidence extrinsic to the settlement.

(Br. 12). As will be discussed, in formulating rules of antitrust liability, objective standards are almost always preferable to subjective standards in terms of achieving predictability, ease of administration and fairness. Whenever possible, subjective assessments and predictions should be eschewed, as should hindsight assessments – even those made by putative experts.

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4. *Tamoxifen*

While the appeals in *Cipro IV and V* were pending before the Federal Circuit and Second Circuit, respectively, another panel of the Second Circuit issued the decision upholding the reverse payment agreements at issue in *Tamoxifen*. The panel in *Tamoxifen* cited the opinions of Judge Trager no less than seventeen times, and then, as already discussed, explicitly adopted Judge Trager's formulation of the applicable consensus rule in *Cipro III*.

The *Tamoxifen* decision also cited Judge Posner's opinion in *Asahi Glass* no less than five times, principally in connection with the public policy favoring the settlement of patent litigation; the uncertainties involved in such litigation; and Judge Posner's suggestion that a ban on reverse payment settlements might itself be deemed anticompetitive to the extent it reduced settlement incentives in violation of public policy.

The Second Circuit denied rehearing *en banc* and, after soliciting and receiving the SG's opinion that certiorari should be denied, the Supreme Court yet again denied certiorari.

C. The Last Two Certiorari Petitions in the *Cipro* Litigation

Bayer owns United States Patent No. 4,670,444 ("the '444 patent" or "the Cipro patent"), claim 12 of which covers the ciprofloxacin hydrochloride molecule, the active ingredient in Bayer's extremely successful Cipro® ("Cipro") antibiotic. In response to an ANDA Paragraph IV filing by Barr Laboratories, Inc. ("Barr"), Bayer sued Barr for infringement of the Cipro patent in the Southern District of New York. That suit was settled on terms which resulted in payments by Bayer to Barr of almost $400 million over a six-year period and represented about 6.5% of Bayer's gross U.S. sales of Cipro over the same period.

Starting in 2000, direct and indirect purchasers of Cipro filed antitrust challenges to the terms of Bayer's agreement with Barr and those cases were consolidated by the MDL Panel before Judge Trager. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 166 F. Supp. 2d 740, 745 (E.D.N.Y. 2001) ("*Cipro I*").

In the 2003 *Cipro II* decision, Judge Trager denied motions for partial summary judgment brought by the antitrust plaintiffs and rejected their contention that the settlement was *per se* unlawful – in part because "reverse payment" settlements represent a natural by-product of the asymmetries in settlement leverage inherent in the Hatch-Waxman process. As we already have seen, much of Judge Trager's Hatch-Waxman analysis in *Cipro II* was adopted by the Eleventh Circuit in *Valley Drug* and *Schering-Plough*.

In 2005, after the indirect purchaser plaintiffs had amended their complaints to charge state law *Walker Process*[24] claims, Judge Trager entered judgment for the defendants on all claims in *Cipro III*.

5. *Cipro IV*

All of the antitrust plaintiffs appealed the judgment in *Cipro III* to the Second Circuit, but the Second Circuit transferred the indirect purchaser cases to the Federal Circuit – based upon its determination that the alleged *Walker Process* claims fell within the exclusive jurisdiction which Congress had assigned to the Federal Circuit under 29 U.S.C. § 1295(a). In *Cipro IV*[25] the Court of Appeals for the Federal Circuit affirmed the very same district court ruling which the Second Circuit later affirmed in *Cipro V*.

In 2008, a unanimous Federal Circuit panel affirmed Judge Trager's *Cipro III* ruling, reasoning that "the court need not consider the validity of the patent in the antitrust analysis" and that the

> essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent.

544 F.3d at 1334-1336 (citations omitted). After the Federal Circuit denied rehearing *en banc*, certiorari was denied by the Supreme Court.

6. *Cipro V*

The Second Circuit's initial ruling on the appeal from Judge Trager's *Cipro III* decision issued on April 29, 2010, and its corrected opinion issued on June 17, 2010. As we have seen, its earlier *Tamoxifen* opinion had incorporated much of Judge Trager's language and reasoning from the very same *Cipro III* decision, and the Federal Circuit already had affirmed that ruling directly in *Cipro IV*. Under the circumstances, the Court of Appeals determined that it could not entertain a number of the economic and policy arguments made by the plaintiff-appellants and amici and ruled that

> These policy arguments cannot be addressed here. As defendants note, this panel is bound by *Tamoxifen* absent a change in the law by higher authority or by way of an en banc proceeding
>
> * * *
>
> However, there are several reasons why this case might be appropriate for reexamination by our full Court.

(App. 31a) (citation and quotation marks omitted).

The Second Circuit panel then outlined four reasons why the full Court might wish to grant rehearing en banc, including the Antitrust Division's argument that

> This Court's *Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract * * * * [T]his standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating undeserved patents.

(App. 32a). The Government proposed "that excessive reverse payment settlements be deemed presumptively unlawful unless a patent-holder can show that settlement payments do not greatly exceed anticipated litigation costs" (*Id*.).

On September 7, 2010, however, the petition for rehearing en banc was denied. As already discussed, on March 7, 2011 the Supreme Court summarily declined to issue the writ in *Cipro V* without soliciting the views of the SG for yet a fourth time.

D. Additional Support for the Consensus Rule of *Tamoxifen*

The consensus rule of *Tamoxifen* might well be characterized as a specific application to reverse ANDA payments of the broader principle that conduct authorized by the patent law cannot violate the antitrust laws. This principle is solidly grounded in Supreme Court law,[26] as are each of the three categories of misconduct identified in *Tamoxifen* which properly can be characterized as exceptions to the basic patent immunity principle.

Thus, category [1] misconduct (fraudulent procurement) is governed by *Walker Process*; category [2] misconduct (sham litigations and settlements) is governed by *PRE*; and category [3] misconduct (conduct which creates an anticompetitive effect beyond the legitimate subject matter or temporal scope of the patent claim in some properly defined relevant product market) is governed by a host of Supreme Court cases – some involving per se unlawful tying of patent rights to unpatented staple goods (use of patent leverage to create subject matter expansion beyond the scope of the claims) or post-expiration royalties (use of patent leverage to create temporal expansion beyond expiration);[27] and others, such as those involving allegations of package licensing, which require a more or less detailed rule of reason analysis of the putative anticompetitive effects of the alleged restraint in a properly defined relevant product market[28] – as well as by Sections 271(c) and (d) of Title 35.

The patent immunity principle as defined by the Supreme Court has been developed further by the Federal Circuit in a line of cases exemplified by *Xerox/ISO* and *Implant Innovations*.[29] Both Federal Circuit cases are well known to the antitrust enforcement agencies.

1. *Xerox/ISO*

As the SG's Amicus Brief in the Supreme Court advising against the grant of certiorari in *Xerox/ISO* explicitly recognized, the Federal Circuit's ruling that "a patent holder generally has no obligation to license or sell its intellectual property" is "subject to three established exceptions" – [1] where "the patent was obtained through fraud", [2] where "the infringement suit is a sham", and [3] where either the temporal or subject matter scope of the patent claim is "illegally extended beyond the statutory patent grant" (Br. 4-5). Once again, these three "exceptions" are the same as the three areas of misconduct identified by the Second Circuit in *Tamoxifen*.

The SG's principal purpose for analyzing the *Xerox/ISO* decision was to determine the extent of its conflict with the Ninth Circuit's *ITS* decision.[30] The NYIPLA had urged the Federal Circuit to affirm the district court's rejection of *ITS* in a brief amicus curiae[31] because:

> to the extent the Ninth Circuit's decision in [*ITS*] can be read as permitting a jury to find that a patentee's unilateral refusal to license or deal is "pretextual", it appears inconsistent conceptually with the Supreme Court's decision in [*PRE*].
>
> * * * * *
>
> In the analogous area of "sham" infringement suits, the Supreme Court in [*PRE*] ruled that no examination of a plaintiff's subjective intent can be undertaken in an infringement suit in the absence of a threshold determination that "the litigation is objectively baseless". [*PRE*], 508 U.S. at 51. The Supreme Court thus recognized the need to protect intellectual property owners against the threat of treble damages based upon untrammeled jury determinations of comparable subjective intent.

(Br. 4, 6). The Federal Circuit's rejection of the rule of *ITS* was predicated upon the Court's preference for objective

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over subjective rules, a principle it drew from both *PRE* and *Implant Innovations*.[32] This reasoning is not unlike that of the SG's amicus brief filed with the Supreme Court in *Schering-Plough* as discussed above.

Although the underlying rationales for the *Xerox/ISO* and *ITS* decisions were poles apart on the scale of objectivity, the SG found that the two Courts of Appeals "may harmonize their approaches upon further reflection" (Br. 16). Accordingly, he advised the Supreme Court that "further percolation of these difficult issues" would be appropriate (Br. 8), and certiorari was denied.

2. *Implant Innovations*

The FTC filed an amicus brief in the consolidated *Buspirone* litigations[33] which characterized the holding of *Implant Innovations* as follows:

> *PRE* and *Walker Process* provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws, and *Walker Process* liability may be imposed without the additional sham inquiry required under *PRE*.

(Br. 23 n.26).

E. A Few Brief Words on Economics

1. The Realities of the Generics Business

The generic segment of the pharmaceutical manufacturing industry favors the consensus rule and its trade association, The Generic Pharmaceutical Association, filed a short but very compelling brief amicus curiae in *Tamoxifen* opposing rehearing and rehearing en banc.[34] A substantial portion of the business of every generic pharmaceutical manufacturer is devoted to researching and challenging patents and the brief points out that at any one time every such manufacturer may have upwards of a dozen patents in litigation with full knowledge that it cannot afford "to try all of those to final judgment on appeal. (Br. 5).

The brief also indicates that the ability to generate income from a reverse payment settlement enables the generic to reallocate its litigation resources. The brief also confirms a number of the economic insights set forth in the *Asahi Glass* decision of Judge Posner.

2. "Pay For Delay" Presupposes "At Risk" Entry

The catchy Madison Avenue slogan that the FTC has employed for many years in its campaign is arguably misleading. The term "delay" presupposes a target entry date, but under the asymmetries of the Hatch-Waxman environment the favorable economics for patent challenges do not extend to "at risk" entry after expiration of the injunction. "At risk" entry in the generics business is extremely rare for the reason that a single miscalculation might well bankrupt even a substantial generic manufacturer.

3. Settlement Leverage Asymmetries Are Not Limited To Generics

The Hatch-Waxman environment does not represent the only situation in which imbalances in leverage can skew the economics of patent challenges and their settlement. The non-practicing entity ("NPE") may have tipped the balance in favor of the "one size fits all" injunctive relief standard in *eBay*,[35] but the primary villain in the FTC's latest report on the IP Marketplace is now the NPE's evil twin the patent asserting entity ("PAE").

Research joint ventures ("RJVs") and standard setting organizations ("SSOs") also may face rapidly changing settlement economics, particularly just before and after periodic standards revisions.

Indeed, there may well be any number of permanent trends or transitory market dislocations that might make reverse payment license agreements economically desirable in a broad range of industries.

F. Conclusions

Under the current consensus rule of *Tamoxifen*, in the absence of category [1] *Walker Process* fraud or a category [2] sham litigation or settlement that meets the requirements of *PRE*, the possibilities for establishing a category [3] Clayton Act Section 4 antitrust claim or patent misuse defense would seem to be limited to (a) assertions of temporal expansion predicated upon provisions impeding third party generic Paragraph IV challenges and market entry by creating regulatory bottlenecks, or (b) assertions of subject matter expansion predicated upon provisions preventing generic marketing of formulations not covered by the claims.

Once the FTC and DOJ face up to *PRE*, they may try to get the Supreme Court to modify or overrule that precedent. Given that they have tried to hide the ball for more than ten years, however, they may well have concluded that their chances for success with the Supreme Court are slim.

In any event, the enforcement agencies will continue to seek implementation of some alteration of the *PRE* standard from Congress. The change to a rebuttable presumption that reverse payment terms are unlawful would wreak havoc on the generic side of the industry and lead to a net reduction in Paragraph IV filings. The result on the innovator side probably would lead to a significant reduction in R&D budgets. Congress must be apprised of those facts.

The uncertainties of patent litigation and the dangers of incorporating subjective assessments into antitrust standards represent additional justifications for preserving the *PRE* standard, and Congress should be educated as to the reasons why the Courts of Appeal have repeatedly rejected the Government's theories.

* This article will also appear in a forthcoming issue of *The Computer & Internet Lawyer* and is published here with permission.

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[2] *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *cert. denied sub nom. Louisiana Wholesale Drug Co. v. Bayer AG*, No. 10-762, ___ U.S. ___ (Mar. 7, 2011) ("*Cipro V*").

[3] Abbreviated New Drug Application ("ANDA") infringement litigations are brought under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1595, as amended (popularly known as the "Hatch-Waxman Act"). Most of the Act's provisions governing ANDA infringement suits have been codified as Section 271(e) of Title 35.

[4] *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs., Inc*. (2007) ("*Tamoxifen*").

[5] *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 363 F. Supp.2d 514, 535 (E.D.N.Y. 2005) ("*Cipro III*").

[6] *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus*., 508 U.S. 49, 60 (1993) ("*PRE*").

[7] In the courts, the FTC apparently had abandoned its initial advocacy for a per se rule before the end of 2003. The FTC also joined in the SG's 2004 brief to the Supreme Court in *Andrx v. Kroger* which argued that, although the underlying *Cardizem* decision in the Sixth Circuit had purported to apply a per se rule, it was not really a per se case at all – but rather involved a species of type [3] misconduct in which the terms of the settlement agreement extended to non-infringing formulations which did not fall within the scope of the claims. Elsewhere, however, the FTC appears less punctilious as evidenced by the very first numbered page of a recent staff study brochure which refers to the *Cardizem* case as holding "that such agreements were automatically (or *per se*) illegal". Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions – An FTC Staff Study (January 2010).

[8] The public phase of the FTC's campaign began on March 16, 2000 with the announcement of a proposed consent judgment in *In re Abbott Labs*. (FTC Dkt. No. C-3945) ("*Abbott*") and the filing of an administrative complaint in *In re Hoechst Marion Roussel, Inc*. (FTC Dkt. No. 9293) ("*Hoechst Marion Roussel*"). The organization of the FTC's website has been vastly improved over the past several years. Whether or not that improvement can be attributed to the technological orientation of the Obama administration, it now seems superfluous to provide lengthy internet footnote cites to the specific locations of FTC docket entries and amicus briefs.

[9] Pursuant to this new stance, the DOJ filed a "Brief For The United States In Response To The Court's Invitation" on July 6, 2009 and a "Brief Amicus Curiae Of The United States In Support Of Rehearing En Banc" on June 3, 2010. Although the DOJ's website is slightly less user friendly than that of the FTC, it is still relatively easy to find the pertinent amicus briefs.

[10] Manifestly, no Court of Appeals would have the power to make such a change.

[11] Indeed, remarks made by FTC Chairman Jon Leibowitz at Georgetown Law Center on September 21, 2010 indicate rather clearly that the FTC intends to press its campaign on both the legislative and litigation fronts.

[12] "Brief For Plaintiff-Appellant Federal Trade Commission" in *Fed. Trade Comm'n v. Watson Pharms., Inc*., No. 10-12729-DD (11th Cir. Jul. 26, 2010) ("*Watson*").

[13] Almost incredibly, and apart from a single district court amicus submission by the FTC in 2002, it appears to the author that *PRE* likewise was never cited or briefed to any court by one of the antitrust agencies for the entire period from its citation in the Federal Circuit's *Xerox/ISO* opinion on February 17, 2000 until it was again cited by the FTC in **Watson** on July 26, 2010.

[14] "Short-lived" because, curiously and despite their new-found detente, neither agency elected to support the certiorari petition in *Cipro V* with a brief amicus curiae.

[15] Although the SG's brief in the Supreme Court criticized the Second Circuit's *Tamoxifen* decision, it advised against the grant of certiorari.

[16] "Motion Of New York Intellectual Property Law Association And Brief Of Amicus Curiae In Support Of Petitioner" in *Andrx v. Kroger*, a copy of which is available on the Association's website at *http://www.nyipla.org*.

[17] *In re Cardizem CD Antitrust Litig*., 332 F.3d 896 (6th Cir. 2003) ("*Cardizem*"), *cert denied sub nom. Andrx Pharms., Inc. v. Kroger Co*., 539 U.S. 939 (2004) ("*Andrx v. Kroger*"). Although the FTC's administrative complaint in *Hoechst Marion Roussel* had been settled by a non-precedential consent judgment in 2002, it nevertheless triggered the Clayton Act treble damages actions that were later consolidated into the multidistrict proceeding in which the Sixth Circuit rendered its decision. As pointed out in the NYIPLA's amicus brief, even proceedings such as *Abbott* which are initiated on the FTC's consent docket invariably provoke the initiation of treble damages actions (Br. 15-16 n.39).

[18] *Valley Drug Co. v. Geneva Pharms., Inc*., 344 F.3d 1294 (11th Cir. 2003), *cert denied*, 543 U.S. 939 (2004) ("*Valley Drug*").

[19] This is a reference to the SG's "Brief For The United States As Amicus Curiae" in *CSU, L.L.C. v. Xerox Corp*., No. 00-62 ("*Xerox/ISO*") which is discussed below.

[20] *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("*Cipro II*").

[21] *In re Schering-Plough*, Docket No. 9297 (Opinion of the Commission December 18, 2003), *vacated sub nom. Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied sub nom. Fed. Trade Comm'n v. Schering-Plough Corp*., 548 U.S. 919 (2006) ("*Schering-Plough*"). The administrative complaint in Schering-Plough had been filed on April 2, 2001.

[22] *Asahi Glass Co. v. Pentech Pharm., Inc*., 289 F. Supp. 2d 986 (N.D. Ill. 2003) ("*Asahi Glass*").

[23] At the time, some of those whose support of the certiorari petition in *Andrx v. Kroger* had been jointly opposed by the DOJ and FTC before the Supreme Court – including the author – could not help but be amused by the ludicrous prospect of doctrinal differences between the two antitrust enforcement agencies having forced them to brief opposite sides of the same issue in a single case before the Supreme Court. Indeed, the doctrinal rift exposed by the filing of the SG's brief amicus curiae in *Schering-Plough* was not closed for another four years at which point the Antitrust Division announced that it would join the FTC's efforts to secure a ruling of presumptive illegality in *Cipro V*.

[24] In *Walker Process Equip., Inc. v. Food Mach. & Chem. Co*., 382 U.S. 172 (1965) ("*Walker Process*"), the Supreme Court ruled that under appropriate circumstances a claim that a patent had been procured by fraud would be cognizable under Section 2 of the Sherman Act, 15 U.S.C. § 2.

[25] *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom. Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S.Ct. 2828 (2009) ("*Cipro IV*").

[26] As the Supreme Court indicated in *Simpson v. Union Oil Co*., 377 U.S. 13, 24 (1964), the patent laws "are in pari materia with the antitrust laws and modify them pro tanto". *See also Dawson Chem. Co. v. Rohm & Haas Co*., 448 U.S. 176, 221 (1980) (Although the "policy of free competition runs deep in our law", "the policy of stimulating invention that underlies the entire patent system runs no less deep") ("*Dawson*"); *United States v. Singer Mfg. Co*., 374 U.S. 174, 196-97 (1962) ([T]he possession of a valid patent * * * does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly") ("*Singer*"). Both *Dawson* and *Singer* were discussed in *Tamoxifen* (466 F.3d at 202).

[27] When such per se offenses are involved, the Supreme Court's cases on misuse are also pertinent. The leading Supreme Court misuse cases were recently discussed at some length by Judge Bryson in *Princo Corp. v. Int'l Trade Comm'n*, No. 2007-1386, ___ F.3d ___ (Fed. Cir. Aug. 30, 2010) (*en banc*) ("*Princo v. ITC*").

[28] The leading Supreme Court cases were discussed by Judge Bryson in *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179 (Fed. Cir. 2005) ("*Philips I*") – an earlier appeal of the same case decided in *Princo v. ITC*.

[29] *Nobelpharma AB v. Implant Innovations, Inc*., 141 F.3d 1059 (Fed. Cir. 1998), *cert. denied*, 119 S.Ct. 178 (1998) ("*Implant Innovations*").

[30] *Image Technical Servs., Inc. v. Eastman Kodak Co*., 125 F.3d 1195 (9th Cir. 1997) ("*ITS*").

[31] "Brief For Amicus Curiae New York Intellectual Property Law Association In Support Of Defendant-Appellee" in *Xerox/ISO*, a copy of which is available on the Association's website at *http://www.nyipla.org*.

[32] "We have held that 'if a [patent infringement] suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial'. We see no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right." 203 F.3d at 1327 (citation omitted).

[33] "Memorandum Of Law Of *Amicus Curiae* The Federal Trade Commission In Opposition To Defendant's Motion To Dismiss" filed in *In re Buspirone Patent Litigation*, MDL Docket No. 1410 (JGK) (S.D.N.Y. Jan. 8, 2002) ("*Buspirone*").

[34] "Brief Amicus Curiae Of The Generic Pharmaceutical Association In Opposition To Rehearing And Rehearing En Banc" filed in *Tamoxifen*, No. 03-7641 (2d Cir. Feb. 23, 2006).

[35] *eBay, Inc. v. MercExchange, L.L.C*., 547 U.S. 388 (2006) ("*eBay*").

Patent "Reform" and the Suppression of Judicial Review in Administrative Proceedings

by Charles E. Miller and Daniel P. Archibald[1]

This note shines a light on the PTO's efforts aimed at achieving through currently pending patent "reform" legislation the agency's long-sought-after goal of eliminating district court review jurisdiction in ex parte patent reexaminations and presumably eventually in all non-contested cases in the PTO.[2] *Such a result has no valid basis in the legislative history of reexamination and, if enacted, would have serious negative consequences that have so far not been addressed in Congressional pronouncements extolling possible "overhaul" of the U.S. patent system amidst a rhetorical blizzard of guesses and factoids to suit one's fancy.*

One might have thought that *Hyatt v. Kappos*[3] had sensitized Congress to the historical significance and procedural importance of de novo judicial review of Patent and Trademark Office (PTO) decisions. But apparently not.

S.23, the Leahy-Hatch-Grassley *America Invents Act* of 2011 was passed by the Senate on March 8th[4] in a 95-5 bipartisan vote. Insofar as it pertains to this discussion, S.23 mirrors in substance the March 4, 2010 Manager's Amendment of S.515 which expired on December 31st at the end of the 111th Congress. A counterpart bill is expected to emerge from the House Judiciary Committee shortly.

S.23 is being touted (as the successor to several failed antecedents) as being a much-needed and indeed, the first comprehensive "overhaul" of the U.S. patent system since the enactment of the current Patent Act in 1952, [5] a claim with which some might take issue. Under the guiding genius of its principal authors, the late Honorable Giles S. Rich [6] and other leaders of the patent community, the passage of the 1952 Act was the culmination of 160 years of developing patent law, selectively incorporating some of the provisions in preexisting statutes, codifying sensible judicial precedents, and introducing new concepts. It has since been kept current as an enduring, operative document that has withstood the test of time through significant modifications as needed over the years, always for the ongoing, explicit, and deliberate purpose of advancing the rights of the inventive community as a whole, the efficiency and overall fairness of our patent system, and the proper administration of justice consistent with other U.S. statutes and this nation's treaty obligations. S.23 on the other hand, is but the latest in a series of divisively controversial legislative efforts beginning with the 108th Congress (2003-2004) aimed by and large at reshaping the U.S. patent system in response to pressures from various quarters, including America's and its inventors' and industries' foreign rivals, all of whom stand to benefit from a system more to their liking.

Certain provisions in SEC. 5, SEC. 6, and SEC. 8 of S.23 have to do with so-called "enhanced post-grant review procedures" that are intended "to provide an alternative to costly – and often lengthy – litigation, thereby providing greater marketplace certainty – at lower cost."[7] But in reality, such provisions spell trouble, and are of no value in achieving these and the overall laudible goals expressed by the proponents of S.23 as a whole. Instead, they will curtail the ability of PTO stakeholders to petition the courts for redress of grievances against erroneous agency actions by abolishing the long standing right of patent owners to de novo judicial review in ex parte reexaminations.[8] In doing so, these provisions violate three of the basic tenets of dispute resolution: efficiency, fairness, and the search for truth.

A. SEC. 5 – POST-GRANT PROCEEDINGS – SEC. 6. – PATENT TRIAL AND APPEAL BOARD – Abolishes District Court Review-Jurisdiction Over PTO Decisions in Patent Reexaminations

Subsection (h) of SEC. 5 on page 64 of S.23 is entitled "REEXAMINATION." Under the heading "(2) APPEAL," it drastically amends 35 U.S.C. § 306 by a seemingly simple deletion as follows:

> *The patent owner involved in a reexamination proceeding under this chapter may appeal under the provisions of section 134 of this title, and may seek court review under the provisions of sections 141 to <u>144</u> ~~145~~ of this title, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.*

Subsection (b) of SEC. 6 beginning on page 67 of S.23 is entitled "ADMINISTRATIVE APPEALS." It rewrites 35 U.S.C. § 134 by deleting § 134(c),[9] and by amending § 134(b) in relation to ex parte reexamination as follows (emphasis added):

> *(b) PATENT OWNER.—A patent owner in <u>a reexamination</u> ~~any reexamination proceeding~~ may appeal the final rejection of any claim by the primary examiner to the Patent Trial and Appeal Board, having once paid the fee for such an appeal.*

Subsection (c) of SEC. 6 on page 67 of S.23 is entitled "CIRCUIT APPEALS." Under the heading "(1) IN GENERAL," it rewrites 35 U.S.C. § 141 in four parts, (a) - (d). Part (b) reads as follows:

> *(b) REEXAMINATIONS - A patent owner who is dissatisfied with the final decision in an appeal of a reexamination to the Patent Trial and Appeal Board under section 134(b) may appeal the Board's decision only to the United States Court of Appeals for the Federal Circuit.*

Together, these revisions sweep away the long standing right of patent owners to obtain judicial review of adverse PTO decisions in ex parte reexaminations by civil action in district court – a right that has existed under 35 U.S.C. § 306 since the inception of patent reexamination in 1980.[10] Abolishing that right will leave direct appeal to the Federal Circuit as the only judicial recourse – an intolerable scenario for patent owners who need to rely on evidence that was unavailable or could not be presented during the administrative appeal stage.[11]

Also, the PTO's own procedures will compound the problem by creating situations in which a civil action in district court affords the only fair opportunity for a patent owner in an ex parte reexamination – or a patent applicant – to confirm or establish with the aid of new evidence the patentability of an invention by judicial correction of an erroneous decision of the agency. Under 37 C.F.R. § 41.50,[12] the Patent Trial and Appeal Board ("Board"), acting as "super examiners" can raise additional grounds of rejection[13] previously unbeknownst to the appellant and *which are not considered final for purposes of judicial review*.[14] When that happens, the Board can issue an order reopening prosecution[15] whereupon the appellant must either (i) revise the claims and/or present new evidence for consideration by the examiner,[16] or (ii) request a rehearing.[17] These administrative options effectively eliminate the prospects for *prompt* judicial review of the agency's decision to revoke a patent or reject an application in circumstances where the Board introduces a new rationale or a new factual basis for invalidity or unpatentability, and as to which the patentee or applicant had no prior opportunity to present rebuttal evidence. Because of the impossibility of introducing new evidence at the Federal Circuit,[18] and the "substantial evidence" constraint upon that court's scope of judicial review,[19] S.23's suppression of the right of de novo review in district court eliminates effective *judicial* recourse.

B. SEC. 8. - VENUE –
Relocates Venue from the District of Columbia to the Eastern District of Virginia

Subsection (a) of SEC. 8 on page 73 of S.23 under the seemingly innocuous heading "TECHNICAL AMENDMENTS RELATING TO VENUE," trammels the ability of all other PTO stakeholders, including, *inter alia*, applicants for patents and trademark registrations, to seek optimally effective de novo review of the agency's decisions by requiring civil actions against the agency to be brought in the Eastern District of Virginia instead of in the District of Columbia where venue has resided for decades. This would not only disadvantage PTO stakeholders from a logistical standpoint, but also, one might question whether the government-agency jurisprudence of the Fourth Circuit is equal in depth to that of the District of Columbia Circuit.

Official justification for this venue change appears in the Senate Report on S.515 at page 21 under the heading "Venue For The USPTO" (emphasis added):

> In 1999, as part of the American Inventors Protection Act (AIPA), Congress established that as a general matter the venue of the USPTO is the district where it resides [referring to 35 U.S.C. § 1(b)]. The USPTO currently resides in the Eastern District of Virginia. However, Congress *inadvertently failed to make this change uniform throughout the entire patent statute, so that certain sections of the patent statute (and one section of the trademark statute) continue to allow challenge of USPTO decisions to be brought in the District of Columbia, where the USPTO has not resided for decades.*
>
> Since the USPTO no longer resides in the District of Columbia, the sections that authorized venue for litigation against the USPTO are changed to reflect the venue where the USPTO currently resides.

But the Report ignores what the Patent Act historically and currently provides. Thus, if attention is paid to the cited operative section of the current Act, namely, 35 U. S.C. § 1(b), one would be hard pressed to discern any prior "inadvertent failure" on the part of Congress to relocate the venue to the Eastern District of Virginia.

§ 1 Establishment

* * *

> *(b) Offices*.—The United States Patent and Trademark Office shall maintain its principal office in the metropolitan Washington, D.C., area, for the service of process and papers and for the purpose of carrying out its functions. *The United States Patent and Trademark Office shall be deemed, for purposes of venue in civil actions, to be a resident of the district in which its principal office is located, <u>except where jurisdiction is otherwise provided by law</u>*. The United States Patent and Trademark Office may establish satellite offices in such other places in the United States as it considers necessary and appropriate in the conduct of its business.

The underscored portion of § 1(b) quoted above has been and is currently satisfied by 35 U.S.C. §§ 32, 145, 306, and 154(b)(4) for non-contested patent cases, and by 15 U.S.C. § 1071(b)(4) for contested trademark cases. All of these laws have for many years expressly provided that venue be in the District of Columbia. So where is the "inadvertence" in Congress's "failure" heretofore to change the venue? Answer: there was none. And what if the PTO outgrows its present facility in Alexandria and is relocated somewhere else, *e.g.*, back to Washington, D.C., or becomes decentralized by the addition of regional offices as some – including Commerce Department and PTO officials – have advocated? In such circumstances what would the patent community gain by the relocation of venue to the Eastern District of Virginia? Answer: nothing. On the contrary, SEC. 8(b) has the effect (presumably intended by the PTO) of hampering and thus discouraging civil actions against the agency.

Aside from the deficient statutory analysis in justifying SEC. 8(a), there appears to be a *sub silentio* two-fold

cont. on page 12

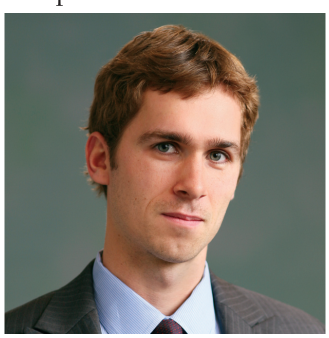
cont. from page 11

purpose behind this venue change that stakeholders in the U.S. patent system should hardly regard as a mere "technical amendment." First of all, a forum in Virginia, where most of the PTO's operations are now physically housed within a complex of office buildings across the street from the Albert V. Bryan Federal Courthouse in Alexandria -- assuming litigation and trial would be held before a judge there -- would be convenient for the agency, compared to the E. Barrett Prettyman Federal Courthouse in downtown Washington, D.C. But that would not necessarily be so for plaintiffs and their counsel who would have to go traipsing with all their luggage, litigation bags, bankers boxes, and other trial accoutrements, not to mention their experts and fact witnesses, out to some potentially remote part of Virginia to try their cases.[20]

Second, the federal administrative-law jurisprudence of the D.C. Circuit is second to none and its courts have traditionally been seen as reviewing the actions of federal agencies with great circumspection compared to courts in other circuits. Of course, SEC. 8(b) would not deprive the Federal Circuit of appellate jurisdiction over substantive patent law issues; however, it would preclude appeals to the D.C. Circuit from interlocutory decisions on procedural matters not involving questions of patent law, such as evidence issues, e.g., the characterization and/or admissibility of lay versus expert testimony, ethics issues, and so on. Such matters would be heard by the court of appeals for the regional circuit wherein trial is being held, *i.e.*, the Fourth Circuit in Richmond.

CONCLUSION

S.23 insulates PTO decisions in ex parte patent reexaminations from effective judicial scrutiny in D.C. Federal district court – an unjustified departure from existing law and practice and a significant setback for PTO stakeholders. Because appeals of the agency's decisions to the Federal Circuit, the only judicial recourse left to patent owners, are subject to the highly deferential "substantial evidence" standard of review, the renamed "Patent Trial and Appeal Board" and its "judges" would in effect become a "judicial tribunal" whose rulings in ex parte reexaminations would for all intents and purposes be tantamount to – but lack the procedural and constitutional safeguards of – adjudications by an Article III trial court. Thus, meaningful judicial review would become a thing of the past in cases where PTO fact-findings are based on any kind of "substantial" evidentiary record. In its present form, S.23 extinguishes the *fundamental*, *meaningful*, and *necessary* right of patent owners in need of judicial review of adverse PTO decisions in ex parte reexaminations to choose civil actions in district court in lieu of direct appeals to the Federal Circuit. To prevent this legislative injustice, the provisions of SECS. 5(h), 6(b), 6(c)(1), and 8(a) should be omitted from whatever bill is ultimately passed by both houses of Congress as a whole. Doing so would not affect any other aspects of patent reform. Failing to do so would hinder rather than "promote the Progress of . . . the useful Arts" as mandated in Art. 1, sec. 8, cl. 8 of the Constitution, and would not advance President Obama's stated goal of "unleashin[g] the ingenuity and entrepreneurial spirit of the American people"[21] to which end Vice President Biden said, "Not only do we have to encourage and unleash those talents of the United States . . . but we also have to protect them." [22]



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[2] Under 37 C.F.R. §§ 41.2 (¶ 5) and 41.60 (¶ 5, third sentence), both ex parte and inter partes reexaminations (35 U.S.C. §§ 302-307 and 134(b); and §§ 311-318 and 134(c), respectively) as well as patent application proceedings (35 U.S.C. §§ 131-133 and 134(a)) are considered to be "non-contested" cases, as opposed to "contested" cases like patent interferences under 35 U.S.C. § 135 (37 C.F.R. § 41.200(e)) and public use proceedings under 37 C.F.R. § 1.292(a), second sentence. The difference between non-contested and contested cases is profound because, unlike the subpoena power of the U.S. district court under Fed. R. Civ. P. 45 in civil actions, the power of the court to issue subpoenas under 35 U.S.C. § 24 in PTO proceedings is applicable only to witnesses in connection with contested cases, 37 C.F.R. §§ 41.100-41.208, and hence is not available in the prosecution (administrative stage) of patent reexaminations. 37 C.F.R. §§ 1.510-1.570 and §§ 41.30-41.56 (ex parte reexaminations); 37 C.F.R. §§ 1.903-1.907 and §§ 41.60-41.81 (inter partes reexaminations). More broadly, patent reexaminations, both ex parte and inter partes, are like patent application proceedings in the sense that once commenced they are in the nature of an *examination* by the PTO to determine if revocation of patent rights is warranted, and the agency has the burden of establishing that one or more of the claims are not valid. A contested case is in the nature of an *opposition* proceeding involving adverse parties other than the PTO, one of which has the burden throughout the proceeding of persuading the PTO that a claim is undeserved, and the agency must ultimately decide whether that party has met its burden. In both contested and non-contested cases, the standard of proof is usually "preponderance of the evidence." 37 C.F.R. §§ 1.104 (patent reexamination) and 41.207(a)(2) (patent interferences). For an exception to the preponderance of the-evidence rule, see the second clause in 37 C.F.R. § 41.207(a)(2). *See also* Senate Report on original S.515 at 57 (2009).

[3] 625 F.3d 1320, 96 U.S.P.Q.2d 1841 (Fed. Cir. 2010) (en banc). *See*, Charles E. Miller, *Federal Circuit Rules in Hyatt v. Kappos*, New York Intellectual Property Law Association Bulletin, p. 17, Nov./Dec 2010 The U.S. Supreme Court has extended to April 7, 2011 the PTO's time to petition for certiorari.

[4] The text of S.23 as passed can be found at: http://thomas.loc.gov/.

[5] Act of July 19, 1952, ch. 950 § 1, 66 Stat. 803 (1952), currently codified in 35 U.S.C. §§ 1-376.

[6] Judge Rich was a celebrated member of the Court of Appeals for the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals. During his involvement in the drafting of the 1952 Act, he was serving as the 28th president (from 1951-1952) of what was then known as the New York Patent Law Association.

[7] *See* Senate Report, *supra*, 14, n. 63; 79 PTCJ 560 (03/12/10).

[8] The right of de novo judicial review in inter partes reexaminations was already precluded from the get-go in the *American Inventors Protection Act* which introduced such post-grant proceedings in 1999.

[9] 35 U.S.C. § 134(c) currently provides requesters in inter partes reexaminations with a right of administrative appeal from examiners' actions favorable to the patent owner. This would be mooted by the morphing of inter partes reexamination into "inter partes review" and "post-grant review" which will be conducted in the first instance by the PTO's newly-named "Patent Trial and Appeal Board" under 35 U.S.C. § 6(b)(4) as amended by SEC. 6, subsection (a) on page 65 of S.23 entitled "COMPOSITION AND DUTIES" instead of by a team of examiners in the PTO's Central Reexamination Unit as it is currently done in inter partes reexaminations.

[10] Act of Dec. 12, 1980, Pub. L. No. 96-517 § 1, 94 Stat. 3015-17 (1980). The PTO would argue that the right of civil action for de novo review of its decisions in ex parte reexaminations was eliminated by the *American Inventors Protection Act* of 1999 and the *21st Century Department of Justice Appropriations Authorization Act* of 2002. Such an argument is grounded on a false premise and is fully rebutted by the authors in their recently published analysis entitled *Interpretive Agency-Rulemaking vs. Statutory District Court Review Jurisdiction in Ex Parte Patent Reexaminations*, 92(4) J. Pat. & Trademark Off. Soc'y, 498-535 (2011).

[11] *See supra* note 2. Neither continuation *application* practice under 35 U.S.C. § 120 nor requests for continued examination (RCE's) of *applications* under 35 U.S.C. § 132(b) nor suspension or deferral of examination of *applications* under 37 C.F.R. § 1.103 are possible in *patent* reexaminations.

[12] The PTO's procedures for administrative appeals in non-contested (ex parte) cases are set forth in 37 C.F.R. §§ 41.30-41.56.

[13] *In re Jung*, Fed. Cir. App. No. 2010-1010, *proceedings below, Ex parte Jung*, 2008 WL 4974150 (PTO Bd. Pat. App. & Int. 2008) (Timm, APJ), *reh'g den.*, 2009 WL 1995983 (2009).

[14] 37 C.F.R. § 41.50(b), second sentence.

[15] 37 C.F.R. § 41.50(b)(1).

[16] *Id.*

[17] 37 C.F.R. § 41.50(b)(2).

[18] 35 U.S.C. § 144 ["The United States Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken *on the record before the Patent and Trademark Office* . . ."] [emphasis added].

[19] *Dickinson v. Zurko*, 527 U.S. 50, 119 S.Ct. 1860, 144 L.Ed. 2d 143, 15 U.S.P.Q. 2d 1930 (1999).

[20] The E. D. Va. employs a rotation system for referring each new case to one of the court's four divisions – i.e., Alexandria, Newport News, Norfolk, or Richmond – regardless of where the complaint is filed. E.D. Va. L. Civ. R. 3(c). Hence, SEC. 8(a) of S.23 would pose a potentially even greater inconvenience to plaintiffs than having to go to Alexandria. However, in a cleverly nuanced end-run around the problem, SEC. 17 of S.23 at p. 102 of the bill adds a new § 1454 to Title 28 the effect of which would be to allow removal of all civil actions against the PTO in the E.D. Va. to the "division embracing the place where such action is pending", i.e., to the Alexandria division in the event they are docketed in one of the other three divisions.

[21] January 25, 2011 State of the Union Address.

[22] 81 PTCJ 419 (02/03/11).

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HISTORIAN'S CORNER

"File Histories and Foreign Affairs"

by John B. Pegram

My first column in this space promised an explanation of the real meaning of "file history," so here it is—before we forget that promise.

Forty years ago, and for many years before that, practitioners distinguished between a prosecution file history and a copy of the prosecution file. The latter was very expensive and not very legible, and therefore only used to make copies of pages necessary for use in court.

For everyday purposes, we relied on one of the several public stenographers working at the Patent Office who provided a unique paralegal service. That person would first order a copy of the patent, determine whether the file was on site at the Office or in storage, and request the file for inspection after receiving the patent copy.

Then she (invariably a talented woman) would review the file history, marking the patent copy in red and blue pencil to indicate changes that had been made during prosecution. She would copy and type the cancelled claims and other matter that did not appear in the final patent, along with the arguments and office actions. Thus, when you received a file history, all of the details of the prosecution were readily apparent.

* * *

Twenty-five years ago, the Japanese patent system was unique and antiquated. The JPO reached out to learn more about the U.S. system by placing an Examiner here as a representative, Mr. Koshi Ohashi. A user group comprising delegates from many U.S. IP groups, the US Bar – JPO Liaison Council, was organized on the model of an EPO Liaison Council, which had started meeting annually with the EPO several years earlier. Our first meeting with five representatives of the JPO was in Chicago in August 1990, following the ABA annual meeting. I was privileged to represent NYIPLA. Several other members of our association also participated as delegates of other groups, including Sam Helfgott and Mike Meller, and Len Mackey, who gave an opening greeting. The JPO group was led by Fumitake Yoshida, who had just retired as JPO Commissioner, known as "Lion" Yoshida for his gruff manner and also to distinguish another Commissioner Yoshida. The meeting, like the meetings since then, was a series of presentations from each side on issues of harmonization and patent practice. Although credit for modernization of the Japanese patent system must go to the Japanese, I believe the US Bar – JPO Liaison Council made a significant contribution.

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

One of the most remarkable developments in patent protection in the past 25 years has been the growth of the Chinese Patent Office from nothing to the world's most active. In 1980-82, our Association hosted a series of seminars with delegations from China to introduce their new patent system. The impressive development of that Office and system are well known and I will focus here on a patent attorney's first hand view of the changes in Chinese society.

At our first seminar, the participants were well-prepared and spoke surprisingly good English. But it was clear they were from a different world. The men wore Mao jackets and one delegate (a watcher?) appeared to have much less knowledge of patents than the rest. They declined alcoholic drinks before dinner with our Board and several invited leaders of the IP profession in New York, even though it was early, to permit them to return to their lodgings before a curfew.

The following year, another seminar was arranged. The delegation arrived in new Western suits having stopped in Hong Kong for a few days to have the suits made. The level of knowledge of the U.S. and European patent systems was impressive. Most of them enjoyed a beer or wine, as their curfew was a half hour later.

A year or so later, at another seminar and dinner, the Chinese delegates seemed quite comfortable with us. A few asked for whiskey during the cocktail hour. At dinner, when one of our members inquired when there would be competing private patent firms in China, instead of the one or two government agencies representing foreign applicants, the Vice President of China's Supreme Court reminded us—with a laugh— that they are still a socialist country. Dinner was early again – this time, so the Chinese could attend a Broadway show.

Unique Product Solutions v. Hy-Grade – False Marking Statute Declared Unconstitutional

by Bobby Greenfeld

An article in the June/July 2010 Bulletin by James Gould and Joseph Farco addressed the patent false marking issue and suggested the use of false marking as a potential infringement defense. This article discusses some recent developments concerning false marking.

I. INTRODUCTION

In a surprising decision, a judge in the Northern District of Ohio in February 2011 declared unconstitutional the *qui tam* provision of the false patent marking statute under the Take Care Clause of the United States Constitution, U.S. Const. Art. II, Section 3. *Unique Product Solutions, Ltd. v. Hy-Grade Valve, Inc.*, No. 5:10-cv-1912 (N.D. Ohio Feb. 23, 2011) ("*Hy-Grade I*").[1] After the government moved to intervene and for reconsideration, the court re-affirmed its earlier decision. *Unique Product Solutions, Ltd. v. Hy-Grade Valve, Inc.*, No. 5:10-cv-1912 (N.D. Ohio March 14, 2011) ("*Hy-Grade II*"). This article reviews the case and evaluates its reasoning and how it fits in with other false marking developments.

II. HY-GRADE I

A. Facts and Procedural History

The *Hy-Grade* lawsuit is a classic false patent marking case. Unique Product Solutions ("UPS") filed suit on August 27, 2010, alleging that Hy-Grade violated the False Marking Statute, 35 U.S.C. § 292, by marking several check valve products with United States Patent No. 4,605,041 which UPS alleged expired no later than April 5, 2005.

Defendant Hy-Grade moved to dismiss the complaint on a number of grounds under Fed. R. Civ. P. 12. During a teleconference on November 15, 2010 to discuss the motion, the Court *sua sponte* asked the parties to brief the constitutionality of Section 292(b). The Court then issued a Minutes Order on November 16, which was served on the Department of Justice ("DOJ") and advised the Government of the briefing schedule for the constitutional challenge. The Court considered this notice as certification of the constitutional challenge under Fed. R. Civ. P. 5.1, which allows the Government 60 days to intervene. The court then called the Director of the Commercial Litigation Branch of the DOJ, who "orally expressed an intent to intervene." *Hy-Grade I*, slip op. at 2 n.2. Hy-Grade filed its opening brief on January 13, 2011 and served the DOJ. Plaintiff UPS responded on February 11, 2011, which the court noted was more than 60 days after it had certified the constitutional challenge. *Hy-Grade I*, slip op. at 2 n.2. The Government did not file a brief. On February 23, 2011, the Court declared the False Marking Statute unconstitutional.

B. The Parties' Arguments

In support of its motion to dismiss on constitutional grounds, defendant Hy-Grade argued that both the Appointments Clause and the Take Care Clause of Article II rendered the False Marking Statute unconstitutional. (Def.'s Mem. In Support of Motion to Dismiss, Jan. 13, 2011, at 2 ("Def.'s Br.").) The Appointments Clause states that the Executive "shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the Supreme Court, and all other Officers of the United States." U.S. Const. art. II, § 2. The Take Care Clause states that the Executive shall "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3. Hy-Grade argued that these Clauses "require the Executive Branch, through the Attorney General, to retain control over all litigation commenced where the Government is the real party in interest" and thus prevent Congress from impermissibly undermining the powers of the Executive Branch. (Def.'s Br. at 2.)

In support, Hy-Grade cited chiefly to the "sufficient control" standard found in the Supreme Court's decision in *Morrison v. Olson*, 487 U.S. 654 (1988), a case that discussed the Ethics in Government Act (EGA) under the separation of powers doctrine. The EGA "allows for the appointment of an 'independent counsel' to investigate and, if appropriate, prosecute certain high-ranking Government officials for violations of federal criminal laws." *Id*. at 659. In *Morrison*, the Court found the EGA constitutional because it gives "the Executive Branch *sufficient control* over the independent counsel to ensure that the President is able to perform his constitutionally assigned duties." *Id*. at 696 (emphasis added). *Morrison* did not explicitly state that the Take Care Clause was coextensive with the separation of powers doctrine. Hy-Grade also cited to a precedential Sixth Circuit case, *U.S. ex rel. Taxpayers Against Fraud v. General Electric Co.*, 41 F.3d 1032 (6th Cir. 1994), which found that the Executive Branch retains "sufficient control" over a False Claims Act (FCA) *qui tam* relator such that "'the President is able

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to perform his constitutionally assigned dut[y]' to 'take Care that the Laws be faithfully executed.'" *Id*. at 1041 (citing *Morrison* and the Take Care Clause). In contrast to the EGA and FCA, Hy-Grade argued that because a false marking plaintiff "is not required to notify the government of the initiation of the action, to allow the government to intervene, or to provide the government with oversight or some measure of control," Section 292(b) is unconstitutional. (Def.'s Br. at 6.)

In response, plaintiff UPS first argued that the long history of *qui tam* suits, which were available in England before the Constitution was ratified, meant that the framers knew that *qui tam* suits were "entrenched in American law" and thus the Constitution must have allowed for them. (Relator's Br. In Opposition to Defendant's Constitutional Challenge to 35 U.S.C. § 292, Feb. 11, 2011, at 2 ("Pl.'s Br.").) UPS cited to *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000), which addressed whether *qui tam* relators suing under the False Claims Act had constitutional standing under Article III, and argued that *Vermont Agency* relied on that history to find standing (citing *id*. at 776 (noting the history of the *qui tam* suit was "well nigh conclusive" on the issue whether *qui tam* actions were traditionally amenable to and resolved by the judicial process)).

UPS next argued that Section 292 does not prevent the Executive Branch from accomplishing its constitutionally assigned functions. (Pl.'s Br. at 5.) It contended that the Constitution does not vest the responsibility for bringing a false marking suit "exclusively in an official of the United States government (as, for example, the Constitution vests the pardon power exclusively in the President)." (*Id*. at 6.) UPS also argued that the Article II issues had been discussed by various courts and rejected. UPS cited the Fifth Circuit's holding in *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001) (en banc), that False Claims Act *qui tam* suits are constitutional under Article II, because that court used the same history relied upon in *Vermont Agency* for finding Article III standing. *Id*. at 752 (stating that "the same history that was conclusive on the Article III question in *[Vermont Agency]* with respect to qui tam lawsuits initiated under the FCA is similarly conclusive with respect to the Article II question concerning this statute"). UPS also cited the denial by other district courts of similar constitutional challenges to Section 292, especially *Pequignot v. Solo Cup Co.*, 640 F.Supp.2d 714, 726 (E.D. Va. 2009).[2] (Pl.'s Br. at 4.)

C. The Decision

In deciding this case, the *UPS* court briefly discussed *qui tam* provisions in general, the *Vermont Agency* case, and the *Morrison* case, and acknowledged that none of those cases addressed the Take Care Clause. *Hy-Grade I*, slip op. at 4-6. The court did note that while *Vermont Agency* also did not address the Appointments Clause, *Morrison* did, finding the EGA constitutional under that Clause. *Id*. at 4-6.

The court declined to follow either the Fifth Circuit in *Riley* or the Eastern District of Virginia in *Pequginot* for a number of reasons. *Hy-Grade I*, slip op. at 10-11. It declined to follow *Riley* because that opinion found *Morrison* inapplicable to the False Claims Act for two reasons: (1) the FCA authorizes the plaintiff to bring a lawsuit "in the name of" the United States while the EGA at issue in *Morrison* assigned the independent counsel "to act as" the United States itself; and (2) FCA *qui tam* relators pursue civil actions while the EGA provides independent counsel the authority to undertake criminal prosecution. The court found no difference between bringing a lawsuit "in the name of" the United States rather than "to act as" the United States itself, and found that the Federal Circuit had already declared the False Marking Statute "criminal" in *Pequignot v. Solo Cup Co*., 608 F.3d 1356, 1363 (Fed. Cir. 2010) ("the false marking statute is a criminal one, despite being punishable only with a civil fine") (citing S.Rep. No. 82-1979, 1952 U.S.C.C.A.N. 2394, 2424 (1952)). *Hy-Grade I*, slip op. at 10. The court stated that its decision "would not change" even were Section 292 considered a civil statute because the Sixth Circuit in *Taxpayers Against Fraud* applied the *Morrison* "sufficient control" analysis to a civil statute. *Hy-Grade I*, slip op. at 10 n.6; *see also id*. at 14 (recognizing that federal law enforcement responsibilities arise in both criminal and civil arenas).

The court also declined to follow the district court's decision in *Pequignot*, which relied on the history of *qui tam* statutes, the government's ability to intervene in False Marking actions (under Fed. R. Civ. P. 24), and the government's decision in that case to intervene without objecting to Pequignot's conduct or to the constitutionality of the False Marking Statute. *Hy-Grade I*, slip op. at 10-11. The court found that history itself was not sufficient to justify constitutionality, and noted the False Marking Statute's history in particular did not go back as far as *qui tam* suits in general. The court also noted that the government did not intervene in this case, unlike in *Pequignot*, even though it had the opportunity to do so. The court also disagreed with the *Pequignot* district court's conclusion that Fed. R. Civ. P. 24 protects the government's right to intervene – since the Federal Circuit has stated that the False Marking Statute is a criminal statute, the court did not understand how a Civil Rule could "ever provide the basis for a right to intervene in a criminal proceeding." *Hy-Grade I*, slip op. at 11.

Thus, the court decided the case using the "sufficient control" standard of *Morrison*. The court stated the False Marking Statute "lacks any of the statutory controls necessary to pass Article II Take Care Clause muster." *Hy-Grade I*, slip op. at 13. More specifically, the court said:

> The False Marking statute essentially represents a wholesale delegation of criminal law enforcement power to private entities with no control exercised by the Department of Justice. *See Pequignot,* 608 F.3d at 1363 (False Marking statute is criminal). It is unlike any statute in the Federal Code with which this Court is familiar. Any private entity that believes someone is using an expired or invalid patent can file a criminal lawsuit in the name of the United States, without getting approval from or even notifying the Department of Justice. The case can be litigated without any control or oversight by the Department of Justice. The government has no statutory right to intervene nor does it have a right to limit the participation of the relator. The government does not have the right to stay discovery which may interfere with the government's criminal or civil investigations. The government may not dismiss the action. Finally, the relator may settle the case and bind the government without any involvement or approval by the Department of Justice.

Id. The court concluded, "it is clear the government lacks sufficient control to enable the President to 'take Care that the Laws be faithfully executed.'" *Id. at 12-13*.

The court then discussed the policy reasons why the Take Care Clause vests law enforcement power in the Executive Branch, and why delegating such power to private litigants must be controlled by the Attorney General. These reasons include prosecutorial discretion, the consideration of the public interest, the potentially disproportionate damages (up to $500 per falsely marked article) against a defendant, and the lack of a financial stake in the outcome by the government.[3] The court thus found the False Marking Statute unconstitutional under the Take Care Clause of Article II.

III. HY-GRADE II

A. The Government's Motion To Intervene And For Reconsideration

As mentioned above, the court stated up front in its opinion that the Government was provided notice of the constitutional challenge on November 16, 2010, had 60 days to intervene, and the court had spoken with the Director of the Commercial Litigation Branch of the DOJ, who had indicated an intention to intervene. The court issued its opinion on February 23, 2011, over 90 days after providing notice to the Government, but the Government had not filed any papers in the case. Thirteen days after the decision, on March 8, 2011, the United States filed a motion to intervene as of right and for reconsideration of the court's February 23, 2011 order.

Regarding its motion to intervene as of right, the Government argued that in the court's November 16, 2010 Minutes Order, "the Court did not certify to the Attorney General that the constitutionality of 35 U.S.C. § 292 was questioned," the words "certify" or "certification" do not appear in that minute order, and the court did not follow the requirements of Fed. R. Civ. P. 5.1. (Govt.'s Motion To Intervene As Of Right And For Reconsideration Of The Court's Order Of February 23, 2011, Mar. 8, 2011, at 3 ("Govt.'s Br.").) The Government argued that it did not receive proper notice until defendant Hy-Grade filed its brief on the constitutional challenge on January 13, 2011, and thus the time to intervene did not expire until March 14, 2011. Thus, the Government argued it could intervene as of right. (*Id*. at 6.)

Turning to the merits, the Government first argued that the court mischaracterized the False Marking Statute as criminal, stating such a characterization was "[a]t the heart of the Court's analysis." (Govt.'s Br. at 8.) The Government termed dicta the Federal Circuit's pronouncement in *Pequignot* of the False Marking Statute as criminal, but acknowledged that the legislative history calls it "an ordinary criminal action." (*Id*. at 8 n.4.) Because the statute is "civil in form," the Government argued that the Federal Rules of Civil Procedure apply, and the government has a right to intervene at any time (*see* Fed. R. Civ. P. 24(a)(2)), thus giving it control over the case.[4] (*Id*. at 9.) The Government then argued that such a civil lawsuit is not a criminal prosecution, *qui tam* relators are civil litigants, not prosecutors, and therefore the lawsuits "do not cut to the 'heart of the Executive's constitutional duty to take care that the laws are faithfully executed'" (citing *Riley*, 252 F.3d at 755). (Govt.'s Br. at 10.)

The Government also contested the court's conclusion in its opinion that there was no difference between bringing a lawsuit "in the name of" the United States rather than "to act as" the United States itself. (Govt.'s Br. at 11-12.) The Government explained that in the latter instance, an individual "is acting as an officer or agent of the United States, directly representing the interests of the United States," whereas in the former instance, the individual is "the assignee of a portion of the interest of the United States" (citing *Pequignot*, 640 F. Supp. 2d at

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725; *Riley*, 252 F.3d at 755; and *Vermont Agency*, 529 U.S. at 771-72). (*Id*. at 12.) The Government then challenged the court's reliance on *Morrison*, because in that case the independent counsel was a prosecutor, "functioning as an inferior officer of the government." (*Id*.) In contrast, under the False Marking Statute, the relator is assigned a partial interest of the United States, is not appointed or an inferior officer, has no law enforcement powers, and brings no criminal sanctions. In short, Section 292 "intrudes itself very little into the Executive's constitutional obligation to see that the laws are faithfully executed and consequently does not offend the Take Care Clause." (*Id*. at 13.)

Finally, the Government cited the history of *qui tam* statutes as an indicator of their constitutionality. The Government stated these statutes are "a staple of the American legal system since its inception and have never been found to encroach unconstitutionally upon the executive's obligation to faithfully execute the laws under the Take Care Clause." (*Id*. at 14.)

B. The Court's Second Decision

Regarding the Government's motion to intervene as of right, the court determined that it had properly certified the constitutional challenge on November 16, 2010, and thus the United States' motion to intervene was out of time. Specifically, the court acknowledged that although the November 16, 2010 minute order "did not contain the words 'certify' or 'certified,' its meaning was obvious and the notice to the government was clear." *Hy-Grade II*, slip op. at 3. Nevertheless, the court allowed the government to intervene to defend the statute.

This allowance by the court was hollow, because the court still found the statute unconstitutional, for many of the same reasons it articulated in the first opinion. Regarding the government's challenge to the court's determination that the False Marking Statute was criminal, the court acknowledged that there is controversy as to whether the statute is civil, criminal, or a civil-criminal hybrid, but said it was bound by Sixth Circuit precedent in *United States ex rel. Taxpayers Against Fraud v. General Electric Co.*, 41 F.3d 1032 (6th Cir. 1994), at least until the Federal Circuit decides the issue for false patent marking cases, to apply *Morrison*'s sufficient control test to the False Marking Statute. *Hy-Grade II*, slip op. at 6. The court again stated that it does not matter how the statute is characterized, calling such a question "academic." *Id*. at 5. Even if the statute were civil, and the Rules of Civil Procedure applied so that the Government could intervene as of right, the court concluded that such a right does not guarantee that the government will receive timely notice of a false marking suit to enable it to intervene prior to the suit settling (which may be settled by a relator without government approval, unlike the False Claims Act), so the government could still be foreclosed from bringing its own suit. *Id*. at 6.

The court rejected the Government's second argument regarding the difference between bringing a lawsuit "in the name of" the United States rather than "to act as" the United States itself. The court said it agreed that a *qui tam* relator is not considered an inferior officer of the United States, but it was bound by its appeals court's *Taxpayers Against Fraud* case to apply the *Morrison* test, since *Taxpayers Against Fraud* found that False Claims Act relators were also not inferior officers. *Hy-Grade II*, slip op. at 7.

Finally, the court again rejected the historical argument, saying that the history of *qui tam* suits in general "has little bearing on whether this particular *qui tam* provision is constitutional." *Hy-Grade II*, slip op. at 6. The court also repeated its dismay with the financial penalties of the statute, citing again the dangers of privatization of these types of lawsuits. In the second suit, the court said the "defendant pays a fine of $500 per falsely marked item," posited a $500 million fine on $10 million of sales, and stated the fine has no relation to the harm, unlike the False Claims Act recovery, which is related to the economic harm to the United States. *Id*. at 7. This differed slightly from the first opinion in which the court said, "The penalty is <u>up to</u> $500 for each article falsely marked" and "could be a staggering amount of money <u>or</u> a trivial amount." *Hy-Grade I*, slip op. at 14 (emphases added). But again, the court found the False Marking Statute unconstitutional under the Take Care Clause and dismissed the complaint with prejudice.[5]

IV. DISCUSSION OF CASE

Based on the judge's *sua sponte* request to the defendant to consider the constitutionality of the False Marking Statute, and his remarks in both opinions regarding "the dangers of privatization of law enforcement," the court was clearly concerned with finding a way to fight the false marking suit epidemic. As can be seen from the second opinion, the court would not be swayed even when the government showed that it could retain some control over the litigation. And even though the Federal Circuit in *Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1304 (Fed. Cir. 2009), stated that the "court has the discretion to determine that a fraction of a penny per article is a proper penalty," the court here seemed fixated on the maximum penalty allowable. The court understood that many cases settle very quickly, and likely for nuisance costs, but even the threat of a large penalty can drive those nuisance costs up. And the court may have been worried about defendants being subject to multiple suits and multiple settlements over the same patent and/or products.

But is finding the statute unconstitutional for violating the Take Care Clause the proper way to stem false marking suits? This case is the first to find the False Marking Statute unconstitutional – more surprising, however, is that not one of the cases relied upon by the court or discussed in depth (*Morrison*, *Vermont Agency, Taxpayers Against Fraud*, *Riley*, *Pequignot*, *Forest Group*, or *Stauffer v. Brooks Brothers*) found any of the subject statutes (EGA, FCA, Section 292) unconstitutional. Thus, the court seems to have thrown judicial restraint to the wind in order to find a way to stop the false marking epidemic. The court failed to abide by the avoidance doctrine – not to address the constitutionality of a statute unless absolutely necessary *See Ashwander v. TVA*, 297 U. S. 288, 346-347 (1936) (Brandeis, J., concurring) ("The Court will not anticipate a question of constitutional law in advance of the necessity of deciding it. It is not the habit of the Court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case" (citations and internal quotation marks omitted)). In fact, the defendant had other motions to dismiss pending under Fed. R. Civ. P. 12, *Hy-Grade I*, slip op. at 1-2, but of course the outcomes of those motions would have affected only this case.

Even though the court took pains to base its decision on *Morrison* and *Taxpayers Against Fraud*, which used the "sufficient control" standard mentioned in *Morrison*, the court did an incomplete job of assessing what "sufficient control" really meant in the context of the *Morrison* case – that is, how "sufficient control" compared to the powers of the independent counsel in that case. Although the court noted that under the EGA, the independent counsel could "conduct grand jury proceedings and other investigations, participate in civil and criminal court proceedings and litigation, and appeal any decision in which the independent counsel participated in an official capacity," *Hy-Grade I*, slip op. at 6 (citing *Morrison*, 487 U.S. at 662), the court failed to mention that the Act grants the independent counsel "full power and independent authority to exercise all investigative and prosecutorial functions and powers of the Department of Justice, the Attorney General, and any other officer or employee of the Department of Justice," and the independent counsel could appoint employees, initiate and conduct prosecutions in any court of competent jurisdiction, frame and sign indictments, file informations, and handle all aspects of any case, all in the name of the United States. *Morrison*, 487 U.S. at 662. Moreover, the Department of Justice must pay all of the "costs relating to the establishment and operation of any office of independent counsel." *Id*. at 663. With such strong and wide-ranging powers, it is no wonder Congress provided the Executive Branch some level of control, which the Supreme Court held was "sufficient." *See id*. at 696.[6]

In the false marking realm, however, Congress has not granted a *qui tam* relator nearly the amount of power as the independent counsel wields under the EGA. *See Hy Cite Corporation v. Regal Ware, Inc*., No. 10-cv-00168, slip op. at 9 (W.D. Wisc. March 15, 2011) (rejecting the argument that "the statute can reasonably be characterized as invoking the executive's core function of criminal prosecution"). The *qui tam* relator can only initiate actions related to false patent marking, has to pay all costs of the lawsuit, cannot appoint employees whose cost is borne by the government, and certainly does not have the "full power and independent authority to exercise all investigative and prosecutorial functions and powers of the Department of Justice, the Attorney General, and any other officer or employee of the Department of Justice." The outcome of a successfully prosecuted false marking suit, whether denominated civil or criminal, is merely a fine – nobody's liberty is at stake and nobody goes to jail. And no defendant has had to pay exorbitant amounts of damages, contrary to the parade of horribles imagined by the court in *Hy-Grade*.[7]

False marking suits also lack the clash between the Legislative and Executive branches seen in *Morrison*. *See supra* note 6. In fact, it could be argued that the Executive Branch welcomes false marking cases. In *Hy-Grade*, the government intervened to defend the statute. *See Pequignot*, 640 F. Supp. 2d at 729 (noting the lack of a separation-of-powers issue when the Government supports the relator's action). The government has collected over $5.3 million (as of March 4, 2011, *see* www.grayonclaims.com/false-marking-settlement-info/) from 191 settlements since May 2010 (in addition to half of any penalties actually imposed by the courts). There is a section in the Department of Justice, the "Intellectual Property Staff," that is routinely apprised of false marking litigation and "routinely reviews settlement agreements in those cases." (Govt.'s Br. at 11.) And all this without initiating one lawsuit and expending relatively little time, energy, and money.

The *Hy-Grade* decision fails to acknowledge that there is a benefit to the False Marking Statute – Congress's desire to rid the marketplace of old and expired patents. Without the False Marking Statute, there would be no mechanism for the Government to deter and punish false markers. For example, in *Stauffer v. Brooks Brothers, Inc*., 619 F.3d 1321, 1322 (Fed. Cir. 2010), the patents used to mark defendant's bow ties expired over 50 years ago. There is no authority given by the Constitution to punish false markers (such as in the patent clause in

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Article I), and there is no inherent historical authority in the Government to do so. When Congress passes a law that divides the enforcement power between the Government and a private litigant, Congress has dictated the extent of the Executive Branch's powers in that realm. Thus, there is no undue "interference," *see Morrison*, 487 U.S. at 693, with the Executive's constitutionally assigned duties to Take Care that the Laws be faithfully executed, because the faithful execution of the false marking law includes the ability of the private litigant to bring an action. There was an issue of separation of powers in *Morrison* because the independent counsel was investigating wrongdoing in the Executive Branch, and the EGA was passed to police the Executive's authority in carrying out other laws that were already put in place. In FCA cases, Congress passed a single law to police third-party wrongdoing in numerous areas of interactions with the Government. In contrast, the False Marking Statute is limited to false marking of patents and is not otherwise applicable to other laws.

In fact, many of the dangers that the court imagined are being addressed by courts without resorting to declaring the statute unconstitutional under a separation-of-powers rationale. The fear of defendants subjected to multiple suits may be dealt with in a number of ways. Subsequent suits may be dismissed because the subsequent *qui tam* plaintiff lacks standing. *See, e.g., San Francisco Tech., Inc. v. Glad Prods. Co.*, No. 10-cv-966-JF, slip op. at 7-8 (N.D. Cal. July 19, 2010) (filing of first lawsuit against defendant Exergen for false marking a patent acts as an assignment of the government's claim for that patent, and thus the subsequent plaintiffs lack standing). If the defendant is not able to escape the subsequent suit, *see, e.g.*, *Simonian v. Hunter Fan Co.*, 2010 U.S. Dist. Lexis 68013, No. 10-cv-1212 (N.D. Ill. July 8, 2010) (holding that the first-to-file rule in the False Claims Act cannot be applied to cases arising under any other *qui tam* statute), once the defendant settles with a plaintiff or the government, that defendant should be free from suit on the same patent, so long as the settlement agreement is broadly written. *See, e.g.*, *Simonian v. Irwin Industrial Tool Co.*, No. 10-cv-1260 (N.D. Ill. Jan. 10, 2011) (denying plaintiff leave to amend *qui tam* complaint to add defendant that had already settled with other relators). These rules may actually benefit defendants – if there is more than one *qui tam* relator suing a single defendant in separate cases, there is an incentive to be the first relator to settle, since a subsequent settlement or decision would be precluded. This reduces the value of settlement immensely.[8] Similarly, there is an incentive for a defendant to attempt to settle directly with the government, likely for very little money. *See* C. Edward Polk Jr. and Justin Gray, *Fighting False Marking Through Gov't Settlements*," *Law360*, November 2, 2010 (http://www.law360.com/web/articles/205540).

The *Hy-Grade* court's fear of disproportionate judgments can be addressed in a number of ways, too. The district court has discretion to award damages of a fraction of a penny per article. *See Forest Group*, 590 F.3d at 1304. One district court penalized a defendant at a rate of 32% of the average sales price. *See Presidio Components Inc. v. American Technical Ceramics Corp.*, No. 08-cv-335 (S.D. Cal. Apr. 13, 2010) (setting penalty at 35¢ per unit, where average sales price was $1.07 per unit). A Federal statute of limitations, 28 U.S.C. § 2462,[9] is being used to limit damages to products mismarked for only the five years before filing. *See Arcadia Machine & Tool, Inc. v. Sturm, Ruger & Co.*, 786 F.2d 1124, 1125 (Fed. Cir. 1986); *Seirus Innovative Accessories Inc. v. Balboa Mfg. Co.*, No. 09-cv-2274 (S.D. Cal. Apr. 26, 2010) (dismissing in part under 28 U.S.C. § 2462 a false marking counterclaim for products sold five years before filing of the complaint).

The courts are also making it more difficult for false marking plaintiffs to pursue their cases without spending money. The Federal Circuit recently ruled that false marking complaints will be held to the higher pleading standard of Fed. R. Civ. P. 9(b). *See In re BP Lubricants USA Inc.*, No. Misc. 960 (Fed. Cir. March 15, 2011). Based on this decision, many defendants will file motions to dismiss (and many have already) bare-bones false marking complaints, requiring plaintiffs to re-plead. In addition, many district courts are transferring cases from the plaintiff's home forum to the defendant's home forum on the basis of convenience, since the decision to mark is often made at the defendant's principal place of business. *See, e.g.*, *Unique Product Solutions, Ltd. v. Holdup Suspender Co.*, No. 10-cv-1951 (N.D. Ohio Dec. 3, 2010) (transferring case to Eastern District of Michigan, home of defendant).

Finally, Congress is working to stem the tide of the false marking suits. On March 8, 2011, the Senate passed S.23 by a margin of 95-5. (*See* http://www.ipfrontline.com/downloads/112s23es.pdf for a copy of the bill.) Among other things, this bill limits false marking cases to (1) the United States and (2) private parties who have suffered a competitive injury from false marking, and limits damages to those adequate to compensate for such injury. This bill would apply to all cases pending on or after the date of the enactment.

V. CONCLUSION

The *Hy-Grade* court found Section 292 unconstitutional for violating the Take Care Clause, even after the Government intervened to defend the statute. This decision failed to adequately analyze the control of the government over the *qui tam* relators compared to the power granted to the relators. The decision also failed to abide by the abstention doctrine to refrain from deciding constitutional issues unless absolutely necessary. Although the false marking cases may be considered by some to be a "plague," the Federal Circuit has recognized the value of the statute. The courts, Congress, and the Department of Justice are dealing with the problems of the false marking suits, and hopefully this case is an anomaly.

Bobby Greenfeld is Counsel in the New York Office of Mayer Brown LLP. His practice focuses on patent litigation and client counseling. He has counseled both defendants and plaintiffs regarding false marking litigation. The views expressed in this article are solely those of Mr. Greenfeld and are not to be attributed to Mayer Brown LLP or any of its clients.

[1] This case is referred to by the defendant's name because the plaintiff Unique Product Solutions filed 31 false marking cases between June 2, 2010 and September 7, 2010, all but one of which was in the Northern District of Ohio.

[2] The Article II issue was not considered on appeal to the Federal Circuit in *Pequignot*, which addressed a different decision of the district court relating to the meanings of unpatented article and intent to deceive in the False Marking Statute. *See Pequignot v. Solo Cup Co*., 608 F.3d 1356 (Fed. Cir. 2010).

[3] The court declined to decide the defendant's constitutional challenge under the Appointments Clause, but cited to the decision *United States ex rel. Taxpayers Against Fraud v. General Electric Co*., 41 F.3d 1032, 1041 (6th Cir. 1994), denying a constitutional challenge to the False Claims Act under the Appointments Clause, and stated such decision "would likely apply to False Marking *qui tam* relators." *Hy-Grade I*, slip op. at 14 n.8.

[4] Fed. R. Civ. P. 24(a)(2) states, "the court must permit anyone to intervene who . . . claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest."

[5] The plaintiff filed a Notice of Appeal from the first Opinion on March 9, 2011, one day after the Government filed its motion to intervene and for reconsideration.

[6] The *Hy-Grade* court also failed to mention that the situation in *Morrison* was that Congress sought the appointment of the independent counsel to investigate the Executive Branch, specifically, directions from the President to withhold documents subpoenaed by Congress. Thus, *Morrison* was a real separation-of-powers case.

[7] The Government in *Hy-Grade* presented the court with a list of settlements defendants had entered into in 2010 with *qui tam* relators. (*See* Govt.'s Br. at 11 n.5 (citing *www.justice.gov/civil/foia/elecread/2010/292%20Payment%20Chart%202010%20through%20Dec%2031%202010.pdf*; *see also* *www.grayonclaims.com/false-marking-settlement-info/* (containing information as of March 4, 2011). Although the largest settlement was $350,000, the smallest was only $500, and the average just over $55,000.

[8] This type of activity may even create a new breed of false marking plaintiffs – called "false marking poachers" – who file a new lawsuit against a defendant who has already been sued, and then negotiate a low settlement with the defendant that undercuts what the first plaintiff is offering.

[9] Section 2462 covers, in pertinent part, "an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture."

Moving UP ▲

& Moving ON ➤➤➤

The Bulletin is introducing a new feature 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: Stephen Quigley (squigley@ostrolenk.com) or Wanli Wu (wwu@wiggin.com).

Martin Schwimmer has joined the Trademark, Copyright and Domain Name Practice Group at **Leason Ellis**. Mr. Schwimmer, publisher of The Trademark Blog, was previously a partner at Moses & Singer.

President's Speech on Behalf of Judge Rich at the 89th Annual NYIPLA Judges Dinner, March 25, 2011

My name is Dale Carlson. I am most pleased to welcome you to this evening's dinner in my role as NYIPLA President. I am the first President in the NYIPLA's history to be from a Connecticut law firm. This is a testament to the NYIPLA's geographical diversity as the largest regional intellectual property law association in the country - with active members reaching from New York and New Jersey to Connecticut and Vermont.

The reason why we call this a "Judges Dinner" is because we take this occasion each year to honor and salute our federal judges. We've done this in good times and bad - through the Roaring Twenties, the Great Depression, the Dot-com boom and bust, and now what we can only hope is the tail end of the Great Recession. Tonight we honor two judges from the Court of Appeals for the Federal Circuit, and we salute one judge from the Eastern District of New York.

During a time when basic tenets of our nation's patent system are being called into question, it is eminently appropriate for us to honor a staunch supporter of a strong patent system, Giles S. Rich. Judge Rich was NYIPLA President exactly sixty years ago - during 1950-51. Tonight we mark the diamond anniversary of his Presidency.

During his presidency, Judge Rich was part of a two-person drafting committee to co-author the Patent Act of 1952. It is the law of the land for patents today. The other co-author was Paul Rose - a patent lawyer at the time with a former employer of mine, Union Carbide Corporation. Back then, Judge Rich was an adjunct professor of patent law at Columbia, and Paul Rose was an adjunct professor of patent law at George Washington University. In drafting the Patent Act, they worked closely with another patent expert - Pasquale Federico of the U.S. Patent Office.

Not long after his term as NYIPLA President, Judge Rich became a federal judge, first with the Court of Customs and Patent Appeals, and later with the Court of Appeals for the Federal Circuit upon its creation in 1982. During his long tenure on the bench, Judge Rich was in the unique position of construing the very statute he co-authored during his time as NYIPLA President.

I mentioned before that basic tenets of our nation's patent system are currently being called into question. One example is the recent *Ebay* opinion from the Supreme Court. In *Ebay*, the Supreme Court opined that a patent owner is no longer entitled to injunctive relief against an infringer as a matter of right.

The Court's ruling in *Ebay* does not comport with the view that Judge Rich expressed to us from this podium at the NYIPLA Judges Dinner in 1997. He said then: "The Supreme Court held over one hundred years ago that all a patentee gets is the right to exclude others, which is not ambiguous. Bearing that in mind, the Patent Act of 1952 changed the wording of the grant from 'exclusive right' to 'right to exclude others'. You may think it unimportant, but it is important because it often affects legal reasoning."[1]

Although clearly inconsistent with the Supreme Court's position in *Ebay*, Judge Rich's view of the patent right deserves to be revisited now, not only because he was an expert in patent law, but also because he co-authored the very statute that he was speaking about.

Further changes to our patent system are proposed in the patent reform bill currently pending in Congress (S.23) - titled the "America Invents Act". In writing about patent reform initiatives, Judge Rich had this to say: "Let it be remembered that the patent system is supposed to be an incentive system. If it ceases to provide incentives...we may as well dispense with it. The question to be asked first about every proposal for change is: What does this do to the incentives?"[2]

One provision of the patent reform bill would strip the so-called best mode disclosure requirement of its force by rendering failure to disclose the best aspects of the invention known to the inventor in a patent application unusable as a basis to later invalidate the patent or render it unenforceable. The answer to Judge Rich's question - what effect will this have on the incentive to disclose? - is that removing the penalty for failure to disclose best mode will diminish the incentive to disclose the best mode. Accordingly, Judge Rich would say: "Don't make this change."

The patent reform bill would also supplement, if not supplant, our current system of post-grant patent review with a European-style Opposition procedure. This radical change to our patent system was first proposed back during the Reagan era - but was not adopted in this country then. It was, however, adopted by Japan, South Korea and China.

The Opposition protocol failed in all three countries, and was abolished. We should learn from the Asian experience, and not adopt this change. We already have a form of post grant review. It is called *Inter Partes* Reexamination. Judge Rich would say that we should try to improve the existing form of post grant review, rather than adopt a radical new system that is likely to be fraught with problems. Here are Judge Rich's exact words: "The way to perfect a legal system which is working very well but is developing problems is first to try solving the problems within the framework of the system, not to junk the system and substitute another with potential problems as yet undreamed of."[3]

As you can see, Judge Rich had a clear and concise style of writing. During his lifetime, he did much of his thinking and writing from his summer home in Newtown, Connecticut. He built that house by hand, and shared it with family and friends, including his law clerks, many of whom have joined us this evening to honor him.

The Federal Circuit Historical Society recently published a two hundred page Journal[4] about Judge Rich's life, his family, and his career, including speeches and articles. The NYIPLA is most grateful to the Federal Circuit Historical Society for allowing us to share the Journal with all attendees at tonight's dinner. A copy of the Journal is on the CD located in the back of your program book. If you are a student of the law or a student of history, then this Journal is a must-read. My hope is that the story of Judge Rich's life will inspire us all.

One of his former law clerks, James F. Davis, wrote of Judge Rich that "he did not need more titles."[5] Nonetheless, our profession benefits by giving a new title because that spreads Judge Rich's name recognition to others who may wish to learn about him. And so, tonight, it is my pleasure to announce that the NYIPLA Law Student Diversity Scholarship given each May at our Association's Annual Meeting will henceforth be called "The Honorable Giles S. Rich Diversity Scholarship".

And now I have the pleasure of presenting a Steuben glass-work in honor of Judge Rich's lifetime of achievements. The award is being accepted by his grand-daughter, Elizabeth Hallinan. As a side note, Elizabeth's great-grandfather attended our first Judges Dinner in 1922. Elizabeth is a first year law student at my alma mater, New York University School of Law. Elizabeth, please step up to the podium to accept this award on behalf of your grandfather.

1 "Giles S. Rich's Speech at the 75th Annual Dinner of the NYIPLA", NYIPLA Bulletin, Volume 37, Number 5, May/June 1997.
2 "Commentary, Proposed Patent Reforms, 1967 - Introduction" by Giles S. Rich, 36 Geo. Wash. L. Rev. 95-99, at 99 (1967-68).
3 *Id*. at 99.
4 Journal of the Federal Circuit Historical Society, Volume 3 (2009).
5 "Giles S. Rich His Life and Legacy Revisited" by James F. Davis, published in ABA's *Landslide* magazine, Volume 2, Number 1 (September/October 2009).

Board of Directors Meetings Reports

Summary of the January 25, 2011 Meeting

The meeting was called to order at the offices of Wiggin and Dana, 450 Lexington Avenue, New York, by President Dale Carlson. Terri Gillis, Charles Hoffmann, Tom Meloro, Dorothy Auth, Susan Progoff, John Delehanty, Walter Hanley, John Moehringer, Mark Abate and Allan Fanucci were present. Alice Brennan, Leora Ben-Ami and Jeffrey Butler participated by conference call. Also present was Feikje van Rein of Robin Rolfe Resources. Absent and excused were Ira Levy and Doreen Costa.

The minutes of the December 14, 2010 meeting and amended minutes were approved.

Alice Brennan presented the Treasurer's report. The Association continues to operate on a solid financial footing. The Association is favorably positioned for the future.

Charles Hoffmann reported on the activities of the Amicus Brief committee. The Board considered a request for an amicus brief in the *Microsoft v. i4i* case. Prior to this discussion, John Moehringer, Dorothy Auth, Sue Progoff and Tom Meloro recused themselves. The Board did not come to a consensus in favor of preparing a brief and Mr. Hoffmann was asked to inform the committee that the Board did not authorize preparation of a brief.

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

Terri Gillis reported on membership and efforts to recapture "lost souls" and attract new members, with special focus on newly admitted and in-house attorneys.

John Delehanty reported on the Law School Diversity Scholarship. Cardozo Law School was contacted and is enthusiastic about the prospect of receiving the scholarship for use in the 2011-12 academic year. The Board previously approved a $10,000 scholarship for a 1 year term. John will ask Cardozo if it is in a position to promptly select a student recipient.

The Committee Liaisons provided status reports for each committee.

Dale Carlson reported that planning for the 2011 Judges' Dinner is moving forward on schedule. Registrations are coming in and two new suites have been re-

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served above and beyond those reserved last year. Feikje is planning to have lunch with several firm coordinators to facilitate registrations and solicit feedback.

Dorothy Auth reported on the planning for the Day of Dinner CLE program. She reported three judges and a moderator have confirmed their participation on the panel and the CLE Committee is still seeking a magistrate judge. A discussion followed regarding possible speakers from among magistrate judges having an interest in IP.

Charles Hoffmann reported that the Annual Meeting will be on May 24th at the Harvard Club. Judge Barbara Jones (S.D.N.Y.) will be approached to present the Conner Writing Competition Award. Chief Judge Raymond Dearie (E.D.N.Y.) has agreed to be the keynote speaker.

Terri Gillis requested that the liaisons remind the Committee Chairs to prepare their Committee Reports and be ready to give a short presentation of their committee's activities at the meeting.

Options for holding the Annual Dinner in the Fall in future years were discussed. However, the existing bylaws mandate that the Annual Meeting be held in the Spring.

Terri Gillis reported on the NYIPLA website redesign project. Fiekje has engaged a company that will provide needed software for the site. Launch of the new site is envisioned to take place in the Spring. The Board discussed the possibility of an NYIPLA presence on one or more social networking sites, such as Facebook.

Tom Meloro reported on the JPPCLE Annual Meeting preparations. Tom reported that the topics are set, an initial agenda has been prepared, and speakers are currently being solicited.

The meeting was adjourned at 2:00 p.m. The next meeting of the Board is scheduled for Tuesday, February 15th, at noon at the offices of Winston & Strawn, 200 Park Avenue.

Summary of the February 15, 2011 Meeting

The meeting was called to order at the offices of Winston & Strawn, 200 Park Avenue, New York by President Dale Carlson. Terri Gillis, Charles Hoffmann, Susan Progoff, John Delehanty, John Moehringer, Mark Abate, Jeffrey Butler and Allan Fanucci were present. Alice Brennan, Leora Ben-Ami, Doreen Costa and Ira Levy participated by conference call. Kevin Ecker, Inventor of the Year ("IOTY") Committee Co-Chair, attended the first part of the meeting. Also present were Robin Rolfe and Feikje van Rein of Robin Rolfe Resources. Absent and excused were Tom Meloro, Dorothy Auth and Walter Hanley.

The minutes of the January 25, 2011 meeting were approved.

Alice Brennan presented the Treasurer's report. The Association continues to operate on solid financial footing. The Association is favorably positioned for the future.

Kevin Ecker, IOTY Committee Co-Chair, reported on the nominations for inventor of the year. The committee received three new submissions plus four repeats from last year. The Board discussed the top three nominations and then passed a motion that agreed with the Committee's choice to extend the award to Dr. Rajiv Laroia for his patents relating to OFDM/LTE cellular communications.

The Board also passed a motion to provide a NYIPLA Young Innovators Award to a group of students, Barber et. al., for their invention made during high school relating to a curb climbing wheelchair.

Charles Hoffmann reported on the activities of the Amicus Brief committee. There were no new requests for amicus briefs filings.

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

John Delehanty reported on the Law School Diversity Scholarship. Cardozo Law School has accepted NYIPLA's offer for the $10,000 Diversity Scholarship. Professor Crawford and a student will be invited to attend the Annual Membership Meeting and Awards Dinner on May 24, 2011.

John Moehringer reported on the Conner Writing Competition. Although papers may be submitted until March 11th, a number of papers have already been received.

The January CLE Luncheon was well attended and well-received by the attendees. The speakers including retired Chief Judge of the Federal Circuit, Honorable Paul Michel, who discussed the ramifications of the *Microsoft v. i4i* case. He and a panel of NYIPLA members engaged in a lively debate about the case. John Delehanty commented that it was one of the most enjoyable and informative CLE luncheons that he has attended.

The Committee Liaisons provided status reports for their respective committee. The Young Lawyers Committee is hosting a networking reception at the Social Bar and Grill on the evening of February 15. The Corporate Practice Committee and the Patent Litigation Committee are each preparing an article for the Bulletin.

Dale Carlson reported that planning for the 2011 Judges' Dinner is moving forward on schedule. Feikje reported on her luncheon with various law firm coordinators and the feedback she received from them.

In the absence of Dorothy Auth, John Moehringer reported on the planning for the Day of Dinner CLE program. John reported that four judges and a moderator have confirmed their agreement to participate on the panel. The panel members will meet via a conference call at the

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beginning of March to discuss their presentations.

Ira Levy reported that the planning for the JPPCLE program on April 27, 2011 is going forward on schedule. All of the NYIPLA speakers have been confirmed.

Charles Hoffmann reported that the Annual Meeting planning is moving forward on schedule.

The meeting was adjourned at 2:00 pm. The next meeting of the Board is scheduled for Tuesday March 15th at the offices of Ropes & Gray, 30 Rockefeller Center.

Young Lawyers' Networking Reception

The Young Lawyers' Committee, chaired by Sonja Keenan and Andrew Stein, hosted a networking reception for young members and prospective members of NYIPLA on February 15, 2011 at the Social Bar & Lounge in Midtown Manhattan.

Approximately 70 attended including members, nonmembers, and a number of law students who expressed a desire to become active members in NYIPLA. The Young Lawyers' Committee would like to thank the Board for its support of this event and the NYIPLA administrators for their help in organizing the event.

Summary of the March 15, 2011 Meeting

The meeting was called to order at the offices of Baker Botts, LLP, 30 Rockefeller Plaza, New York by President Dale Carlson. Terri Gillis, Charles Hoffmann, Tom Meloro, Dorothy Auth, Doreen Costa, Susan Progoff, John Delehanty, Walter Hanley, Jeffrey Butler were present. Alice Brennan and John Moehringer participated by conference call. Also present was Feikje van Rein of Robin Rolfe Resources. Absent and excused were Mark Abate, Ira Levy, Leora Ben-Ami and Allan Fanucci.

The minutes of the February 15, 2011 meeting were approved.

Alice Brennan presented the Treasurer's report. The Association continues to operate on a solid financial footing, and is favorably positioned for the future. A major portion of the revenue for the Judges Dinner has been received, and is higher than budgeted.

Charles Hoffmann reported on the activities of the Amicus Brief committee. There are currently no new requests for Amicus Briefs.

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

Tom Meloro reported that the planning for the 2011 Judges Dinner is well under way and is proceeding smoothly. The attendance is projected to be higher than last year.

Committee Liaisons provided status reports for their respective committees.

John Moehringer noted that the Conner Writing Competition Committee has received almost fifty submissions from students attending a variety of law schools in the region.

Dorothy Auth reported on the planning for the Day of Dinner CLE program. The CLE Committee had a conference call with the panel of judges, and plans to have another such call, as well as a panel meeting on the morning of the program. The program is projected to draw over 100 attendees.

Charles Hoffmann reported on planning for the Annual Meeting set for May 24th at the Harvard Club. Judge Barbara Jones (S.D.N.Y.) has agreed to present the Conner Writing Competition Award. Chief Judge Raymond Dearie (E.D.N.Y.) will be the keynote speaker.

Tom Meloro reported on the JPPCLE Annual meeting preparations. Tom reported that the topics are set, broadcast emails with the agenda have been sent out, and all speakers have been confirmed.

Dale Carlson provided to the Board comments he received from Patent Litigation Committee Chair, Tony Lo Cicero, in support of proposed local patent rules for the District of Connecticut.

The meeting was adjourned at 2:00 p.m. The Committee Chairs and Co-Chairs will be invited to attend the next meeting of the Board scheduled for Tuesday April 12, 2011 at noon at the Union League Club.

27th Annual Joint Patent Practice Seminar

Wednesday, April 27, 2011 – Hilton New York

8:40 - 8:45	Welcome Remarks
8:45 – 9:35	Featured Morning Address - **David Kappos, Director of the U.S. Patent and Trademark Office**

Panel I – USPTO Practice

9:35 - 9:45	*Hyatt v. Kappos,* 96 USPQ2d 1841 (Fed. Cir. 2010) (en banc): The right to introduce new evidence and the standard of review in a Section 145 trial in district court
9:45 - 9:55	Bringing the Fight to the Patentee: Ex parte and inter partes reexaminations
9:55 - 10:05	*Encyclopaedia Britannica v. Alpine Electronics of America:* Chains of Priority Are Only As Strong As Their Weakest Link
10:05 - 10:15	2010 KSR Guidelines Update, 75 FR 53643-60 (September 1, 2010): Updated PTO guidelines on obviousness determinations in a post-KSR world

Panel II – Pharmaceuticals / Life Sciences

10:45 - 10:55	*King Pharmaceuticals Inc. v. Eon Labs Inc.,* 95 USPQ2d 1833 (Fed. Cir. 2010): Federal Circuit affirms district court's summary judgment of invalidity.
10:55 - 11:05	*Prometheus Labs Inc. v. Mayo Collaborative Services,* 2010 U.S. App. LEXIS 25956, *and Classen Immunotherapies, Inc. v. Biogen,* Fed. Cir. Dkt. 2006-1634: Are methods of diagnosis and treatment based upon natural correlations patentable subject matter under the *Bilski* criteria?
11:05 - 11:15	*Association for Molecular Pathology v. USPTO,* Fed. Cir. Dkt. 10-1406 (Myriad Case): Are isolated gene sequences patentable subject matter?
11:15 - 11:25	*Daiichi Sankyo Co., Ltd. v. Matrix Laboratories Ltd.,* 619 F.3d 1346 (Fed. Cir. 2010): Applying the Graham factors to chemical compound patents

Panel III – Licensing / Foreign Practice

11:35 - 11:45	In Search of Clarity on the State of Mind Requirement for Inducing Patent Infringement --*Global Tech Appliances, Inc. v. SEB, S.A.* (Supreme Court)
11:45 - 11:55	*Stanford v. Roche,* Sup. Ct. Dkt. 2009-1159: Does the Bayh-Dole Act preempt common law rights of inventors employed by a university using federal funds?
11:55 - 12:05	*Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp.,* 604 F.3d 135 (Fed. Cir. 2010): Licensor standing to sue for infringement when exclusive licensee declines to do so
12:05 - 12:15	*Costco v. Omega, 562 US___(per curiam):* Are foreign-sold grey market goods exempt from first sale doctrine? Implications for patent and trademark rights
12:15 - 12:25	*Abraxis Bioscience, Inc. v. Navinta,* 625 F.3d 1359 (Fed. Cir. 2010) and *Spine Solutions v. Medtronic,* 620 F.3d 1305 (Fed. Cir. 2010): What must assignees and licensees show to have standing to assert patent rights?
12:35 – 1:50	Lunch and Keynote Speaker **Hon. Arthur J. Gajarsa** **Circuit Judge, United States Court of Appeals for the Federal Circuit**

Panel IV – Ethics

1:50 - 2:00 *TheraSense Inc. v. Becton, Dickinson & Co.,* Fed. Cir. Dkt. 2009-1511: The Federal Circuits en banc consideration of the inequitable conduct defense

2:00 - 2:10 *TiVo Inc. v. EchoStar Corp.,* 597 F.3d 1247 (Fed. Cir. 2010) – Contempt: When Colorable Imitation Is Not Flattering

2:10 - 2:20 *Princo Corp. v. International Trade Commission,* 616 F.3d 1318 (Fed. Cir. 2010) (en banc): Patent misuse and licensing pools

2:20 - 2:30 *Ring Plus Inc. v. Cingular Wireless Corp.,* 614 F.3d 1354 (Fed. Cir. 2010): Can attorney argument constitute a material misrepresentation?

2:30 - 2:40 The *Qwest* to Analyze Infringement of System Claims: "Use" of System Claims That Include Elements in the Possession of More Than One Actor *(Centillion Data Systems, LLC v. Qwest Communications International, Inc. et al.)*

2:40 - 2:50 *Lockwood v. Sheppard Mullin:* Sham reexamination requests and federal preemption

2:50 - 3:00 Ethical Considerations under the Federal Rules of Civil Procedure as Amended as of December 2010

Panel V – Litigation

3:30 - 3:40 False Patent Marking Cases such as *Forest Group Inc. v. Bon Tool Co.,* 590 F.3d 1295 (Fed. Cir. 2009), *Pequignot v. Solo Cup Co.,* 608 F.3d 1356 (Fed. Cir. 2010), and *Stauffer v. Brooks Brothers Inc.,* 619 F.3d 1321 (Fed. Cir. 2010): What is required to establish violation of the statute?

3:40 - 3:50 Relevance, Motivation and Common Sense – The Federal Circuit's Linchpins to Invalidating Claims to a Hitch Pin

3:50 - 4:00 *Hewlett-Packard Co. v. Acceleron LLC,* 587 F.3d 1358 (Fed. Cir. 2009): Declaratory judgment jurisdiction

4:00 - 4:10 *Fujitsu Ltd. v. Netgear Inc.,* 620 F.3d 1321 (Fed. Cir. 2010): Whether patent infringement can be proven by evidence of compliance with industry standard

4:10 - 4:20 *Microsoft v. i4i,* Sup. Ct. Dkt. 2010-290*:* Whether patent invalidity must be proved by a clear and convincing evidence standard – particularly for prior art issues that were not decided in the PTO

4:20 - 4:30 *Goeddel v. Sugano,* 617 F.3d 1350 (Fed. Cir. 2010): Whether envisioning an invention not yet made constitutes constructive reduction to practice

4:30 - 4:40 *Transocean Offshore Deepwater Drilling Inc. v. Maersk Contractors USA Inc.,* 617 F.3d 1296 (Fed. Cir. 2010): Can an offer made outside the U.S. be an offer to sell within the U.S. under 35 U.S.C. 271(a)?

4:40 - 4:50 *Uniloc USA v. Microsoft,* 2011 U.S. App. LEXIS 11: Curtailing the reasonable royalty calculation - 25% rule of thumb and entire market value as inadmissible evidence

Program concludes at 5:00 PM

NYIPLA

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