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In This Issue

New Procedural Rights for IP Owners and the Promotion of Judicial Economy and Efficiency through the use of Arbitration in Civil Actions against the USPTO

by Charles E. Miller[1]

SYNOPSIS

Compulsory, forum-administered arbitration of suits in federal district court seeking review of Patent Office Board decisions affirming examiners' final rejections of patent applications (35 U.S.C. 145) and in ex parte patent reexaminations (35 U.S.C. 306), and of the Director's decisions on petitions for reconsideration of patent term adjustments (35 U.S.C. 154(b) (4)), is enabled by proposed legislation amending these statutes and by court rules implementing the arbitral procedure. The proposal extends the ADR concepts contained in antecedent legislation, case law, and official statements by the Executive Branch, while satisfying all constitutional, statutory, judicial, and public policy requirements.[2] According to the proposed legislation, upon plaintiff's motion and without dismissing the action, the judge assigned to a case would refer the issues to a court Administrator for arbitration by a party-approved tribunal of court-certified arbitrators. The tribunal's decision would be announced in a reasoned arbitral award which the court would then enter in the form of a judgment as though the case had gone to trial, and which would be binding on the parties, but non-precedential. Arbitrators' fees and expenses would be borne by the plaintiff consistent with the current fee-shifting provisions of § 145.

I. INTRODUCTION

Recent judicial precedents, ongoing case law developments, and administrative enactments have caused the scope and duration of U.S. patent rights to depend increasingly upon the records of administrative proceedings in patent applications and patent reexaminations. This trend impacts the task of interpreting patents so that their owners, and enterprises faced with third-party patents, can make informed business decisions affecting patent enforcement; licensing; and research, development, and marketing plans. The situation becomes acute when a patent is tested in the sobering realities of threatened or actual litigation or in the cold light of licensing negotiations. As a result, scope-restricting amendments and representations made in the U.S. Patent and Trademark Office ("Patent Office" or "USPTO") to hasten the allowance of claims are contraindicated in favor of administrative appeals to the Patent Office Board of Patent Appeals and Interferences ("Board") and, if necessary, subsequent judicial review of adverse decisions of the Board.[3]

Optimizing the quality of patent applications by front-loading the effort (and cost) of patent procurement into the pre-filing stage can increase the odds of obtaining allowance of claims initially presented. Such "best practices" are informed by the growing

cont. on page 3

NYIPLA

EDITOR'S CORNER

February 26, 2007

Dear Members:

It is with great pleasure to bring to you this and each issue of the NYIPLA Bulletin. As with every issue, the Bulletin seeks to apprise our membership on a broad spectrum of current topics from different perspectives of the law. This issue is an excellent illustration.

The articles that you will read herein examine three diverse areas of relevance to our members. The first article proposes a compulsory, forum-administered arbitration of particular civil actions brought against the USPTO in the U.S. District Court for the District of Columbia. The author opines on the benefits underscoring his proposal, and details his proposed legislation and local court rules for implementation. The next article, of particular value to trademark attorneys, examines the applicability of the doctrine of foreign equivalents in determining genericness and descriptiveness of a mark. The final article studies the strategy by pharmaceutical companies on the marketing and sale of "authorized generics", and examines the challenges that this strategy may present to consumers and generic companies. The authors dedicated much time and effort in preparing their articles and we thank them for their insight.

You will also find in the Bulletin a variety of informative columns of particular value to our members practicing in the Second Circuit. For several years now, we have included a Southern District of New York Case Review, a study of IP opinions by the U.S. District Court for the Southern District of New York. Also recently incorporated in the Bulletin is a column dedicated to appellate and district court procedural rulings of particular relevance to our IP litigators. Thanks to Arun Chandra and Eric Lobenfeld for their work on the procedural case review, and to Mark Abate and Andrew Stein for their work on the SDNY case review.

As a publication of the NYIPLA, we also seek to keep our members abreast of programs that the Association sponsors, including the Judge's Dinner, the Annual Dinner and the various CLE programs offered throughout the year. The present issue discusses the Association's January 24 CLE Program on the topic of Fraud in the Trademark Office after *Medinol Ltd. v. Neuro Vasx Inc.* The Bulletin also keeps members current on Board of Directors meetings, while also keeping members apprised on past significant events of the Association through the Historian's Corner prepared by the Association's Historian Dale Carlson.

In addition to publishing the Bulletin, the Publications Committee also dedicates much time to fostering a community within our membership. By now, you should have received the 2006-2007 annual Greenbook. The Greenbook provides to you a listing of all members of the Association, and the Board of Directors, Officers, Committees Chairs and Members. Also included this year in the Greenbook are the Association's Proposed Local Patent Rules for the Southern District of New York and the Association's Recommendations to the United States Patent and Trademark Office in regards to two of the USPTO's Proposed Rules Changes. Special thanks to Stephen Quigley as the Greenbook Editor and Johanna Sturm for her graphics work on the Greenbook as well as on the Bulletin.

Finally, I would like to thank all those on the Publications Committee as well as those in the Association who continue to make our publications an informative tool. I hope that you enjoy this issue.

Sincerely,

Ashe P. Puri

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importance of patent drafting and prosecution as key factors in the interpretation of words in a specification and the construction of claims, and in holdings of patent scope and enforceability. But also it implicates the need for greater confidence in and reliance on appellate practice in patent procurement under conditions of optimal efficiency and economy in a process that promotes truth and accuracy in the result.

The Patent Office is one of those federal agencies whose final decisions are expressly subject by statute to dual routes of judicial review.[4] Thus, patent applicants, and owners of patents in *ex parte* patent reexamination, who are dissatisfied with the Board's decisions on appeals from examiners' rejections[5] can seek judicial review either (i) by appealing directly to the Court of Appeals for the Federal Circuit,[6] or (ii) by suing the Patent Office under 35 U.S.C. § 145 (patent applicants) or § 306 (patent owners) in the U.S. District Court for the District of Columbia. The two routes of judicial review are mutually exclusive.[7]

A patentee dissatisfied with the USPTO's determination of a patent term adjustment[8] can seek judicial review by civil action under 35 U.S.C. § 154(b)(4).

II. COMPARATIVE ASPECTS OF CIVIL ACTIONS AGAINST THE PATENT OFFICE VS. DIRECT APPEALS TO THE FEDERAL CIRCUIT

Lawsuits in D.C. federal district court seeking review of Board decisions offer several advantages to applicants or patent owners, as plaintiffs, in comparison to direct appeals to the Federal Circuit.

First, the district court reviews Board decisions *de novo* as to the operative facts if additional evidence or different evidentiary modalities are proffered by either party.[9] Thus, the plaintiff is afforded an opportunity not only to reargue the applicable law (which the court reviews *de novo* in any event), but also to buttress its case with evidence newly obtained, or which was before the Board if reintroduced in a different form, e.g., as expert testimony.[10] In contrast, Federal Circuit review is strictly limited to "the record before the Patent and Trademark Office."[11]

Second, unlike the Federal Circuit, the district court may consider new issues upon a showing of good cause why they were not presented below.[12]

Third, negotiated settlements -- usually accompanied by agreed-upon claim amendments -- are possible in § 145 actions.

Fourth, judgments in § 145 actions are appealable as of right to the Federal Circuit[13] which reviews them without deference to the district court's *ratio decidendi* after examining the district court's findings of fact under the "clear error" standard of review.[14] This contrasts with the more deferential "substantial evidence" standard applicable at the district court level when no new proofs are presented,[15] and in direct appeals from the Board to the Federal Circuit.[16]

The foregoing observations would seem to validate the role of civil actions against the Patent Office as a hybrid of trial and appellate practices.[17] Yet, such suits are usually avoided in favor of direct appeals to the Federal Circuit.[18] Why? There are several reasons.

First, there is a significant financial disincentive against suing under § 145 because all expenses -- including those of the Patent Office -- from commencement of the action through trial and judgment are taxed to the plaintiff.[19] In the aggregate, a plaintiff's outlay resulting from such expense-shifting can exceed the cost of a direct appeal to the Federal Circuit.

Second, many in the patent bar perceive that there is less than optimal certainty of obtaining correct results in trials of § 145 actions, particularly when the subjects matter involved are technologically complex. Federal district court judges cannot always be expected to have scientific or engineering backgrounds sufficient to enable them to appreciate what are often non-intuitive nuances of the technological issues that must be decided. The end result is an increased risk of reversible error and the consequent need to appeal from the district court to the Federal Circuit for review upon a less deferential "clear error" standard.[20]

Third, because of the court's case load, it is often difficult to achieve expedition in civil actions against the Patent Office so as to (i) minimize both delay in commencement and loss of duration of the injunctive enforceability of exclusive rights conveyed under a patent that may ultimately issued on an application, or (ii) avoid undue delay in the practicable disposition, assertion, or licensing of a patent whose claims have been rejected in an *ex parte* reexamination proceeding.

In such a setting, arbitration presents an attractive alternative to litigating to trial and judgment before a D.C. federal district court judge, incorporating the advantages of civil action in the district court, while offsetting some of the disadvantages.

III. CONCEPTS OF ADR IN RELATION TO THE PRESENT LEGISLATIVE AND RULE-MAKING PROPOSALS

ADR Methodologies in the Federal Context

The term "alternative means of dispute resolution" (ADR) is defined in the *Alternative Dispute Resolution Act of 1998* ("ADRA")[21] as "any process or procedure… in which a neutral third party participates to assist in the

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resolution of issues in controversy."[22] Non-adjudicative ADR includes mediation and mini-trials; adjudicative ADR is most often associated with arbitration.

Arbitration

"Arbitration" connotes an adversarial, adjudicative ADR proceeding in which the operative facts and apposite law implicated in a dispute are presented, through testimonial and/or documentary evidence and attorney argument, to a tribunal of one or more arbitrators or "neutrals" with opportunities for cross-examination and rebuttal.

The arbitral tribunal serves as both fact-finder and decision-maker in a process that usually involves a hearing, followed by briefings and deliberations culminating in an arbitral award. Depending on the ground rules, the award may include findings of fact and conclusions of law in support of the tribunal's decision. In such a case the arbitral award is termed a "reasoned award."

Arbitrations involving issues of federal law are governed by the Federal Arbitration Act ("FAA").[23] For procedural matters not spelled out in the ground rules of the arbitral proceeding, the Federal Rules of Civil Procedure serve as the default rules.[24]

Properly conducted, an arbitration results in an award that is definitive, final, binding, and mutually dispositive of the parties' claims and defenses. The award is not merely advisory but rather, becomes binding (enforceable) when confirmed by an appropriate court.[25]

A fundamental aspect of arbitration is that the scope of judicial review of arbitral awards is very limited compared to appellate review of judgments entered following court trials. Thus, a party to an arbitration generally has no right to judicial review of the underlying merits (proofs, ratio decidendi and holding) decided in the award. However, under the FAA an award can be challenged and vacated on the basis of (a) corruption, fraud, or undue means in procuring the award, (b) previously undisclosed non-evident partiality, malice or bias, or corruption on the part of an arbitrator, (c) arbitrator misconduct that unduly prejudices a party's case, (d) an arbitrator's exceeding his or her powers, or so imperfectly executing them that a mutual, final, and definitive award upon the terms of reference was not made, (e) non-arbitrability of the dispute, and/or (f) entry of the award entered in the wrong jurisdiction.[26]

Forum-Administered Arbitration

"Forum-*administered* arbitration" is the type of arbitral proceeding contemplated by the present proposal. It is to be understood more narrowly than "court-*annexed* arbitration" [27] in that the court itself, by its own rules and administrative personnel, supervises the arbitration of, and without dismissing, cases pending before it by a tribunal of arbitrators who have been certified by, and are answerable directly to, the court. This enables and implements direct judicial control of the process.

The legislation and court rules proposed herein require reasoned arbitral awards explaining the tribunal's factual analysis and legal conclusions. This minimizes the vulnerability of such awards to vacatur on any of the foregoing statutory (FAA) bases or on judicially created grounds such as overriding public policy, total irrationality, and arbitrary and capricious decision making in manifest disregard of the operative law.[28] Also, arbitrability and jurisdiction are non-issues because the D.C. federal district court would directly administer the arbitral proceeding and enter the award as a judgment under an express, detailed statutory mandate. Furthermore, the constitutionality of compulsory arbitration involving government agencies was analyzed and confirmed in a report prepared in the U.S. Department of Justice which reverses over 150 years of government opposition to binding arbitration by independent arbitral tribunals.[29]

IV. PROPOSED LEGISLATION

In commercial settings, "arbitration is a creature of contract"[30] which is typically used for non-judicial resolution of disputes between entities whose rights and obligations may or may not be governed by applicable law. Normally, a party cannot be compelled to arbitrate a dispute if it has not agreed to do so.[31] In contrast, the present proposal calls for a statutory deployment of an ADR methodology for dealing with issues embedded in civil actions against the Patent Office that goes beyond traditional, voluntary arbitration and the *ADRA*. In particular, the proposed legislation enables forum-administered arbitral review of the Board's decisions through compulsory (mandatory) proceedings upon an incontestable motion of the plaintiff-applicant or plaintiff-patent owner, as the case may be.

The proposed legislation provides an optional avenue within the existing framework of federal district court review of administrative decisions in patent cases. Because such legislation operates beyond the jurisdiction of the defendant-agency, it would neither be affected by nor require any changes in the Patent Office Rules of Practice.[32] And because it is designed to complement the current appellate process without displacing it, the proposal would not alter or diminish the plaintiff's access to existing judicial procedures. And it comports with the generally favorable attitude of Congress and among jurists and the business community toward the use of innovative ADR methodologies in judicial settings.[33]

The non-reviewability of judgments entered as confirmations of arbitral awards in many cases would be a desirable trade-off in lieu of appeal, making arbitration an attractive alternative to litigating cases to trial. This is particularly true in the present judicial environment that places an increasingly high premium on patent draftsmanship and efficient prosecution, coupled with appeals from examiners' rejections in lieu of amending claims or presenting claim-narrowing arguments in order to obtain the allowance of patent applications or certification of the validity of patent claims undergoing reexamination.

A. Amendment of 35 U.S.C. § 145 and § 306

To enable the forum-administered arbitration of civil actions against the Patent Office seeking review of Board affirmances of examiners' final rejections of patent applications and in *ex parte* patent reexaminations, it is proposed to augment § 145 as follows wherein changes are indicated in boldface with additions underscored and deletions in brackets:

§ 145. Civil action to obtain patent**, or to certify validity of patent claims in reexamination; arbitration**.

(a) An applicant **for patent, or the owner in an ex parte reexamination of a patent who is** dissatisfied with the decision of the Board of Patent Appeals and Interferences in an appeal under section 134(a) **or (b)** of this title may, unless appeal has been taken to the United States Court of Appeals for the Federal Circuit, have remedy by civil action **as plaintiff** against the Director in the United States District Court for the District of Columbia if commenced within such time after such decision, not less than sixty days, as the Director appoints.

(b) Upon motion of the plaintiff made between the time of completion of the service and filing of the pleadings in the action commenced in accordance with paragraph (a) of this section and the earlier of the filing of any motion of plaintiff for summary judgment or the completion of pretrial discovery, the court shall, without dismissing the action, order and directly administer the arbitration of the issues pleaded, based on the record then obtaining and as may be further developed during the arbitration by a tribunal of one or more arbitrators.

(c) A person may receive compensation for services and expenses as an arbitrator in the action, which shall be paid for by the plaintiff in accordance with paragraph (f) of this section, but such person shall not be an employee of any government and shall receive no pay or employment benefits from any government by reason of his or her status or service as an arbitrator under this section.

(d) The court may adjudge**, or as the case may be, the tribunal may render an award that shall be entered as a judgment upon submission of the award to and confirmation thereof by the court,** that such applicant is entitled to receive a patent for his invention **or that such owner is entitled to a certificate of reexamination confirming the patentability of his invention**, as specified in any of his claims involved in the decision of the Board of Patent Appeals and Interferences, as the facts in the case may appear and such adjudication **or judgment entered on the award** shall authorize the Director to issue such patent or **such certificate as the case may be** on compliance with the requirements of law. **An arbitral award shall be reasoned and non-precedential as to all the issues, shall be binding only on the parties to the action, and shall not be subject to trial de novo or otherwise reviewed on the merits by the court.**

(e) The appointment and compensation of the arbitrator(s), the entire arbitration proceedings and the evidence therein, the arbitral award, and the confirmation and entry of such award as a judgment shall be part of the court record in the action as the court may direct and shall be in accordance with the rules established therefor by the court and shall be governed by title 9 and title 28, United States Code, to the extent such rules and such titles are not inconsistent with this section. The court shall give notice of its judgment to the Director who shall, upon receipt of the notice, enter the same in the application file or in the reexamination record of the patent, as the case may be.

(f) All the expenses of the proceedings **under this section** shall be paid by the **[applicant] plaintiff, except that if arbitration is ordered under paragraph (b) of this section, then thereafter only taxable costs under section 1920 of title 28, United States Code and the compensation of each arbitrator for his or her services and expenses incurred during the course of the proceedings shall be paid by the plaintiff**.

Because § 145 is incorporated by reference in § 306, no amendment of the latter section is required to effect the proposed legislation in the context of patent reexamination.

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The proposal augments and partitions the single paragraph of current § 145 into six subsections (a) through (f) to facilitate the introduction of the following precepts.

First, clarifying language has been added in subsections (a) and (d) to correct a legislative oversight in not explicitly enabling civil actions by patent owners in *ex parte* reexaminations.

Second, subsection (b) requires the court to grant plaintiff's motion for referral of the action to arbitration on terms of reference which are embodied in the pleadings. The defendant-Patent Office cannot oppose the motion, which only the plaintiff can make. Such an incontestable motion must be made during the period between the time the issues have been joined in the pleadings and the scheduled close of pretrial discovery (or the filing of an earlier motion by plaintiff for summary judgment). These requirements ensure that if the plaintiff desires arbitration, then it must initiate the process within the appropriate time frame so that the arbitral proceeding and award can be conducted and rendered effectively. It can be expected that the motion would be made shortly after the pleadings are in, and the terms of reference in the order granting the motion would include the issues pleaded as well as any issues to be decided in pending motions.

Third, under subsection (b), the court, upon granting plaintiff's motion, refers the entire case to arbitration. In doing so, the court would not dismiss the complaint; rather, the court would maintain the case on its docket in order to retain jurisdiction consistent with the forum-administered nature of the proceeding, which is conducted under the court's own rules that are beyond the control of the Patent Office in keeping with the constitutional requirements of the Judicial Vesting Clause.[34]

Fourth, under subsections (b), (c), and (f), the arbitral tribunal -- consisting of one or more arbitrators -- is in effect a structured jury of independent experts who know that their compensation and expenses will be taxed to the plaintiff. Subsection (f), in addition to softening the expense-shifting burden on the plaintiff, is in harmony with the constitutional prohibition under the Appointments Clause[35] against arbitrators being government employees by virtue of any payments to them by the court or by the Patent Office.

Fifth, under subsections (b), (d), and (e), the arbitral proceeding is governed by the *FAA* (title 9, U.S.C.) and the *Federal Judiciary Act* (title 28, U.S.C.). All of the issues raised in the pleadings must be decided on the basis of the factual record that was before the Board, and which may be supplemented by additional evidence or further developed in the same manner as if the case had gone to trial. When the action is terminated upon entry of the arbitral award as a judgment of the court, the entire record of the proceeding becomes part of the record in the case.

Sixth, under subsection (d), the award (i) must be reasoned as to all issues decided, (ii) is submitted to the assigned judge for confirmation and entry as a judgment, (iii) is binding only on the defendant-Patent Office, and the plaintiff-applicant or patent owner, (iv) is not subject to trial *de novo*, and (v) may not be reviewed on the merits.

B. Amendment of 35 U.S.C. § 154(b)(4)

To enable the compulsory, forum-administered arbitration of civil actions against the Patent Office seeking review of the Director's decisions on petitions for reconsideration of patent term adjustments, it is proposed to augment § 154(b)(4) as indicated by underscoring in boldface as follows:

§ 154 Contents and term of patent; provisional rights

* * *

(b) Adjustment of Patent Term –

* * *

(4) Appeal of patent term adjustment determination–

(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5, **and the arbitration, expense, and taxation of costs provisions of section 145 of title 35** shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

Section 154(b)(4)(A) cites the Administrative Procedure Act ("APA")[36] rather than § 145 as the basis for the district court's review of administrative patent term adjustment determinations. The proposed arbitration provisions of § 145 are made applicable to § 154(b)(4)(A) by parallel amendment of the latter.

V. PROPOSED COURT RULES

To implement the kind of arbitration described herein, it is proposed to supplement the civil rules of the U.S. District Court for the District of Columbia with a set of rules the highlights of which are as follows.[37]

A. Purpose and Scope of the Proposed Rules

The proposed court rules provide an "Arbitration Program" to be administered directly by the court itself through an "Administrator of the Arbitration Program" -

- a court employee appointed to the position by the Chief Judge. Additional court employees may be appointed to serve as "Assistant Administrators" by the Chief Judge in consultation with the Circuit Executive. One of the key roles of the Administrator is to promote the avoidance of improprieties and misunderstandings by serving as a conduit for communications between the arbitrator(s) and the assigned judge, and between the parties and the arbitrators. Another job of the Administrator would be to construe and apply the applicable court rules in consultation with the assigned judge in situations where a sole arbitrator cannot decide, or the arbitrators (if there be more than one) are unable to agree among themselves, on what the correct interpretation should be and/or how they are to be applied in the case.

B. Qualifications, Certification, Panel, Registry, Oath, Training and Status of Court- Certified Arbitrators

Certification of Arbitrators

The proposed rules establish requirements for court-certification of those qualified to apply for membership in a standing panel of arbitrators. The requirements include (i) U.S. citizenship, domicile, and residency, (ii)(a)(1) registration to practice before the Patent Office, (ii)(a)(2) state or D.C. bar admission, (ii)(b) admission to the bar of the D.C. federal district court, (iii) appropriate technical education, and professional experience, and (iv) the absence of any government-derived compensation.

Registry of Panel Members

The court would establish and maintain a publicly accessible registry of its certified arbitrators which would include their resumes and hourly billing rates.

Oath, Training, and Status of Arbitrators

Arbitrators would be required to take an appropriate oath and undergo training as the court may prescribe. To avoid constitutional issues, arbitrators would have the status of independent contractors.[38]

C. Referral of a Case to Arbitration

Motion for Arbitration; Terms of Reference

Under the proposed rules, the option to arbitrate can be exercised only by timely written motion of the plaintiff in accordance with existing court rules for referral of the action to arbitration of all the issues pleaded which form the terms of reference set forth in the motion. The plaintiff's proposed terms of reference are subject to modification based on the defendant's objection(s) or counterproposal(s), and plaintiff's reply thereto within the time limits set forth. In all other respects the motion is incontestable. The motion for referral to arbitration may be made at any time between the filing of the last responsive pleading and the time set for the close of discovery or the filing of an earlier motion by plaintiff for summary judgment.

D. Appointment of Arbitrator(s) to Serve on a Case Tribunal

Each case referred to arbitration would be heard by one or more arbitrators (an odd number) who would constitute the arbitral tribunal. The plaintiff may request multiple arbitrators; otherwise the tribunal would consist of a sole arbitrator.

Selection and Appointment of Arbitrators

Candidates for the tribunal are selected by the Administrator from the panel for the parties' consideration and approval. The administrator would submit the names of those selected by the parties to the assigned judge who will then issue an order confirming their appointments to serve on the tribunal. Alternatively, the parties, with the approval of the assigned judge, may themselves select as members of the tribunal arbitrators who may or may not be on the panel.

E. Obligations, Powers, and Immunities of Tribunals and Arbitrators Serving on Tribunals

To maintain the integrity of the arbitral process, and protect the arbitrators' own professional interests as well as those of the parties, the rules explicitly set forth the disclosure obligations, standards for disqualification, powers, and immunities of and procedures for complaints against arbitrators serving on tribunals. With respect to the tribunal's authority, the following aspects of it should be particularly noted.

Construction of Claims in Patent Applications and in Patents Undergoing Reexamination

Since 1982, compulsory arbitration of <u>any</u> and <u>all</u> issues of contention between consenting parties in patent cases has been permitted by statute.[39] Further, there are no legal precedents that would preclude arbitral tribunals in § 145 actions from construing claims in patent applications or in patents undergoing reexamination in assessing their validity in light of relevant evidence presented under the terms of reference. Indeed, the appropriateness, merits, and advantages of arbitrating patent claim construction issues *in lieu* of full-court Markman hearings in patent infringement litigations have recently been noted.[40] To be sure, claim constructions by arbitral tribunals in § 145 actions would not be conclusive against third parties or in courts in subsequent cases involving such claims.[41] However, just as the citation of non-precedential Federal Circuit opinions is permitted in cases before that court, so too arbitrated claim constructions should be admissible as evidence in future cases, subject to whatever evidentiary weight the courts

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would choose to accord them. And, given the credentials and expertise of arbitrators serving on tribunals in § 145 actions -- which actions are adversarial rather than administrative in nature -- one would expect that such weight could be substantial.

Discovery; Subpoenas

The FAA confers authority on arbitral tribunals to issue subpoenas for the production of documents and testimony of witnesses deemed relevant to the issues presented in the terms of reference.[42] Such subpoenas are enforceable in the same manner as if they had been issued by the court in the district in which the arbitral proceeding is taking place.[43]

The U.S. Court of Appeals for the District of Columbia in a recent case involving the subpoena power of a district court, dispelled any doubt that an agency of the federal government can be subpoenaed under Rule 45 of the Federal Rules of Civil Procedure to produce documents and testimony in a civil action against that agency. In particular, the court held that "the Government is a 'person' that is subject to subpoena under Rule 45 regardless of whether or not it is a party to the underlying litigation."[44]

Therefore, the Patent Office, as an agency of the federal government, can, like any other person, be compelled by subpoena issued by an arbitral tribunal to produce relevant evidence, both testimonial and documentary in a civil action under 35 U.S.C. § 145.

F. Arbitration Procedures

The rules contain detailed provisions for carrying out pre-hearing procedures, conducting evidentiary hearings, pre- and post- hearing briefings, and closing of the hearings.

G. Award and Judgment

The arbitral award would be (i) based on a majority vote of the arbitrators, (ii) reasoned with respect to the operative facts and applicable law, (iii) in writing and signed by the arbitrators, and (iv) submitted to the Administrator within two (2) months following the close of the hearing. The Administrator then forwards it to the assigned judge and mails copies to the parties. When the judge confirms the award, the Clerk of the Court then enters it as a judgment and sends copies of it to the parties, whereupon the entire record of the arbitral proceeding becomes part of the court record in the case.

Challenges to Award

The rules set forth the timeframe and procedure for challenging an arbitral award, on the non-substantive grounds discussed above, prior to its confirmation and entry as a judgment.

Settlement During Arbitration

The arbitral proceeding may be terminated by a consent award reflecting the terms and conditions upon which the parties may choose to settle the dispute.

Availability of the Arbitral Record

The entire record of the arbitral proceeding would be publicly available so as to optimize the evidentiary (if not binding) effect of the award in future disputes stemming from the patent application or the patent in reexamination.

H. Taxation of Costs and Expenses; Compensation of Arbitrators

The rules conclude with specific provisions and procedures for the taxing of costs and expenses -- including the compensation of the arbitrators -- consistent with the court's obligation under 35 U.S.C. § 145(f) as proposed to be amended. In particular, the court (through the assigned judge or the Administrator) assesses all costs and the Patent Office's expenses incurred before the case was referred to arbitration, and all costs and each arbitrator's vouchered fees and expenses (but not the Patent Office's expenses) incurred thereafter. These are then taxed to the plaintiff by the Clerk of the Court.

VI. THE BENEFITS AND ADVANTAGES OF ARBITRATION UNDER THE PRESENT PROPOSAL

The arbitration of disputes between private entities and the federal government is not new. What is new and innovative is the synthesis of the present proposal from the novel and legally and constitutionally sound combination of established precepts from which the following advantages flow:

Under the court rules proposed herein, the D.C. federal district court's standing panel of certified arbitrators would include a spectrum of patent practitioners who

are steeped in the tenets of their craft by years of professional experience and who are possessed of meaningful expertise in specific industries and technologies appropriate to the cases on which they serve, to a degree rarely found among Article III courts. As lawyers who are both members of the Patent Office bar and officers of the D.C. federal district court, their activities would be strictly informed by the codes of ethics and standards of conduct prevailing in that forum.[45]

Compared to litigating patent cases to trial, particularly in the context of disputes with the Patent Office, arbitration of the type proposed herein presents an attractive alternative because it affords multiple benefits not available in a trial, including: (i) selective and focused expertise and experience of the arbitrator(s) with consequent greater expedition and efficiency at lower cost, (ii) privacy during the course of the proceeding in a locale convenient to the parties, and (iii) finality. These benefits inure not only to the parties; the public also gains from having access to a record in a proceeding that ultimately becomes part of the overall record of the action as well as the prosecution history of the patent or patent application. Thus, plaintiffs who are confident in the merits of their cases should feel comfortable by-passing the time and expense associated with educating a generalist trial judge on technical and industry-specific issues. Parties attuned to the process will appreciate its precision in the identification and application of apposite law to the evidence at hand in arriving at a result whose probability of accuracy one can expect to be greater than in a regular trial.

The holdings and *ratio decidendae* in arbitral awards under the present proposal would be non-precedential in subsequent cases, thus leaving undisturbed the judiciary's precedent-setting function and the principle of uniformity of appellate review, while at the same time obviating any concerns over results that might conflict with the *corpus juris* embodied in past and future patent-law rulings of the Board and the courts. Indeed, the continuing development of substantive patent law is amply provided for in other judicial settings.

Prompt, efficient, and correct resolution of disputes is important in today's fast-changing markets, where important technologies can become obsolete before matters in dispute involving them are tried and before any appeals are decided or where markets can quickly become so saturated with infringements that litigation and appeal procedures cannot repair the damage by the time such procedures are concluded.[46] The recent histories of the computer, communications, and semiconductor industries, in particular, illustrate the rapidity of product life cycles where superseding technological advances occur on a regular basis. The interposition of arbitrators with the requisite experience and skill sets in the pertinent technologies will invariably result in substantial savings in time and money compared to trials and appeals. The arbitral process proposed herein does so in part by substantially eliminating the need for expensive tutorials and expert testimony, thereby saving the time and expense that would be required to educate the court.[47] And while arbitration expenses overall are usually substantial, they are generally less than 50% of the cost of litigating to trial.[48]

A major benefit of arbitration under the present legislative and rule-making proposals is the opportunity to engage disinterested, non-activist neutrals (i) who, as officers of the court by virtue of being members of the bar thereof, are directly answerable to the assigned judge, (ii) who are fully conversant in patent law and in the technologies underlying the dispute, and (iii) who are professionally motivated, by financial compensation[49] and a personal commitment to maintaining the integrity of the process, to perform with optimal intensity of effort in arriving expeditiously at correct and timely results, undistracted by administrative duties and unencumbered by philosophical biases fed by preconceived notions of being able to set precedent. While no arbitration process can claim infallibility, and not all arbitral awards are entirely immune from challenge, nevertheless, in the instant setting it is unlikely that the court would be asked to entertain a challenge to an award under the statutory criteria of the FAA or as being arbitrary and capricious in (non-statutory) manifest disregard of the operative law.[50]

There are no legal, constitutional, or public policy impediments to the use of arbitration to resolve lawsuits against the Patent Office. And several indicators suggest that § 145, § 306, and § 154(b)(4) actions readily lend themselves to it and from which palpable public benefits will flow.

First, arbitrators would perform the role of fact finders in technical fields suited to their expertise, thereby

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in effect constituting them as a hybrid between (i) a blue-blue-ribbon traverse jury[51] sitting in equity unencumbered by the trappings of the lay jury trial system,[52] special masters, and pretrial motions, and (ii) an appellate tribunal, whose scope of arbitral authority is clearly delineated by the proposed legislation and by the very nature of the proceeding itself.

Second, the arbitration would be comparatively straightforward. Because the issues (terms of reference) to be arbitrated are delineated in the pleadings, there would be no questions about the scope of the tribunal's jurisdictional authority to make awards. Thus, identification of the issues in contention and questions of their arbitrability, jurisdiction, choice of law, venue, and execution of awards in foreign countries -- often overarching concerns in the arbitration of other types of disputes -- would not be implicated.

Third, forum-administered arbitration offers real advantages to patent applicants, and to patent owners in *ex parte* reexaminations and patent term adjustment cases in a setting that (i) utilizes the district court's own local rules without the expense of participation by commercial ADR service providers, (ii) avoids Patent Office administrative rule-making, and (iii) comports with legislative antecedents. These include an entirely optional, nonprecedential, flexible, conclusive, time-saving, and cost-effective way of resolving dissatisfaction with the Patent Office's administrative (Board) reviews of examiner's final rejections by enabling applicants and patentees to enlist the services of proficient, neutral decision makers.

Fourth, legislative history indicates that Congress has had a continuing desire for cost reduction, speed, and more streamlined procedures and evidence rules to aid an overburdened federal judiciary.[53] These same considerations apply to civil actions under § 145: the arbitrability of such actions would encourage patent applicants and patent owners in many cases to avail themselves of § 145 while at the same time decreasing the workloads of the D.C. federal district court and the Federal Circuit. It would reduce delays throughout both courts' dockets and increase judicial efficiency.

Fifth, because arbitration can significantly shorten the time required for review of Board decisions, it could (if a party asserting a patent in an infringement action were so inclined to use it) promote synchrony between patent litigation and the *ex parte* reexamination of patents-in-suit, which in turn supports the argument for staying litigation pending reexamination, a concept that is disfavored by some courts. Thus for example, the court in *NTP Inc. v. Research in Motion Ltd.*,[54] citing Federal Circuit precedent,[55] noted that it "is under no obligation to delay its own proceedings by yielding to ongoing patent proceedings, regardless of their relevancy to infringement claims which the court must analyze." Referring to the "lengthy, complex, fair and fully exhaustive" trial and appellate process of the case so far, the court stated that "[e]ven in the unlikely event that all final [Patent Office] actions were taken in the next few months, [the plaintiff-patent owner], if not satisfied, could appeal the PTO's findings. Reality and past experience dictate that several years might very well pass from the time that a final office action is issued by the PTO to when the claims are finally and officially 'confirmed' after appeals."[56]

Finally, one might question the arbitrability of suits against the Patent Office on the grounds that arbitrations in patent cases should be confined to determining the rights of private entities, rather than in cases entailing the granting of rights (e.g., the issuance of patents or the certification of patent claims) enforceable against the public.[57] But that argument ignores the fact that Congress long ago provided for the voluntary arbitration of patent disputes in interferences[58] and in cases involving patent validity, infringement and enforceability.[59] Arbitration of these disputes affects the public interest notwithstanding that patent rights are determined privately. Also worth noting is the fact that civil actions are sometimes concluded by pretrial settlement agreements. And just as an arbitral award of priority in an interference does not preclude the public from subsequently testing the patentability of the invention, so too, after a patent is granted or patent claims are certified in reexamination following the entry of judgment on an arbitral award in a § 145 action, the public can still challenge the patent since the award and judgment, albeit relevant, admissible, and potentially persuasive in subsequent cases, are neither conclusive nor do they estop third parties from litigating issues of patent validity.

VII. CONCLUSION

The present proposal does not advocate any changes in substantive patent law. Instead, it will create new *procedural* rights for intellectual property owners while promoting economy and efficiency in the judicial review of administrative decisions of the Patent Office.

Informed by legislative considerations, validated by constitutional analysis, tacitly endorsed by the U.S. Department of Justice, and justified by recent judicial holdings, the present proposal responds to the need for a shift in the focus of patent procurement away from the traditional give-and-take between patent applicants/owners and Patent Office examiners toward an emerging new paradigm that elevates the importance of optimal patent draftsmanship, aggressive prosecution, and greater precision in the appeals process. This article

seeks to invite appropriate legislative interest and action at the interfaces of patent procurement, government agency litigation, and administrative law.

Congress, the federal judiciary, inventors, the business community, and the intellectual property bar are thus presented with a unique and historic opportunity for innovative groundbreaking legislative and rule-making initiatives in the adjective law of patents. Enacted, these proposals will inevitably benefit the creators, owners, and legitimate users of inventions and patent assets, the investment community, the federal court system, the Patent Office, and, ultimately, the public at large.


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[1] Partner, Dickstein Shapiro LLP and member of the Alternative Dispute Resolution, Legislative Oversight & Amicus Briefs, and Patent Law & Practice Committees of the NYIPLA. The views expressed herein are solely those of the author.

[2] The author's full report on which this article is based can be obtained by emailing him at millercharles@dicksteinshapiro.com.

[3] During the U.S. government's FY 2006, the number of appeals from the Board's decision in patent cases rose 18.2% over the previous year's total. Source: *IPO Daily News*, January 17, 2007.

[4] *Civil Actions Against the United States, its Agencies, Officers and Employees*, ch. 1 & 6 (2d ed. Thomson West 2003).

[5] 35 U.S.C. § 134(a); 37 C.F.R. § 1.303(a). During the USPTO's FY 2006, some 3,349 *ex parte* appeals in patent cases were filed with the Board and 2,874 appeals were decided. *(*Source: *USPTO's Performance and Accountability Report for Fiscal Year 2006*, pt. 5.3, tbl. 14).

[6] 35 U.S.C. §§ 141-144; 28 U.S.C. § 1295(a)(4)(A); 37 C.F.R. §§ 1.301 and 1.303(a), (b). The USPTO has no right of appeal and hence cannot itself seek judicial review of Board decisions. *Abbott Labs v. Brennan*, 952 F.2d 1346, 21 U.S.P.Q.2d 1192 (Fed. Cir. 1992); *In re Alappat*, 33 F.3d 1526, 31 U.S.P.Q. 2d 1545 (Fed. Cir. 1994).

[7] 28 U.S.C. § 1295(a)(4)(A).

[8] 35 U.S.C. § 154(b)(3)(B); 37 C.F.R. §§ 1.702-1.705.

[9] *Mazzari v. Rogan*, 323 F.3d 1000, 1004, 66 U.S.P.Q.2d 1049, 1054 (Fed. Cir. 2003).

[10] *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1344-48, 53 U.S.P.Q.2d 1580, 1583-86 (Fed. Cir. 2000).

[11] 35 U.S.C. § 144, first sentence; also *In re Varga*, 511 F.2d 1175, 1178, 185 U.S.P.Q. 47, 50 (C.C.P.A. 1975).

[12] *DeSeversky v. Brenner*, 424 F.2d 857, 858-59, 164 U.S.P.Q. 495, 496 (D.C. Cir. 1970); *Dotolo v. Quigg*, 12 U.S.P.Q.2d 1032, 1035 (D.D.C. 1989); *In re Watts*, 354 F.3d 1362, 1365, 69 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 2004).

[13] 28 U.S.C. § 1295(a)(4)(C).

[14] *Winner Int'l*, 202 F.3d at 1344-5, 53 U.S.P.Q.2d at 1583 ("We review the district court's factual findings for clear error and its conclusions of law *de novo* as with any bench trial").

[15] 5 U.S.C. § 706(2)(E).

[16] *In re Gartside*, 203 F.3d 1305, 1311, 53 U.S.P.Q. 2d 1769, 1775 (Fed. Cir. 2000).

[17] *Winner Int'l*, 202 F.3d at 1345, 53 U.S.P.Q.2d at 1584 (referring to civil actions under 35 U.S.C. § 146).

[18] During the USPTO's FY 2006, there were 22 civil actions against the USPTO compared with 42 appeals to the Federal Circuit. (Source: USPTO's *Performance and Accountability Report for Fiscal Year 2006*, pt. 5.3, tbl. 25). Since the enactment of Title 35 of the U.S. Code in 1953, there have been far fewer reported trial court decisions in § 145 cases compared to the number of reported Court of Customs and Patent Appeals and Federal Circuit decisions in direct appeals under § 141. *See also*, D.S. Chisum *et al.*, *Principles of Patent Law*, 130 (3d ed. Foundation Press 2004) ("In practice, a vast majority of appeals are taken directly to the Federal Circuit").

[19] The last sentence in § 145 states that "All the expenses of the proceedings shall be paid by the applicant."

[20] *See* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 35 Intell. Prop. L. Rev. 3 (West Group 2003).

[21] 28 U.S.C. §§ 651-658.

[22] 28 U.S.C. § 651(a)., [23] 9 U.S.C. § 1 *et seq*.

[24] Fed. R. Civ. P. 81(a)(3)., [25] 9 U.S.C. § 9.

[26] 9 U.S.C. § 10; also, *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 569 (1985) (Article III of the U.S. Constitution allows binding arbitration, with judicial review only for fraud, misrepresentation, or other misconduct); Katherine A. Helm, *The Expanding Scope of Judicial Review of Arbitral Awards: Where Does the Buck Stop?*, Disp. Resol. J. 16-26 (Nov. 2006/Jan. 2007).

[27] The term "court-*annexed* arbitration" connotes arbitral proceedings in pending court actions which are often administered by commercial ADR service providers.

[28] *Wilko v. Swan*, 346 U.S. 427, 436-37 (1953).

[29] Memorandum prepared in 1995 by Assistant U.S. Attorney General Walter E. Dellinger, III of the Office of Legal Counsel at the request of the Associate Attorney General John Schmidt, entitled *Constitutional Limitations on Federal Government Participation in Binding Arbitration*. The Memorandum is available at www.usdoj.gov/dc/arbitration.fn.htm[ADR]. *See also*, 7 World Arb. & Mediation Rep. 23 (Dec. 1995/ Jan. 1996). The policy enunciated in the Memorandum is binding on all Executive Branch Agencies and represents their official positions. *See Tenaska Washington Partners II, L.P. v. United States*, 34 Fed. Cl. 434 (Ct. Fed. Cl. 1995).

[30] *United Steelworkers of Am. v. Am. Mfg. Co.*, 363 U.S. 564, 570 (1960) (Brennan, J., concurring).

[31] *Howsam v. Dean Witter Reynolds, Inc.*, 537 U.S. 79, 83 (2002) citing *Steelworkers v. Warrior & Gulf Nav. Co.*, 363 U.S. 574, 582 (1960).

[32] 37 C.F.R. chap. 1.

[33] *Howsam*, 537 U.S. at 83 citing *Moses H. Cone Memorial Hosp. v. Mercury Const. Corp.*, 460 U.S. 1, 24-25 (1983).

[34] U.S. Const. art. III, § 1., [35] U.S. Const. art. II, § 2, cl. 2., [36] 5 U.S.C. chap. 7.

[37] The text of the proposed court rules is contained in the full report.

[38] 18 U.S.C. §§ 201-211., [39] 35 U.S.C. § 294.

[40] Stephen P. Gilbert, *Arbitrating to Avoid Markman Do-Over*, Disp. Resol. J., 60-64 (Aug./Sept. 2006).

[41] See 35 U.S.C. § 145(d) as proposed to be amended., [42] 9 U.S.C. § 7.

[43] *Dynegy Midstream Servs., LP v. Trammochem Div. of Transammonia, Inc.*, 451 F.3d 89 (2d Cir. 2006).

[44] *Yousuf v. Samantar*, 451 F.3d 248, 255-57 (D.C. Cir. 2006); *In re Vioxx Prods. Liab. Litig.*, 235 F.R.D. 334, 342 (E.D. La. 2006) ("reading Rules 30(a)(1) and 30(b)(6) in conjunction, a party may take the deposition of a governmental agency, and compel the attendance of witnesses through the use of a Rule 45 subpoena.").

[45] Also, the District Court for the District of Columbia has adopted the Rules of Professional Conduct of the District of Columbia Circuit Court of Appeals. *See* D.D.C. L.Cv.R. 83.12 and D.D.C. L.Cv.R. 83.16.

[46] Jennifer J. Mills, *Alternative Dispute Resolution in International Intellectual Property Disputes*, 11 Ohio St. J. on Disp. Resol. 227 - 31 (1996); Konstantinos Petrakis, *The Role of Arbitration in the Field of Patent Law*, 52 Disp. Resol. J. 24 (Fall 1997).

[47] Steven J. Elleman, *Problems in Patent Litigation: Mandatory Mediation May Provide Settlement and Solutions*, 12 Ohio St. J. on Disp. Resol. 759, 771-72 (1997).

[48] Thomas L. Creel, *Factors in Deciding Whether to Use ADR in Patent Disputes*, Alternative Dispute Resolution Guide 33 (AIPLA Alt. Disp. Resol. Comm. ed., 1995).

[49] 28 U.S.C. § 658(a) ("The district court shall . . . establish the amount of compensation, if any, that each arbitrator or neutral shall receive for services rendered in each case under this Chapter.").

[50] *Wilko v. Swan*, 346 U.S. at 436-37 ("the interpretations of the law by the arbitrators in contrast to manifest disregard are not subject, in the federal courts, to judicial review").

[51] See *Black's Law Dictionary*, 860-61 (7th ed. 1999).

[52] Jury trials under the Sixth Amendment are not available in Section 145 actions; *see Joy Tech. v. Quigg*, 12 U.S.P.Q.2d 1112, 1114 *further opinion*, 732 F. Supp. 227, 14 U.S.P.Q. 2d 1432 (D. D.C. 1989), *aff'd*, 959 F.2d 226, 22 U.S.P.Q.2d 1153 (Fed. Cir. 1992) ("there is no right to a jury trial under 35 U.S.C. § 145.").

[53] H.R. Rep. No. 97-542, reprinted in 1982 *U.S. C.C.A.N.* 765, 777.

[54] 397 F.Supp.2d 785, 76 U.S.P.Q.2d 1857 (E.D. Va.), *aff'd*, 418 F.3d 1282 (Fed. Cir. 2005), *cert. denied*, 2006 U.S. LEXIS 1053 (Jan. 23, 2006).

[55] *Medichem S.A. v. Eng'g Rolabo S.L.*, 353 F.3d 928, 69 U.S.P.Q. 2d 1283 (Fed. Cir. 2003) and *Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 59 U.S.P.Q. 2d 1823 (Fed. Cir. 2001).

[56] *See* fn. 54.

[57] Citing *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614 (1985), the Court of Appeals for the Second Circuit in *JLM Industries v. Stolt-Nielsen SA*, 387 F.3d 163 (2d Cir. 2004) held that nothing in the *Sherman Act* or in its legislative history suggests that antitrust claims based on either horizontal or vertical conspiracies between competitors are inappropriate for arbitration -- regardless of complexity of the issues or notions of public policy.

[58] 35 U.S.C. § 135(d) enacted as part of the *Patent Law Amendments Act of 1984*, P.L. 98-622 § 202, 98 Stat. 33, 86-87 (Nov. 8th, 1984).

[59] 35 U.S.C. § 294 enacted as part of the *Patent Law Amendments Act of 1982*, P.L. 94-287 § 17(b)(1), 96 Stat. 322 (Aug. 27, 1982).

Trademark Doctrine of Foreign Equivalents

By Sujata Chaudhri[*]

I. INTRODUCTION

Much of the United States market place is a melting pot. Consumers speak, understand, and are exposed to brand names in numerous foreign languages. So how does trademark law serve the interests of consumers and trademark owners with regard to marks in languages other than English? The answer lies in the "doctrine of foreign equivalents."

Under the doctrine of foreign equivalents, words from common foreign languages are translated into English to determine genericness and descriptiveness as well as similarity of connotation with English marks in determining likelihood of confusion. *Palm Bay Imports Inc. v. Veuve Clicquot Ponsardin Maison Fondee En 1772*, 73 U.S.P.Q.2d 1689, 1696 (Fed. Cir. 2005). However, the doctrine of foreign equivalents is merely a guideline, not an absolute rule. *Id.* Thus, the doctrine does not apply to every non-English word that appears in a trademark or service mark. *Sutter Home Winery, Inc. v. Madrona Vineyards, L.P.,* 2005 U.S. Dist. LEXIS 4581 (N.D. Cal. 2005) (quoting *In re Pan Tex Hotel Corp.,* 19 U.S.P.Q. 109, 110 (T.T.A.B. 1976)).

II. POLICY RATIONALES

There are two important policy rationales for the doctrine of foreign equivalents – the domestic competition rationale and the international comity rationale. The Second Circuit discussed the domestic competition rationale in *Otokoyama Co. v. Wine of Japan Import Inc.,* 50 U.S.P.Q.2d 1626 (2d Cir. 1999):

> The same rule applies when the word designates the product in a language other than English. This extension rests on the assumption that there are (or someday will be) customers in the United States who speak that foreign language. Because of the diversity of the population of the United States, coupled with temporary visitors, all of whom are part of the United States marketplace, commerce in the United States utilizes innumerable foreign languages. No merchant may obtain the exclusive right over a trademark designation if that exclusivity would prevent competitors from designating a product as what it is in the foreign language their customers know best. *Id.* at 1629.

The Trademark Trial and Appeal Board ("T.T.A.B." or "the Board") explained the international comity rationale in *In re Le Sorbet, Inc.,* 1985 T.T.A.B. LEXIS 27 *9 (T.T.A.B. 1985):

> The international trade foundation for the rule is significant from the standpoint of the protection of the United States trading interests in foreign countries. Since prior to the Lanham Act, the United States, through its Departments of State and Commerce, has protested the registration in foreign countries of terms considered to be generic names in the English language of products sold in the United States and sold or intended to be sold in export trade. The rationale of these protests is that registration of generic terms as trademarks would interfere with the free flow of international trade in products known by that generic term…. Obviously, to permit registration here of terms in a foreign language which are generic for products sold in a foreign country would be inconsistent with the rationale supporting these international protests. *Id.* at 30-31.

Courts have consistently referred to these two policy rationales in applying the doctrine of foreign equivalents. For instance, in *Enrique Bernat F., S.A. v. Guadalajara, Inc.,* 210 F.3d 439 (5th Cir. 2000), *reh'g and reh'g en banc denied*, 218 F.3d 745 (5th Cir. 2000), international comity weighed heavily in determining that the Spanish word "chupa" was generic for lollipops. The court stated:

> Moreover, the policy of international comity has substantial weight in this situation. If we permit Chupa Chups to monopolize the term "chupa", we will impede other Mexican candy makers' ability to compete effectively in the U.S. lollipop market. Just as we do not expect Mexico to interfere with Tootsie's ability to market its product in Mexico by granting trademark protection to the word "pop" to another American confectioner, so we cannot justify debilitating Dulces Vero's attempts to market "Chupa Gurts" in the United States by sanctioning Chupa Chups' bid for trademark protection in the word "Chupa." *Id.* at 445.

III. WHEN IS THE DOCTRINE APPLICABLE?

The doctrine of foreign equivalents applies only to non-English words from modern languages that consumers are likely to translate into English. Moreover, courts have applied the doctrine irrespective of whether the non-English words have precise English translations.

Application to Non-English Words Likely to be Translated into English

The doctrine of foreign equivalents applies to non-English words that consumers are likely to translate into their English equivalents. *Palm Bay Imports*, 73 U.S.P.Q.2d at 1696. In *Palm Bay Imports*, the Federal Circuit upheld the T.T.A.B's holding that VEUVE ROYALE for sparkling wine and VEUVE CLICQUOT PONSARDIN and VEUVE CLICQUOT, both for champagne, were likely to be confused. However, the Court reversed the T.T.A.B's holding of likelihood of confusion between VEUVE ROYALE for sparkling wine and THE WIDOW for wine. *Id.*

In comparing VEUVE ROYALE with VEUVE CLICQUOT PONSARDIN and VEUVE CLICQUOT, the T.T.A.B. had found that "*an appreciable number of purchasers*" are unlikely to translate the marks into English. *Veuve Clicquot Ponsardin v. Palm Bay Imports, Inc.,* Opp. No. 115,438, 2000 W.L. 21953664 (T.T.A.B. August 4, 2003). However, in comparing VEUVE ROYALE with THE WIDOW, the T.T.A.B. found that "[A]n appreciable number of purchasers in the United States" speak and/or understand French and will translate VEUVE ROYALE as ROYAL WIDOW. *Id.*

On appeal, the Federal Circuit held that the T.T.A.B. was inconsistent in its application of the doctrine of foreign equivalents because "[a]n appreciable number of U.S. consumers either will or will not translate VEUVE into 'widow.'" *Palm Bay Imports*, 73 U.S.P.Q.2d at 1696. It agreed with the T.T.A.B. that "it is improbable that the average American purchaser would stop and translate VEUVE into 'widow.'" Thus, VEUVE ROYALE was not likely to be confused with THE WIDOW. *Id.*

It is notable that although the Federal Circuit agreed with the T.T.A.B. that consumers were not likely to translate VEUVE into "widow," it used the phrase "average American purchaser" in contrast to the T.T.A.B's "appreciable number of U.S. consumers." It appears that the Federal Circuit was using "average American purchaser" as a synonym for "appreciable number of U.S. consumers."

In *In re Thomas*, 79 U.S.P.Q.2d 1021 (T.T.A.B. 2006), the T.T.A.B. held that MARCHE NOIR (French for 'black market') for jewelry and BLACK MARKET MINERALS (MINERALS disclaimed) for retail jewelry and mineral store services were likely to be confused. In that case, it held that the doctrine of foreign equivalents is applied when it is likely that "the ordinary American purchaser" would stop and translate a non-English word into its English equivalent. The "ordinary American purchaser" means an ordinary American purchaser who is knowledgeable in a foreign language. *Id.* at 1024.

In *Thomas*, the applicant reasoned that it was unlikely that the "average American buyer" would translate the French phrase MARCHE NOIR into BLACK MARKET because, according to the 1990 census, only 0.6% of the population in the United States spoke French "very well" or "well." The T.T.A.B. rejected the applicant's argument because "French is a common foreign language spoken by an appreciable segment of the population. Indeed, applicant's own evidence shows that of the foreign languages with the greatest number of speakers in the United States, French is ranked second only to Spanish." *Id.* Thus, concluded the Board, the "one and only meaning" of MARCHE NOIR is "black market" and "that is how it would be recognized and understood by the French-speaking public." *Id. at* 1025.

In *Thomas*, the T.T.A.B. used the term "average American purchaser." However, the decision also refers to the phrases "appreciable segment of the population" and "French-speaking public." Thus, there seems to be confusion over the description of a relevant consumer under the doctrine of foreign equivalents.

It seems most logical to say that the relevant consumer in cases involving the doctrine of foreign equivalents is an average (as opposed to sophisticated) consumer (U.S. citizens and non-U.S. citizens) living in the United States who speaks and/or understands a common foreign language and is likely to stop and translate non-English wording in a mark into English.

Application Only to Words from Modern Foreign Languages

The doctrine of foreign equivalents applies only to modern languages. Thus, words from languages such as Italian, French, Spanish, German, Hungarian and Polish should be translated into English. 2 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 11.34 at 11-67 and 11-68. The Trademark Manual of Examining Procedures (T.M.E.P.) uses the terms "language familiar to an appreciable segment of American consumers" and "modern languages." T.M.E.P. § 1207.01(b)(vi). Thus, only words in modern languages which are understood and/or spoken by the purchasing public must be translated into their English equivalents.

Consistent with the influx into the United States of immigrants from different parts of the world, the scope of the term "modern languages" has expanded over time. For instance, in *In re Oriental Daily News, Inc.,* 230 U.S.P.Q. 637 (T.T.A.B. 1986), the T.T.A.B. recognized Chinese as a contemporary language. *Id.* at 638. It stated that readers in the United States, including a sizable number of readers familiar with both the Chinese and English languages, will perceive Chinese characters which translate as "Oriental Daily News" as

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merely descriptive of a newspaper. In *Otokoyama Co. v. Wine of Japan Import Inc.,* 50 U.S.P.Q. 2d 1626 (2d Cir. 1999), the Court found that the doctrine of foreign equivalents applies to Japanese. In that case, the Japanese term "otokoyama" was held to be a generic term for sake. In *Consolidated Cigar Corp. v. Rembrandt Tobacco Corp. (Overseas) Ltd.,* 176 U.S.P.Q. 159 (T.T.A.B. 1972), the T.T.A.B. held that words in Afrikaans fall under the doctrine of foreign equivalents.

Application to Non-English Words With or Without Precise Translations

Moreover, the doctrine of foreign equivalents applies whether or not a non-English word in a modern language has a precise translation. If the non-English word has a precise English translation, courts generally do not have to go through extensive analysis to determine its registrability on relative or absolute grounds. For instance, in *Ex parte Odol-Werke Wien Gesellschaft M.B.H.*, 111 U.S.P.Q. 286 (Comm'r Pat. 1956), CHAT NOIR for eau de cologne was held confusingly similar to BLACK CAT for cosmetic items, including toilet waters and perfumes because "black cat" was the exact English equivalent of CHAT NOIR. *Id.* In *Blue & White Food Products Corp. v. Shamir Food Industries Ltd.*, 76 U.S.P.Q.2d 1940 (S.D.N.Y. 2004), the Court held that SHAMIR SALADS (dill in Hebrew) was not a generic term for vegetable salads, dips, spreads and herring products that may or may not contain dill. *Id.* at 1944-1945.

On the other hand, if a non-English word does not have an exact English equivalent, courts have to go through a more complicated analysis. In such cases courts look to the "primary and common translation" of the word. In *In re Sarkli, Ltd.,* 220 U.S.P.Q. 111, 113 (Fed. Cir. 1983), the Federal Circuit held that REPECHAGE for skin care products was not likely to be confused with SECOND CHANCE for face creams and other toiletries because none of the dictionary meanings of REPECHAGE made it the exact equivalent of SECOND CHANCE. *Id.* at 112-113. In *Burke v. Cassin*, 45 Cal. 467 (1873), the California Supreme court held that the German word "schnapps" was generic for gin, although its literal translation was "dram" or "drink." *Id.* at 476. In *Enrique Bernat*, the Court held that "chupa" was generic for lollipops, despite the fact that its literal translation is "to lick" or "to suck." 210 F.3d at 445.

Thus, if a word in a foreign language does not have an exact English translation, courts have applied the translation that is most likely to be used by a consumer who understands and/or speaks the foreign language.

IV. WHEN IS THE DOCTRINE INAPPLICABLE?

The doctrine of foreign equivalents does not apply to non-English words that consumers are not likely to translate into English. Furthermore, words from dead languages and marks that combine English and non-English words are not within the ambit of the doctrine. Lastly, there is some inconsistency regarding the applicability of the doctrine when the marks being compared consist of foreign words.

Inapplicable When Consumers are Unlikely to Translate Non-English Word into English

The doctrine of foreign equivalents is inapplicable if an average purchaser is unlikely to stop and translate a non-English word into English. In *In re Tia Maria, Inc.*, 188 U.S.P.Q. 524 (T.T.A.B. 1975), the T.T.A.B. found that TIA MARIA for restaurant services was not confusingly similar to AUNT MARY'S for canned fruit and vegetables because a Spanish speaking consumer was unlikely to translate AUNT MARY'S into TIA MARIA. *Id.* at 526. In *Continental Nut Co. v. Le Cordon Bleu, S.A.R.L.*, 181 U.S.P.Q. 646 (C.C.P.A. 1974), the mark CORDON BLEU was found not confusingly similar to BLUE RIBBON although the English translation of CORDON BLEU is BLUE RIBBON. The court held that it was unlikely that a consumer would translate CORDON BLEU into BLUE RIBBON because CORDON BLEU has been adopted into the English language and has acquired a very different meaning from BLUE RIBBON. *Id.* at 647.

Inapplicable to Words from Dead Languages

The doctrine of foreign equivalents does not apply to words from dead languages such as Classical Greek or obscure languages such as those of the Hottentots or Patagonians or the Taino Indians of the Dominican Republic. 2 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 11.34 at 11-66 and 11-67. The determination of whether a language is "dead" is made on a case-by-case basis, based upon the meaning that the term would have to the relevant purchasing public. T.M.E.P. 1207.01(b)(vi). For instance, Latin is generally considered a dead language. However, if there is evidence that a Latin term is still in use by the relevant purchasing public, then a Latin term is not considered dead. *Id.*

Inapplicable to Mark that Combines English and Non-English Words

The doctrine of foreign equivalents does not apply when a mark is a combination of foreign and English words because a consumer is considered more likely to translate a mark in its entirety than to translate a part of a mark. This principle has been applied consistently by courts and the T.T.A.B. In *In re Universal Package Corp.*, 222 U.S.P.Q. 344 (T.T.A.B. 1984), the T.T.A.B. refused to apply the doctrine of foreign equivalents to the mark LE CASE for jewelry boxes and gift boxes not made of

precious metal. It held that because LE CASE combined the French article LE with the English word CASE, its commercial impression was different from that created by "the case." *Id*. at 347. In another case involving the French article LE and the word SORBET, the T.T.A.B. applied the doctrine in holding that LE SORBET was generic for fruit ices because LE SORBET was a French term in its entirety. It rejected the applicant's argument that "sorbet" was primarily an English term. In *In re Le Sorbet, Inc*., 1985 T.T.A.B. LEXIS 27, at *4 (T.T.A.B. 1985). *In French Transit Ltd. v. Modern Coupon Systems Inc.,* 29 U.S.P.Q.2d 1626 (S.D.N.Y. 1992), the Court held that the doctrine of foreign equivalents was not applicable to the mark LE CRYSTAL NATUREL because the mark is a combination of an English word and two French words. *Id*. at 1626-1627.

Application When both Marks are Non-English Words Determined on a Case-by-Case Basis

There is some confusion about the application of the doctrine of foreign equivalents if both involved marks are foreign words. The T.M.E.P. states that although the doctrine of foreign equivalents is not "normally" invoked if the marks are both foreign words, application of the doctrine is not barred in every case where the marks consist of terms from different foreign languages. T.M.E.P. § 1207.01(b)(vi). In the absence of clear law, court decisions have been inconsistent on the issue. In *Safeway Stores Inc. v. Bel Canto Fancy Foods Ltd.,* 5 U.S.P.Q.2d 1980 (T.T.A.B. 1987), the T.T.A.B. held that the mark BEL ARIA for sauces, spreads and dried tomatoes was not likely to cause confusion with BEL-AIR for food and frozen concentrated juice products. The Board reasoned that it is not proper to take the French expression BEL-AIR and the Italian expression BEL ARIA and convert both into English, and compare the English translations to determine whether there is similarity as to connotation. *Id*. at 1982. The Board stated that the marks were "somewhat similar in appearance", "only slightly similar in sound or pronunciation", and "essentially dissimilar in terms of meaning or connotation." *Id*. According to the Board, BEL-AIR conveyed a geographical connotation, whereas BEL ARIA conveyed an Italian connotation. *Id*. However, in *In re Lar Mor Int'l, Inc*., 221 U.S.P.Q. 180 (T.T.A.B. 1983), the Board applied the doctrine of foreign equivalents in finding that two French language marks, TRES JOLIE and BEIN JOLIE, both for clothing, were not likely to be confused. In the more recent case of *DC Comics v. Pan Grain Mfg. Co.,* 77 U.S.P.Q.2d 1220 (T.T.A.B. 2005), the Board applied the doctrine of foreign equivalents in holding that KRIPTONITA for a prepared alcoholic fruit cocktail was likely to be confused with KRYPTONITE for clothing, toys and sporting goods. The T.T.A.B. held that both marks were equivalents because "kryptonita" was the Spanish term for "kryptonite." Thus, "Spanish-speaking people would clearly view the marks as the same." *Id*. at 1225.

Thus, the applicability of the doctrine of foreign equivalents to two non-English marks must be determined on a case-by-case basis. Consumers are more likely to translate words from the same language than they are likely to translate words from different languages. Ultimately, however, courts should consider the commercial impressions conveyed by the marks in determining whether the doctrine should be applied.

V. APPLICATION OF THE DOCTRINE TO LIKELIHOOD OF CONFUSION REFUSALS

It is well settled that in determining likelihood of confusion, marks must be compared, in their entireties, for similarities/dissimilarities in sound, appearance and commercial impressions. *In re E. I. DuPont DeNemours & Co.,* 177 U.S.P.Q. 563 (C.C.P.A. 1973). The doctrine of foreign equivalents only requires translation and comparison of the non-English mark and its English equivalent as to meaning or connotation, not as to sight and sound. 3 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 23.37 at 23-124. However, any similarity in meaning or connotation must be weighed against the dissimilarity in appearance, sound and all other factors, before reaching a conclusion on likelihood of confusion as to source. *In re Sarkli, Ltd.,* 220 U.S.P.Q. at 113 (Fed. Cir. 1983).

In *In re Hub Distributing, Inc.,* 218 USPQ 284 (T.T.A.B. 1983), the T.T.A.B. affirmed the refusal to register EL SOL for wearing apparel on the ground of likelihood of confusion with SUN & Design[1] for footwear on the ground that the marks "evoke identical commercial impressions." *Id*. at 286. In *In re Am. Safety Razor Co*., 2 U.S.P.Q.2d 1459 (T.T.A.B. 1987), the T.T.A.B. held that BUENOS DIAS for bar soap and GOOD MORNING for shaving cream were likely to be confused because their overall connotations were similar. *Id*. at 1460.

Sometimes marks have identical or similar meanings, yet they are not likely to be confused because their commercial impressions are different. In *In re Ness & Co.,* 18 U.S.P.Q.2d 1815 (T.T.A.B. 1991), the T.T.A.B. refused to hold that GOOD-NESS and LABONTE (French for "the goodness") for cheese were confusingly similar. It held that not only were GOOD-NESS and LABONTE different in appearance and sound, they also had different meanings. GOOD-NESS was a play on applicant's trade name, Ness & Co. Thus, the mark indicated "goodness" and also indicated "good" Ness which would be perceived in a manner like "good Smith" or "good Jones." *Id*. at 1816. In *Horn's Inc. v. Sanofi Beaute Inc*.,

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43 U.S.P.Q.2d 1008 (S.D.N.Y. 1997), the Court found that addition of a design element distinguished the marks DECI DELA (translated into English as "here and there") for perfumes and HERE & THERE & Design for fashion reporting and consulting services. In *Continental Nut*, the Court held that CORDON BLEU (BLUE RIBBON in English) was not likely to be confused with BLUE RIBBON because it had acquired its own meaning in English. 181 U.S.P.Q. at 647. Thus, under the doctrine of foreign equivalents, similarity in meaning is not the ultimate factor in deciding likelihood of confusion. Courts also look to all relevant circumstances, including the marks' appearances and sounds.

VI. APPLICATION OF THE DOCTRINE TO SURNAME REFUSALS

The doctrine of foreign equivalents has also been applied to primarily merely surname refusals under Section 2(e)(4) of the Trademark Act. In *In re Isabella Fiore LLC*, 75 U.S.P.Q.2d 1564 (T.T.A.B. 2005), the Board considered the registrability of the term FIORE (meaning "flower" in English) in connection with bags and other items. The examiner contended that FIORE was primarily merely a surname. The T.T.A.B. held that whether a term is primarily merely a surname must take into consideration the meaning the term has in a foreign language. "[I]f there is a readily recognized meaning of the term apart from its surname significance, registration should be granted…if the term's dictionary meaning is not obscure, it may be a significant factor in determining that the term is not primarily merely a surname." *Id*. at 1569. Holding that the common meaning of the term FIORE is flower, the Board concluded that it is not primarily merely a surname because "it does have a meaning that detracts from the surname significance of the term." *Id*. at 1570.

VII. APPLICATION OF THE DOCTRINE TO GEOGRAPHIC DECEPTIVE MISDESCRIPTIVENESS REFUSALS

The T.T.A.B. has also considered the doctrine of foreign equivalents in the context of geographic deceptive misdescriptiveness refusals under Section 2(e)(3) of the Trademark Act. In *In re Broyhill Furniture Industries Inc*., 60 U.S.P.Q.2d 1511 (T.T.A.B. 2001), the Board considered the registrability of the term TOSCANA for furniture. It held that the term was not registerable since under the doctrine of foreign equivalents the term TOSCANA is an Italian word which means "Tuscany" in English and is the name of a region in Italy, and the furniture did not originate in that region. *Id*. at 1512. The doctrine should also be applicable to refusals on the ground of geographic descriptiveness.

VIII. PRACTICE POINTERS

From a practical standpoint it is important that attorneys ask their clients whether a proposed mark has a meaning in a foreign language. It may also be a good idea to do an internet search in this connection. If the proposed mark has a meaning in a foreign language, attorneys must ensure that the trademark search accounts for translations of the proposed mark.

Applications for marks that include non-English wording are required to include a statement translating the wording. T.M.E.P. §809. Applicants must provide the English meaning that has significance in the United States as the equivalent of the meaning in a non-English language. T.M.E.P. §809.01. It follows that an English translation of a non-English word is not required if the English translation does not have any significance to consumers. For instance, an English translation of the German word "Schwarzkopf" is not required because although the word "Schwarzkopf" literally translates as "black head", its primary significance is that of a surname. English translations are also not required if the non-English word appears in an English dictionary or the non-English word is from a dead or obscure language. T.M.E.P. § 809.01.

If applicants do not provide a translation or do not provide an "accurate" translation, attorneys examining trademark registration applications at the USPTO ("Examining Attorneys") are required to ask applicants for translations. T.M.E.P. §809. Thus, it is possible that applicants and Examining Attorneys disagree on translations. If so, applicants should provide evidence to support their translations. This evidence may be in the form of affidavits from certified translators and/or evidence from foreign dictionaries, research databases, newspapers and other publications. An interesting question is whether an Examining Attorney would accept a ruling from a foreign

Trademark Office as evidence of registrability of a non-English word as a mark. The Second Circuit Court of Appeals, in *Otokoyama Co. v. Wine of Japan Import Inc.*, 50 U.S.P.Q.2d 1626 (2d Cir. 1999), allowed the defendant to submit a ruling of the Japanese Patent Office denying plaintiff trademark rights in the term "otokoyama" on the grounds of genericness. Would Examining Attorneys accept such rulings?

IX. SUMMARY AND CONCLUSION

The doctrine of foreign equivalents provides a guideline to analyze marks that incorporate foreign words from common languages. The doctrine has been applied in determining registrability of marks on absolute and relative grounds. Courts apply the doctrine of foreign equivalents when an average American purchaser who speaks and/or understands a foreign language is likely to stop and translate a word in that language into English. Courts have held that the doctrine is inapplicable if a mark is a combination of English and foreign words. Moreover, the doctrine may not be applicable if both involved marks incorporate non-English words.

The doctrine of foreign equivalents is not an absolute rule. Accordingly, there have been inconsistencies in its application and confusion still exists between courts and within the T.T.A.B. on issues such as the relevant consumer base and whether the doctrine should be applied in comparing two non-English marks.

The USPTO has also demonstrated inconsistencies in applying the doctrine of foreign equivalents. For instance, it has allowed coexisting applications to register the word mark MITSU[2] (meaning NECTAR in Japanese) and NECTAR & Design[3] for related goods. It has also allowed an application to register the word mark SWAD[4] (meaning TASTE in Hindi, the national language of India) for food products. Arguably, an applicant for the mark TASTE for food products would have encountered descriptiveness problems in getting its application through the USPTO. Although the T.M.E.P. requires applicants to provide English translations of foreign wording in marks, the USPTO must examine such marks closely so that trademark law serves its purpose of enhancing market competition and preventing consumer confusion.

There is no doubt that as immigration to the United States continues its upward swing, the doctrine of foreign equivalents will continue to assume greater importance here. Moreover, the doctrine will continue to be important because the United States is part of the global market place, especially with the advent of the internet.

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[1] "& Design" indicates that the mark has a design component.

[2] Application Ser. No. 76/653,233

[3] Application Ser. No. 78/633,713

[4] Application Ser. No. 76/617,256

NYIPLA CALENDAR

March 23, 2007

85th Annual Dinner in Honor of the Federal Judiciary and CLE Day of Dinner Program

Waldorf=Astoria • 301 Park Avenue, NY, NY

See pages 24 & 26 for more details

SAVE THESE DATES

April 20, 2007

CLE Program • Details to follow

May 9, 2007

23rd Annual Joint Patent Practice Seminar

Marriott Marquis • 1535 Broadway, New York, NY

May 23, 2007

Annual Meeting and Awards Dinner

Princeton-Columbia Club • 15 West 43rd Street, New York, NY • Details to follow

AUTHORIZED GENERICS: A BITTER PILL TO SWALLOW?

By: Stacey L. Cohen & Edward L. Tulin[1]

Over the past two decades, generic drug producers have become a critical force in the pharmaceutical marketplace. As generic market share has swelled, brand-name pharmaceutical producers have employed a variety of tactics designed to recapture revenues lost in the rising tide of generic production. The latest strategy involves the marketing and sale of "authorized generics"—drugs produced by or for a brand-name manufacturer (and NDA holder) and sold under a generic label. While federal law does not currently prohibit this practice, critics argue that it will likely contribute to higher consumer prices, stifle innovation, and destabilize the generic industry. Indeed, if left unchecked, authorized generics may become a prescription for trouble, both for consumers and generic manufacturers.

A Brief History: Hatch-Waxman Hatches a Fragile Balance

The Drug Price Competition and Patent Term Restoration Act of 1984[2] (more commonly referred to as the Hatch-Waxman Amendments) attempted to balance the need to encourage industry investment in new drug research against the consumer interest in quickly obtaining low-cost versions of patented drugs.[3] The Amendments thus created a new regulatory scheme, under which generic drug producers could bypass the arduous process of filing a New Drug Application (NDA), which was mandatory in order to obtain FDA approval to market a new drug. Instead, prospective generic producers may now opt to file an Abbreviated New Drug Application (ANDA), which requires that an applicant: (i) show that the generic drug is bioequivalent to a brand-name drug that has been the subject of a prior NDA, and (ii) certify that the applicant is not impermissibly interfering with the NDA-holder's patent(s).[4]

The effects of the Hatch-Waxman Amendments have been staggering. In 1984, less than one in five prescriptions filled in the U.S. were generics,[5] but by 2005, that number had grown to more than half of all prescriptions. This influx of lower-cost, generic drugs has saved consumers billions of dollars each year.[6] While many applaud the savings that the Hatch-Waxman Amendments have brought, its reception among brand-name drug makers has been decidedly different. Since its inception, brand-name drug manufacturers have sought to limit the reach of this legislation, allegedly seeking "inconsequential patents unrelated to the basic functioning of the drug," and filing "frivolous assertions of patent infringement" designed to artificially prolong market exclusivity.[7] The use of authorized generics is thus best understood as the latest in a long line of strategies used by brand-name manufacturers to neutralize the Hatch Waxman Amendments' impact.

How do Authorized Generics Fit Into the Pharmaceutical Mix?

An ANDA applicant must certify that it will not interfere with the NDA-holder's patent(s) by choosing one of four certification options. The most important of these options is the "paragraph IV" certification, in which the ANDA applicant states that the relevant patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug" for which ANDA approval is being sought.[8] Unlike the other possible certifications, paragraph IV certifications generally result in challenges to the NDA-holder's patent(s), involving costly and time-consuming infringement suits. Congress recognized that consumers benefit when generic manufacturers work to invalidate improperly granted patents, but was also aware that the prospect of a protracted and expensive patent battle might deter generic companies from doing so. As a result, Congress created an incentive for generic producers to challenge NDA patents under paragraph IV. If the generic challenge is successful (and the patent is invalidated, held unenforceable, or not infringed), the challenger receives 180 days of exclusive generic market share, during which no other ANDA application will be granted final approval.[9]

While the statute guarantees that a successful NDA-patent challenger will not face initial competition from other generic firms, the Hatch-Waxman Amendments do not confer such protection against an NDA-holder launching a generic version of its own drug: enter the authorized generic. These drugs, usually introduced at below brand-name price prior to the expiration of the patent term and coincident with the start of a 180-day exclusivity period, decrease the revenue available to a generic producer. Accordingly, critics maintain that while the Hatch-Waxman Amendments do not prohibit authorized generics, their use undercuts the statutory incentive of the 180-day market exclusivity period. Indeed, when it comes to authorized generics, everybody's doing it—according to one industry analysis, authorized generic versions have appeared for virtually all drugs with expiring or invalidated U.S. patents.[10]

Authorized generics enter the marketplace prior to patent expiration when brand name firms: (i) make exact copies of their own drug and market it under a different

name, (ii) enter into licensing arrangements with generic firms, or (iii) create or acquire a separate entity for the sole purpose of making authorized generic drugs.[11] Although not contrary to the letter of the law, these practices have been viewed as an assault on the spirit of the Hatch-Waxman Amendments, which were designed in part to allow paragraph IV challengers to recoup the substantial litigation costs associated with an invalidity, unenforceability, or non-infringement assertion. Brand-name companies have defended the use of authorized generics as a way to lower consumer prices, but independent analyses have confirmed that any short-term benefit to consumers is illusory, while potential long-term consumer and industry detriment is significant.

Marginal Short-Term Benefit vs. Significant Long-Term Detriment

Supporters of authorized generics argue that while generic drug manufacturers may lose a portion of their 180-day exclusivity period profits, consumers are nonetheless winners. This argument certainly makes intuitive sense—anytime that a monopoly can be converted into a multi-player market, the competition is bound to result in lower prices. Indeed, one empirical study, conducted by IMS Consulting (the "IMS Study"), found that "[a]t the outlet level . . . the generic discount to brand (during the 180-day exclusivity period) is about 16 percentage points greater than comparable examples without an authorized generic."[12]

However, independent analyses suggest that the IMS Study exaggerates the extent of short-term consumer price benefits. Shortly after the IMS Study was published, two well-respected academics published their own study of authorized generics' short-term consumer price effects (the "Hollis/Liang Study").[13] The Hollis/Liang Study highlights a variety of problems with the IMS Study, including flaws in the comparison method, inconsistent data choice, incorrect generic entry dates, and unsupported conclusions.[14] These methodological objections notwithstanding, the Hollis/Liang Study also points out that the IMS Study does not even purport to study consumer prices; it is concerned solely with wholesale prices (referred to as prices at the "outlet level")[15]. Analyzing precisely the same markets and same drugs as the IMS Study, the Hollis/Liang Study concludes that for *retail* prices, the introduction of an authorized generic results in a 5% average discount to consumer prices.[16]

Even this figure overstates the actual consumer benefit for two reasons. First, it treats all markets the same, so that a small market is treated the same as a large market in calculating the aggregate consumer benefit. If the revenues are weighted so as to better reflect the realities of consumer expenditures, then "the difference between AG [authorized generic] and no-AG discounts more or less disappears—if anything, the no-AG sample has *larger* discounts."[17] Second, when an authorized generic is introduced, brand-manufacturers often raise brand prices, so that consumers in such markets pay roughly the same costs for generic drugs, while those choosing brand-name drugs will pay more for the particular drug in question.[18] Thus, although there may be isolated instances of lower prices resulting from the launch of authorized generics, at least one study has shown that the aggregate short-term consumer benefit is marginal at best.

Moreover, industry insiders contend that the long-term drawbacks of authorized generics, particularly with regard to the 180-day exclusivity period, are significant. The exclusivity period is not a reward or incentive in the conventional sense, but rather has been characterized as a "quid pro quo for generic companies."[19] Without this period of exclusivity, many generic firms may lack the financial resources to undertake expensive and lengthy paragraph IV patent challenges, particularly in smaller markets.[20] Authorized generics, when launched at the start of the 180-day exclusivity period, will serve as a disincentive for generic manufacturers to bring paragraph IV challenges by marginalizing the available, post-invalidation revenue stream for the ANDA applicant. As the Hollis/Liang Study concludes, "[w]hen AG's enter during the exclusivity period, [the] statutory incentive for generic companies to challenge patents and to develop non-infringing products is severely compromised."[21]

The Hollis/Liang Study thus supports the proposition that by creating disincentives to file paragraph IV certifications, authorized generics will have an adverse effect on consumer prices. According to this argument, if generic drug makers are deterred from pursuing paragraph IV challenges, which are frequently successful,[22] the ultimate loss will be to consumers, who will be forced to pay higher prices for drugs that are protected by invalid patents. Industry analysts also predict ominous longer-term effects on the generic industry. Indeed, the profitability, and ultimately the survival of the generic industry, depends in no small part on the revenue generated during the 180-day exclusivity period. When an authorized generic enters the market during this exclusivity period, it usurps a portion of the paragraph IV challenger's revenue. For instance, in September 2003, on the same date that Apotex Corp. (a successful paragraph IV challenger) launched a generic version of Paxil®, the NDA-holder began to sell an authorized generic. Although Apotex had projected revenues of nearly $600 million for the 180-day period, it made only a third of its projected amount in the face of competition with the authorized generic.[23] Similarly, when Mylan Pharmaceuticals successfully invalidated Proctor & Gamble's patent on nitrofurantoin,

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Proctor & Gamble responded by launching an authorized generic version of this drug, reducing Mylan's revenues for this period by 75%.[24] Looking at the industry as a whole, financial analysts have concluded that "an authorized generic cuts in half or more the profitability of the value of the six-month [180-day] exclusivity."[25]

An independent analysis by David Reiffen and Michael Ward confirms that particularly in smaller markets, eliminating the profitability of the 180-day exclusivity period might eventually eliminate all generic products.[26] This analysis also warns that if generic drug makers are not forced to abandon products, lower profits may make them more vulnerable to consolidation with other generic firms or brand-name drug makers, thus decreasing the number of market participants.[27] Or, as one FTC Commissioner has noted, there may be "fewer generic applications for smaller drugs," leading to "fewer generic products on the market, which could then result in less competition down the road."[28]

As generic revenues go down, less money is necessarily available for research and development of new drugs. Although much of an ANDA applicant's expenditures are directed toward making a bioequivalent version of the NDA drug, in the process, the generic firm may discover new forms of an active ingredient, new ways of making the product, or synergistic treatment strategies.[29] Although revenues from authorized generics would be diverted to innovator firms, i.e., brand name manufacturers, who would then theoretically have more money available for their own investment and R&D, critics of authorized generics suggest that it is not clear that the brand firms would pursue such research as robustly as generic makers, or with as great of a commitment in the absence of a healthy generic sector.[30]

Finally, even if a generic firm is able to survive the pressure to consolidate with other generic firms or brand-name drug makers, authorized generics may lead to indirect consolidation and delayed generic entry by encouraging paragraph IV settlement agreements. As reported by the Federal Trade Commission, in 2005 three settlements provided compensation to a generic firm and restricted the ability of the generic firm to market its product.[31] Two of the three settlements involved "side deals," that further eroded the generic makers' independence. In one of these "side deals," the brand and generic firm agreed to co-promote the brand product, with the generic firm receiving royalties from those sales, while in the other deal, the brand firm granted a license to the generic firm to sell authorized generic versions of unrelated products.[32] If these side deals become the industry norm, generic firms' revenues will be tied more and more to non-generic drugs, decreasing their incentives to robustly manufacture and market generic versions of drugs. Under such circumstances, generic drugs will not enter the marketplace as soon as they otherwise would.[33]

Congress Responds to the Trend: Breathing New Life into the Hatch-Waxman Amendments

Given the success that brand name firms have had in launching authorized generics, it is little wonder that this trend shows no signs of slowing. In fact, in November 2006, after AstraZeneca's patent on Toprol XL® was invalidated under a paragraph IV challenge, it entered into an agreement with Par Pharmaceuticals to produce an authorized generic.[34] Absent a legislative change,[35] authorized generics are well on their way to becoming a prevalent and permanent fixture in the pharmaceutical market.

However, Congress has not been blind to the potentially harmful effects of authorized generics, particularly with respect to the 180-day exclusivity period. On July 19, 2006, Senators Rockefeller (D-WV), Schumer (D-NY), and Leahy (D-VT) co-sponsored legislation to prohibit the sale of authorized generics during this 180-day exclusivity period.[36] When introducing the bill, Senator Rockefeller noted that the use of authorized generics "undermines congressional intent and harms consumers by preventing generic competition and eliminating billions of dollars in prescription drug savings over the long-term."[37] An identical House Resolution was introduced by Representative Jo Ann Emerson (R-MO) on July 28, 2006.[38] Both bills were referred to committees, but no action was taken before Congress adjourned. Senator Rockefeller then reintroduced the bill in the new session of Congress as the "Fair Prescription Drug Competition Act of 2007" on January 30, 2007.[39] While the fate of this legislation remains uncertain, the reintroduction of this proposed alteration lends credence to the idea that authorized generics are not consistent with the purposes of the original Hatch-Waxman Amendments, and that a change is necessary to protect consumers and the generic industry.[40]

Additional Protection: State Unfair Competition Laws

Whatever happens on the federal level, authorized generics may already run afoul of state unfair competition laws. In March 2004, Mylan Pharmaceuticals, Inc. ("Mylan") brought suit against Proctor & Gamble Co., Proctor & Gamble Pharmaceuticals, Inc. (collectively, "P&G"), Watson Pharmaceuticals, Inc. ("Watson"), and unknown individuals identified as Does 1-100, alleging that the launch of an authorized generic version of P&G's brand drug Macrobid violated California Business and Professions Code §§ 17200 (fraudulent business practice) and 17500 (untrue and misleading and false advertising),

as well as several sections regarding price discrimination and predatory pricing. Specifically, Mylan alleged that the defendants' marketing of a generic, yet identical version of a branded product on the market creates a "false generic," which is misleading to the public and which drives away true generic competition.[41] Mylan also alleged that P&G offered the authorized generic to Watson at a price below cost, thus engaging in predatory pricing.[42] To date, the case remains pending and trial is expected to begin in February 2007.

Conclusion

The sale of authorized generics does not break any federal laws, but may break the tenuous balance that the Hatch-Waxman Amendments attempted to enshrine. Industry analysts contend that while the introduction of an authorized generic drug may generate lower short-term prices, any such benefits pale in comparison with the long-term disadvantages for generic manufacturers, and in turn, consumers. By eliminating competition, particularly in smaller markets, stripping away revenues that otherwise would be available for R&D, and promoting dependence on the brand-name firms, authorized generics cannot help but eventually lead to higher prices at the pharmacy counter. If these predictions prove accurate, it will mean bad business for generics, bad medicine for consumers, and bad policy for the country.

[1] The authors are Associates in the Intellectual Property & Technology Group of Skadden, Arps, Slate, Meagher, Flom, LLP. The views expressed herein do not represent those of Skadden, Arps, Slate, Meagher, Flom, LLP.

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[3] *See, e.g.*, *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987).
[4] 21 U.S.C. § 355(j)(2)(A); Beth Understahl, *Authorized Generics: Careful Balance Undone*, 16 Fordham Intell. Prop. Media & Ent. L.J. 355, 361–63 (2005).
[5] Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, at i.
[6] Generic Pharmaceutical Association Online, *at* www.gphaonline.org.
[7] Understahl, *supra* note 4, at 368.
[8] 21 U.S.C. § 355(j)(2)(A)(vii) (2006).
[9] *Authorized Generics: Here to Stay?*, 3 Pharma's Cutting Edge (Mar. 1, 2005), *at* http://pharmaweblog.com/blog/2005/03/01/authorized-generics (hereinafter Cutting Edge).
[10] John R. Thomas, Authorized Generic Pharmaceuticals: Effects on Innovation, CRS Report for Congress (Aug. 8, 2006).
[11] David A. Balto, *We'll Sell Generics, Too*, 29 Legal Times (Mar. 20, 2006), *available* at www.legaltimes.com.
[12] Report to PhRMA: Assessment of Authorized Generics in the U.S., IMS Consulting, at 1-2 (Spring 2006).
[13] Aidan Hollis & Bryan A. Liang, *An Assessment of the Effect of Authorized Generics on Consumer Prices* (July 31, 2006) (hereinafter Hollis & Liang).
[14] *Id.* at 5–8.,
[15] *Id.* at 14., [16] *Id.*.
[17] *Id.* at 15 (emphasis added)., [18] *Id.* at 16–18.
[19] Kathleen Jaeger, Remarks to Senate Committee on Aging, at 4, July 27, 2006.
[20] Although more than half of all prescriptions filled are for generic drugs, only 13.1% of revenue in the pharmaceutical industry is attributable to generic sales, and this figure includes authorized generics. Tim Gilbert, *Hatch-Waxman: Upsetting the Balance*, Presentation to ABA Section of Antitrust Law, Sept. 14, 2006.
[21] Hollis & Liang, *supra* note 13, at 20.
[22] *See, e.g.*, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission, at 13 (July 2002) ("Generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute.").
[23] Comment of Apotex Corp. in Support of Citizen Petition Docket No. 2004P-0075/CP (Mar. 24, 2004).
[24] Vicki Smith, *Mylan Lawsuit Warns of Looming Threat to Generic Drug Industry*, Miami Herald, *at* miamiherald.com, Aug. 27, 2004.
[25] David Maris, *Future of Generics: A Wall Street Perspective*, February 2005.
[26] David Reiffen & Michael R. Ward, "*Branded Generics" as a Strategy to Limit Cannibalization of Pharmaceutical Markets*, at 26–28 (May 2005).
[27] Cutting Edge, *supra* note 9, at 3.
[28] Remarks by Jon Leibowitz, *Health Care and the FTC: The Agency as Prosecutor and Policy Wonk*, Antitrust in Healthcare Conference, May 12, 2005, p. 10; *see also* Hollis & Liang, *supra* note 13 (concluding that the long-term effect of allowing authorized generics on the market during the 180-day generic exclusivity period will be less competition and reduced access to cheaper drugs).
[29] Gilbert, *supra* note 20.
[30] Understahl, *supra* note 4, at 366.
[31] Bureau of Competition Issues FY 2005 Summary of Pharmaceutical Company Settlement Agreements, Federal Trade Commission, at 4, Apr. 24, 2006, *available at* www.ftc.gov/opa/2006/04/drugsettlements.htm., [32] *Id.*
[33] At least one industry watchdog group has explicitly drawn the link between authorized generics and coercive settlement agreements. Comments of Prescription Access Litigation Project and Others on FTC Project P062105, at 4–5 (June 5, 2006).
[34] Jayshree Shah, *AstraZeneca: "Authorized Generics" Strategy Could Be Extended*, Pharmaceutical Business Review Online.
[35] Courts have held that as currently written, the Hatch-Waxman Amendments do not prohibit the launch of an authorized generic during the 180-day exclusivity period. *See, e.g.*, *Teva Pharm., Indus. v. FDA*, 355 F. Supp. 2d 111 (D.D.C. 2004), *aff'd*, 410 F.3d 51 (D.C. Cir. 2005).
[36] S.B. 3695
[37] *Sen. Leahy, Others Introduce Bill to Bar Big Drug Firms from Gambit of Pushing 'Authorized Generics,'* U.S. Fed. News, Jul. 20, 2006, *available at* 2006 WLNR 12557114. Senator Schumer further noted that "[a]t a time when drug prices continue to soar, authorized generics make it harder for those most in need."
[38] H.R. 5993., [39] S.B. 438.
[40] Further support for a change in the current position regarding authorized generics can be found in the recent announcement by the Federal Trade Commission that it would study the economic impact of authorized generics on the pharmaceutical market, with a final report expected sometime in mid-2007. Authorized Generic Drug Study: FTC Project No. P062105, *available at* http://www.ftc.gov/os/2006/03/P062105AuthorizedGenericDrugStudyFRNotice.pdf.
[41] *See* Plaintiff's Third Amended Complaint for Damages and for Injunctive and Declaratory Relief, *Mylan Pharms., Inc. v. Procter & Gamble Co.*, Case No. CGC-04-429860, Dec. 28, 2004 at ¶¶ 15, 21, 26, 29-32, 34, and 63.
[42] *See id.* ¶¶ 27-28, 32-33, and 57-60.

RULINGS OF NOTE

S.D.N.Y. Intellectual Property Rulings Of Note

by Mark J. Abate and Andrew N. Stein*

Preliminary Injunction Denied for Inhaled Diabetes Drug

Novo Nordisk A/S v. Pfizer, Inc.
2006 U.S. Dist. LEXIS 90387
December 14, 2006
Judge Leonard B. Sand

Novo Nordisk ("Novo") brought a patent infringement suit against Pfizer, claiming that five of its patents were infringed by Pfizer's diabetes drug Exubera. Novo accompanied its infringement claim with a motion for preliminary injunction, seeking to prevent Pfizer from making, using or selling Exubera in the United States. The motion for preliminary injunction concerned U.S. Patent No. 5,884,620 (the "'620 patent"), one of the Novo patents in suit.

The '620 patent, along with the remaining patents in suit, disclosed and claimed a system for the efficient and reproducible inhalation of aerosolized insulin through the lungs and into the bloodstream to control diabetics' blood sugar levels. By way of background, insulin must be precisely administered – irregular ingestion of insulin can produce hazardous side-effects, and even death. Consistent insulin delivery into the body was the biggest problem facing an inhalable product, and the patents in suit tried to solve this problem.

Claim 1 of the '620 patent recites a "method of administering insulin to a human patient by inhalation…" which comprises the steps of: (1) exhaling; (2) aerosolizing the insulin; (3) inhaling the insulin; and (4) repeating steps 1, 2, and 3 a plurality of times. Novo argued that repetition of a breathing technique was a novel solution to the problem of inconsistent insulin dispersal in the bloodstream via the lungs.

Pfizer had filed a New Drug Application for Exubera, which was subsequently approved by the FDA – making Exubera the first FDA-approved device to provide for aerosolized insulin delivery. The instructions for Exubera are: (1) push the "blue button" on the device and "watch the insulin cloud fill the chamber;" (2) breathe out normally; (3) in one breath, breathe in the insulin cloud through the mouth; (4) breathe out normally. During the preliminary injunction proceedings, Novo argued that these instructions infringe the method of claim 1 of the '620 patent, and that the words "breathe out normally" infringe on its claim to a method of assuring uniform predetermined quantities of inhalable insulin.

The Court considered the usual factors for a preliminary injunction: reasonable likelihood of success on the merits; irreparable harm; balance of hardships in favor of movant; and the impact of injunction on the public. See Jack Guttman, Inc. v. Kopycake Enter., Inc., 302 F.3d 1352, 1356 (Fed. Cir. 2002). With respect to the first factor, the Court evaluated both patent validity and infringement. Novo contended that the '620 patent is presumptively valid, infringed, and satisfies a long-felt need for an alternative method of insulin delivery. Novo presented expert testimony to substantiate its argument that when Pfizer instructs patients to "breathe out normally" at the end of their inhalation, it is infringing claim 1. Pfizer countered that the patent did not cover Exubera's instructions and was also invalid as anticipated by prior art. Pfizer argued that under Novo's proposed construction, the '620 patent would encompass prior art breathing techniques, i.e., asthma treatments.

The Court was persuaded that there were substantial questions as to the alleged infringement and the '620 patent's validity which required a trial. Further, the remaining factors were also found to weigh in favor of Pfizer, and the preliminary injunction was denied.

Production of Foreign Patent Documents Ordered

In re Rivastigmine Patent Litigation
2006 U.S. Dist. LEXIS 84737
November 22, 2006
Judge Harold Baer

Plaintiff Novartis moved for reconsideration of a discovery ruling by Magistrate Judge James C. Francis, IV, compelling production of certain communications between Novartis and its Swiss patent agents and Swiss in-house counsel. Novartis claimed attorney-client privilege for these communications. The communications at issue were documents authored by a patent agent registered in the United States, who was formerly employed by Novartis. The Magistrate found that under Swiss law, attorney-client privilege did not extend to the documents at issue.

Because the patent applications were prosecuted in Switzerland, it was conceded that Swiss law governed privilege issues with respect to those applications and the related documents. The Magistrate conducted an extensive review of Swiss law, including the Civil Procedure Code of Basel, the Swiss Penal Code, the Swiss Code of Obligations and additional Swiss statutes. While he noted that U.S. courts do not uniformly find Swiss law to extend attorney-client privilege to Swiss patent agents and in-house counsel, Magistrate Francis found that Swiss law did not establish an absolute privilege comparable to the attorney-client privilege in the United States.

In reviewing the Magistrate's decision, Judge Baer noted that the Swiss statutes proffered by Novartis created at most a "professional secrecy obligation" for patent agents, but did not create an absolute evidentiary privilege comparable to the U.S. privilege. Judge Baer differentiated a professional secrecy obligation from absolute privilege by noting that a Court can require disclosure of a communication held under a professional secrecy obligation. As a result, Judge Baer found the Magistrate to have acted well within his discretion.

Summary Judgment of Validity Granted for Acid Reflux Drug

Eisai Co., Ltd. v. Teva Pharms. USA, Inc.
2006 U.S. Dist. LEXIS 73516
October 5, 2006
Judge Gerard E. Lynch

Eisai moved for summary judgment of validity of its patent, U.S. Pat. No. 5,045,552 (the "'552 patent"), in the face of Teva's counterclaim of obviousness. The '552 patent claimed the gastric-acid-inhibiting compound "Rabeprazole."

Teva alleged that the '552 patent would have been obvious to a person having ordinary skill in the art at the time of the invention in light of a combination of three references: a European Patent claiming the ulcer-treatment compound "Lansoprazole;" a U.S. patent; and a scientific article. Teva argued that a person of ordinary skill would have been motivated to choose Lansoprazole as the lead compound and change its structure in ways suggested by the U.S. patent and by the scientific article, resulting in the claimed Rabeprazole compound.

The Court granted summary judgment because even if it resolved all issues of material fact in Teva's favor, the evidence would still be insufficient to sustain a finding of obviousness. The Court found that if Teva's argued teachings were undisputed, they would be insufficient to provide clear and convincing evidence that one of ordinary skill would have made Rabeprazole from the combination of the three prior art references. Teva advanced three reasons for its argument.

First, Teva argued that Lansoprazole would have been selected because it was far superior to the then most widely-known gastric-acid-inhibitor. The Court noted that this was the only evidence that would support the proposition that one of ordinary skill would have picked Lansoprazole, but was ultimately unpersuaded.

Second, Teva argued that one of ordinary skill would have picked Lansoprazole because of its abil-

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cont. from page 23

ity to cross lipid membranes in the body (lipophilicity) - a trait of the compound readily identifiable to one of ordinary skill. However, Teva's own expert suggested that lipophilicity was a pharmacological property already considered important by one of ordinary skill. To substantiate obviousness of the '552, Teva's argument regarding Lansoprazole's lipophilicity must be understood to mean that the compound taught some "special path" to achieve lipophilicity – a claim that was unsubstantiated by Teva's expert witness testimony. In fact, Teva's expert testified to the contrary – he stated that a different reference, and not Lansoprazole, was responsible for teaching the special path necessary for the Court to accept Teva's argument. Thus, the Court dismissed this argument.

Third, Teva argued that one of ordinary skill would have chosen Lansoprazole because it had a desirably low molecular weight. Teva, however, offered no evidence of the particular desirability of Lansoprazole's weight, and thus, this argument did not persuade the Court.

Since Teva unsuccessfully argued that Lansoprazole was the correct starting point in an obviousness inquiry, the asserted combination to invalidate the patent at issue faltered, and its invalidity claim was ineffective.

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The 85th Annual Dinner IN HONOR OF THE Federal Judiciary

The New York Intellectual Property Law Association Announces its Keynote Speaker and Outstanding Public Service Award Recipient for the 85th Annual Dinner in Honor of the Federal Judiciary March 23, 2007 Waldorf=Astoria Hotel

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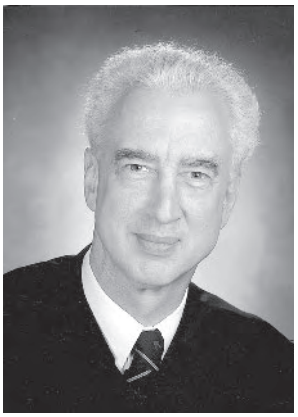

Chief Judge of the United States Court of Appeals for the Federal Circuit

Honorable Paul R. Michel

January 24, 2007 CLE Luncheon Program

Topic: Update on Fraud in the Trademark Office after *Medinol Ltd. v. Neuro Vasx Inc.*

On January 24, 2007, the NYIPLA hosted a CLE luncheon program at the Princeton/ Columbia Club to discuss the topic of fraud before the Trademark Trial and Appeal Board (TTAB). The *Medinol Ltd. v. Neuro Vasx, Inc*. case was discussed as well as other more recent cases before the TTAB.[1] The speakers at this program were Frances F. Wolfson, currently an Interlocutory Attorney at the Trademark Trial and Appeal Board, and Linda K. McCleod, formerly an Administrative Attorney at the Trademark Trial and Appeal Board, and currently a member of Finnegan, Hendersen, Farabow, Garrett & Dunner, L.L.P. The meeting was moderated by Kathleen E. McCarthy, Morgan & Finnegan, LLP, Chairperson of the NYIPLA Trademark Practice Committee.

Left to Right: Linda McLeod, Frances Wolfson, Kathleen McCarthy, Peter Thurlow

The program began with Ms. Wolfson's summary of the *Medinol* case. In *Medinol*, the Board granted summary judgment against the registrant, holding that fraud was committed where the registrant procured its registration by making material representations of fact in its declaration which it had known or should have known to be false. The registrant in *Medinol* claimed use of its mark on the goods listed in the Notice of Allowance, which included both catheters and stents. In fact, the registrant used the mark only on catheters. This false statement that the mark was used on stents was sufficient for the Board to find fraud and cancel the entire registration on summary judgment. The applicant's excuse, that the inclusion of stents in the Notice of Allowance was apparently overlooked, was found to be insufficient. According to the Board, the applicant's knowledge that the mark was not in use on stents, or its reckless disregard for the truth, was sufficient to establish intent to commit fraud in the procurement of a registration.

Ms. Wolfson also reviewed several post-*Medinol* cases, including a very recent TTAB decision, *Hurley International LLC v. Volta*[2], that issued just one day before this program. In *Hurley*, the TTAB also granted summary judgment on a fraud claim. The applicant, a couple from Australia who proceeded pro se without U.S. counsel, argued that they had misunderstood the requirements of use in commerce. This excuse was insufficient to overcome the fraud claim in that the applicant made a number of use claims that were not true not only as to use in the U.S. but also anywhere in the world. The TTAB did note that a misstatement in an application as to the goods or services on which a mark has been used does not rise to the level of fraud where the applicant amends the application to correct the problem prior to publication.

Ms. Wolfson ended by noting the TTAB rationale for these seemingly harsh decisions. Specifically, the USPTO relies on applicants to disclose information as requested by the Office and statements made under oath with such degree of solemnity clearly are - or should be - investigated thoroughly prior to signature and submission to the USPTO.

Ms. McCleod then followed with a review of practical considerations for plaintiffs and defendants faced with *Medinol* type fraud claims. Ms. McCleod included examples of pleadings used successfully in various cases, as well as a Top Ten list of excuses that had been rejected by the TTAB (such as "assuming the statement of use was accurate" or "improper legal advice from non-attorney known as 'Mr. Trademark'"). Ms. McCleod concluded with a non-exhaustive list of steps to take to avoid a *Medinol* fraud claim.

The nearly full program responded with a number of questions, evidencing the high degree of concern regarding the dangers presented to the trademark prosecution practitioner by this line of cases.

[1] 67 USPQ2d 1205 (TTAB 2003)
[2] Opp. No. 91158304

Meeting Of The Board Of Directors

Minutes Of December 12, 2006 Meeting

The meeting of the Board of Directors was called to order at the Penn Club at 12:25 p.m. by President-Elect Christopher Hughes. W. Edward Bailey, Dale Carlson, Ronald Clayton, Anthony Giaccio, Theresa Gillis, Christopher Hughes, Thomas Meloro, Karl Milde, Philip Shannon and Alexandra Urban were present. Also present was Dan DeVito, the liaison to AIPLEF, and Michael Isaacs from Star Consulting.

The minutes of the November 14, 2006 meeting as amended were approved.

Mr. DeVito provided a report with respect to AIPLEF noting that, from July 1, 2005 through June 30, 2006, the AIPLEF had awarded 14 scholarships. He solicited the continued support by the NYIPLA.

Mr. Isaacs presented the Treasurer's report. He reported that the Association's finances continue to be strong, with dues collections remaining high.

Mr. Giaccio reported that planning for the Judges' Dinner 2007 was well underway, with efforts to find a speaker continuing.

Mr. Isaacs reported that under New York CLE procedures the NYIPLA was being required to update its attendance form to conform to a standard form.

Mr. Meloro reported on the November all-day CLE program. There were approximately 160 attendees. The program was well received, although it may be necessary to reconsider whether materials should be provided only on CD-ROM as a number of attendees objected to not having paper versions of the presentations on which they could take notes during the presentations. It was also noted that at future programs efforts should be made to keep the panels within their allotted time frames.

The meeting was adjourned at 1:25 p.m.

The next meeting of the Board is scheduled for Tuesday, January 9, 2007 at noon at the Penn Club.

New York Intellectual Property Law Association,
On Behalf of the
Committee on Meetings and Forums
and the
Committee on Continuing Legal Education,

Presents

CLE Day of Dinner Program and Luncheon

In Conjunction with the *85th Annual Dinner*
In Honor of the Federal Judiciary

Friday, March 23, 2007

The Starlight Roof at The Waldorf-Astoria
301 Park Avenue • New York, New York
11:30-12:00 Welcome Reception
12:00-12:20 PM Lunch
12:20-2:00 PM Program

- **Hon. Randall R. Rader,**
  Circuit Judge, U.S. Court of Appeals, Federal Circuit
- **Hon. Denise Cote,**
  District Judge, U.S. District Court, Southern District of NY
- **James Galbraith,**
  Kenyon & Kenyon LLP
- **Leora Ben-Ami,**
  Kaye Scholer LLP
- **Thomas J. Meloro,**
  Willkie Farr & Gallagher LLP: Moderator
- **Marylee Jenkins,**
  Arent Fox PLLC: Welcome

Course: Preliminary Injunction Motions In Patent Litigation – Is This Your Day In Court?

Course Description:

- What constitutes a "substantial question" on the merits?
- Where does *Markman* fit in a case with an early preliminary injunction motion?
- What harm truly is "irreparable"?
- How will immediate appellate review affect your overall case?

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For further information about this program, please visit

www.nyipla.org

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cont. on page 28

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