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NEWSLETTER

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Losing Ground

The Extension of *Festo* in *Honeywell v. Hamilton Sundstrand*

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I. Introduction

On June 2, 2004, the U.S. Court of Appeals for the Federal Circuit once again placed prosecution history estoppel and the *Festo* doctrine in the limelight. In *Honeywell International, Inc. v. Hamilton Sundstrand Corp.*,[1] the court held *en banc* that rewriting a dependent claim into independent form, coupled with cancellation of the original independent claim, creates a presumption of prosecution history estoppel under *Festo*. This newest edition to the growing line of decisions seeking to clarify the *Festo* presumption of surrender exemplifies how far the Federal Circuit is willing to take the doctrine. *Honeywell* is yet another decision that benefits would-be copyists by further limiting patentees' access to the doctrine of equivalents.

The question addressed in this article is, has the Federal Circuit expanded the *Festo* doctrine to excess? In answering this question in the affirmative, we first consider the Supreme Court and Federal Circuit decisions that impacted the majority's opinion in *Honeywell*, namely, the *Festo*, *Deering*, and *Ranbaxy* decisions. On that foundation, we then turn to the *Honeywell* decision, with particular emphasis on Judge Newman's solo dissent. Finally, we consider the practical ramifications of *Honeywell* and suggest a possible—and simple—statutory solution to correct the harmful balance we believe has been established by this recent authority governing presumptive surrender of equivalents.

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II. Background

A. The Road to Honeywell: the Festo, Deering, *and* Ranbaxy *Decisions*

In recent years, the Federal Circuit has issued a number of opinions addressing amendment-based prosecution history estoppel and the circumstances under which it operates to presumptively preclude access to the doctrine of equivalents for infringement purposes. Most notably, in 2000, the Federal Circuit sitting *en banc* held in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* (*Festo I*)[2] that any narrowing amendment made to a claim element for purposes of patentability completely bars any resort to the doctrine of equivalents with respect to the amended limitation. On writ of *certiorari*, the U.S. Supreme Court abrogated this holding somewhat, replacing the absolute bar with a presumption that such a narrowing amendment surrenders any coverage beyond the literal meaning of the amended limitation.[3] The Court further held that this presumption could be rebutted in any one of three ways: (1) by showing that the equivalent in question would have been unforeseeable at the time of the amendment; (2) by showing that the rationale underlying the amendment bore no more

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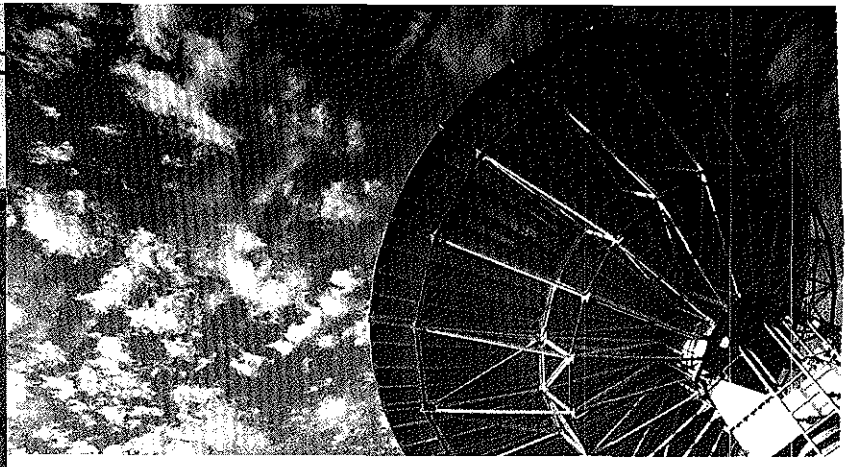

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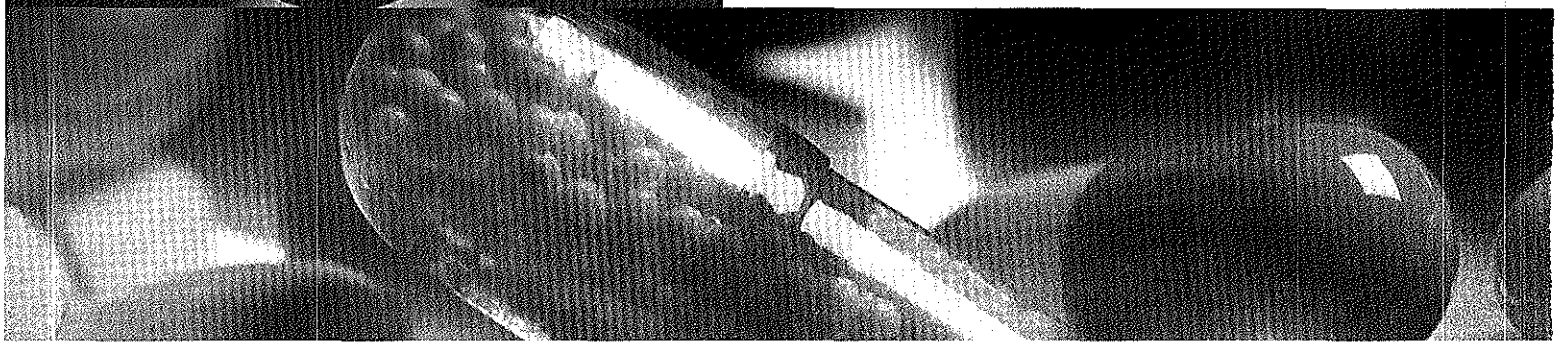

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Keeping Current with the Chair

ROBERT W. SACOFF

It has been a busy and productive year for our Section and it has been my pleasure and privilege to serve as its Chair. For my last column, I offer the following informational report which we have submitted to the ABA House of Delegates, summarizing the Section's main activities and accomplishments during the year. My gratitude goes out, both personally and on behalf of the Section, to the many Section members and leaders whose generous and talented contributions made these achievements possible.

ABA Section of Intellectual Property Law

Informational Report to the House of Delegates

The Section of Intellectual Property Law has conducted robust advocacy on an exceptional number of domestic and international IP policy issues during the 2003–2004 association year, and has served its members' interests through meetings, publications, CLE, diversity, and young lawyer initiatives. Section leadership started the year with a member satisfaction survey, and held its triennial strategic planning retreat in September 2003. The Section Council had twelve meetings during the year, either in person or via conference calls. This report briefly summarizes major Section activities during the year, but excludes many other excellent committee activities and accomplishments due to space limitations.

Advocacy and Policymaking

- Written response to Notice of Proposed Rulemaking of September 12, 2003, "Changes to Support Implementation of the U.S. Patent & Trademark Office 21st Century Strategic Plan."
- Ongoing written advocacy to the House and Senate, opposing the diversion of user-generated funds from Patent Office funding.
- USPTO implemented the Madrid Protocol for international trademark registrations on November 2, 2003, as previously advocated by Section policy.
- *Amicus curiae* brief filed November, 2003, in *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*
- Task Force and meeting of NGOs in London on patent improvement and harmonization, November 10–11, 2003.
- U.S. Ambassador's IP Roundtable in Beijing in November 2003.
- Written comments on Draft EU Commission Regulation on technology transfer agreements and block exemptions (with Sections of Antitrust Law, Business Law, and International Law), November 2003.
- Written comments opposing the Weldon Amendment to the appropriations bill, H.R. 2673, prohibiting the use of appropriated funds to issue patents on claims directed to or encompassing a "human organism," January 2004.
- Written comments on the Report of the Study Group on the Antimonopoly Act of Japan, opposing the extension of the essential facilities doctrine to intellectual property (jointly with the Sections of Antitrust Law and International Law), January 2004.
- Written comments in response to the USPTO's Notice of Proposed Rulemaking of November 26, 2003, to revise the Rules of Practice Before the Board of Patent Appeals and Interferences, February 2004.
- Participated in the USPTO conference and hearings on the Hague Convention on Jurisdiction and Enforcement of Foreign Judgments, March 2004.
- Participated in ABA Day on Capitol Hill, May 2004.
- Written and live testimony in the House Judiciary Committee hearing on proposed amendments to the Federal Trademark Dilution Act, April 2004.
- Participated in ABA Day at the United Nations, April 2004.
- Written comments in response to the USPTO's Notice of Proposed Rulemaking to revise the USPTO Rules of Professional Conduct, June 2004.
- Task Force on Federal Trade Commission Report of October 2003, "To Promote Innovation; The Proper Balance of Competition and Patent Law and Policy," which made twenty citations to IPL Section testimony in the FTC hearings held as a basis for the report.

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Nick Setty

From the Editors

Claim Construction—Is There a Perfect Path?

My last column in the Winter 2004 issue focused on the *Knorr-Bremse*[1] case and the Federal Circuit's *en banc* review of the contours of willfulness and evidentiary presumptions. I have always seen the tension between protection from willfulness, which "advice of counsel" opinions are supposed to afford, and waiver of privilege to be an unfair box for litigants. For this reason and others, the Federal Circuit invited comment on and critique of this issue by issuing a *sua sponte* order setting *Knorr-Bremse* for *en banc* rehearing.

While we wait to see how *Knorr-Bremse* unfolds, the Federal Circuit has opened the door again with the recent *en banc* rehearing order in *Phillips v. AWH Corporation*.[2] This Summer 2004 issue of *IPL Newsletter* will be my last as co-editor, so I have chosen to cover *Phillips* and the ever-evolving focus of claim construction as topics near and dear to my patent litigator heart.

Predictable claim construction methodology appears to be as elusive as predictability of the doctrine of equivalents and prosecution history estoppel. These topics receive enormous attention in the world of patent litigation, including a specific focus in this issue of *IPL Newsletter*, where you will treatments of important new *en banc* rulings such as *Honeywell*,[3] which are redefining the patent litigation landscape daily.

Texas Digital

From my perspective, the most recent iteration of the claim construction journey started in Texas—well sort of. On October 16, 2002, the Federal Circuit issued its opinion in *Texas Digital Systems, Inc. v. Telegenix, Inc.*,[4] redefining the playing field for all claim constructions from that day forward with a new emphasis on dictionary definitions. Courts continue to seek the "ordinary meaning" of disputed claim terms, but likely do so with a newfound interest in the works of Webster, among others. The Federal Circuit's earlier vacillation in the use or nonuse of dictionaries is well documented, so I have not recounted those events or rationales.

Instead, it is probably more interesting to trace the events from *Texas Digital*, to the so-called disclaimer cases, to the recent order in *Phillips*. Using different approaches and occasionally blunt tools, these cases attempt to improve on claim construction methodology.

Texas Digital relies on the presumption that dictionaries actually provide meaningful definitional help.[5] Based on that premise, patent litigants now engage in the exercise the Federal Circuit must have known would come. Post-*Texas Digital*, litigants begin each case with a flurry of dictionary searches and "Ah ha! I knew that's what that word meant." Should I use one dictionary with good definitions for some terms in dispute and "not so good" definitions for other terms, or should I use two dictionaries and risk that opposing counsel finds the bad definitions anyway, or just use a bouquet of dictionaries and keep them off my trail? Rather like Scooby Doo chasing his tail; so much for predictability from *Texas Digital*.

Disclaimer Cases

The disclaimer cases focus on what subject matter one has disclaimed, either during patent drafting or in prosecution.[6] Again, they provide little by way of uniformity or predictability in underlying methodology because of the inconsistency in how different judges see the scope and effect of what appears to have been disclaimed. Ultimately, the threads of the dictionary cases and the disclaimer cases come together on occasion under the "ordinary meaning" rubric. Given that interplay, disclaimers can trump dictionary definitions and vice versa, often depending only on the author of the majority opinion.

Phillips v. AWH

So where do we find ourselves now? On July 21, 2004, the Federal Circuit issued another *en banc* rehearing order, this time to focus squarely on claim construction conundrums. The questions posed are:

1. Is the public notice function of patent claims better served by referencing primarily technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee's use of the term in the specification? If both sources are to be consulted, in what order?

2. If dictionaries should serve as the primary source for claim interpretation, should the specification limit the full scope of claim language (as defined by the dictionaries) only when the patentee has acted as his own lexicographer or when the specification reflects a clear disclaimer of claim scope? If so, what language in the specification will satisfy those conditions? What use should be made of general as opposed to technical dictionaries? How does the concept of ordinary meaning apply if there are multiple dictionary definitions of the same term? If the dictionary provides multiple potentially applicable definitions for a term, is it appropriate to look to the specification to determine what definition or definitions should apply?

3. If the primary source for claim construction should be the specification, what use should be made of dictionaries? Should the range of the ordinary meaning of claim language be limited to the scope of the invention disclosed in the specification; for example, when only a single embodiment is disclosed and no other indications of breadth are disclosed?

4. Instead of viewing the claim construction methodologies in the majority and dissent of the now-vacated panel decision as alternative, conflicting approaches, should the two approaches be treated as complementary methodologies such that there is a dual restriction on claim scope, and a

patentee must satisfy both limiting methodologies in order to establish the claim coverage it seeks?

5. When, if ever, should claim language be construed narrowly for the sole purpose of avoiding invalidity under, for example, 35 U.S.C. §§ 102, 103 and 112?

6. What role should prosecution history and expert testimony by one of ordinary skill in the art play in determining the meaning of the disputed claim terms?

7. Consistent with the Supreme Court's decision in *Markman v. Westview Instruments, Inc.*,[7] and our *en banc* decision in *Cybor Corp. v. FAS Technologies, Inc.*,[8] is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what aspects, in what circumstances, and to what extent?

These questions are as clear as they are cloudy. It appears the Federal Circuit wants to revisit the methodology—again. I am not saying it is a bad thing to inspect a process and attempt to improve it. Much of the work of the masters in the arts and sciences has evolved from such processes. In fact, I am pleased that the Federal Circuit is interested in surveying the fallout from *Texas Digital* and attempting to determine the appropriate balance for all sources of available information.

But what is a little frustrating is the search for a doctrinal solution to a reasonably *ad hoc* problem. That is, there may be no golden key to unlock the secrets of what words mean *in context*. In some cases, the ordinary dictionary meaning may be the most fair, particularly if there is no specification or history to consult. In other cases, there may be consistent use of a term in the specification and history, but *Texas Digital* may keep the parties from ever getting that far because of a more concrete dictionary definition.

The construction process is intended to reflect fairness, both to the patentee in what she vested in society in trade for a limited term "monopoly," and to the competitor who needs to be able to read a claim and determine whether to stay, or change, the course. In terms of these more lofty goals, it is good that the Federal Circuit is revisiting the roles of the public notice function, specification, prosecution histories, and expert testimony.

I hope that the spirit of these questions is carried out in the upcoming *en banc* process; that is, that what one may see as "conflicting approaches" (Question 4), can be reconciled into more fluid "complementary methodologies" for defining claim terms and phrases. The difficulties with reliable and predictable claim construction methodology have much to do with the lack of a doctrinal solution. Sometimes, the best answer is it just depends. Claim construction may fit that formless mold. The best definition for a claim term may be "d. All of the above." A proper method must take into account the fact that technologies vary, sources of information important in one are not so important in others.

Fluidity with some guidance may be the answer.[9] But this is just one opinion and, like you, I will wait and see what presents the *Phillips* case will bring.

Nagendra Setty

Endnotes

1. Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp., 344 F.3d 1336 (Fed. Cir. 2003) (order *sua sponte* granting rehearing *en banc*). The Federal Circuit's order sought briefing from the parties on four questions and from *amicus curiae* on all but Question 3:

> 1. When the attorney-client privilege and/or work product privilege is invoked by a defendant in an infringement suit, is it appropriate for the trier of fact to draw an adverse inference with respect to willful infringement? 2. When the defendant has not obtained legal advice, is it appropriate to draw an adverse inference with respect to willful infringement? 3. If the court concludes that the law should be changed, and the adverse inference withdrawn as applied to this case, what are the consequences for this case? 4. Should the existence of a substantial defense to infringement be sufficient to defeat liability for willful infringement even if no legal advice has been secured?

2. Nos. 03-1269, -1286 (July 21, 2004).

3. Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., Nos. 02-1005, -1082, 2004 WL 1202997 (Fed. Cir. June 2, 2004).

4. 308 F.3d 1193 (Fed. Cir. 2003).

5. For cases interpreting and applying *Texas Digital*, *see, e.g.,* Abbott Laboratories v. Syntron Bioresearch, Inc., 334 F.3d 1343, 67 U.S.P.Q.2d 1337 (Fed. Cir. 2003); Apex Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 66 U.S.P.Q.2d 1444 (Fed. Cir. 2003); CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 62 U.S.P.Q.2d 1658 (Fed. Cir. 2002); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 67 USPQ2d 1132 (Fed. Cir. 2003); E-Pass Technologies, Inc. v. 3COM Corp., 2003 U.S. App. LEXIS 17027 (Fed. Cir., Aug. 20, 2003); Resonate Inc. v. Alteon Websystems, Inc., 338 F.3d 1360 (Fed. Cir. 2003); Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 63 U.S.P.Q.2d 1374 (Fed. Cir. 2002); Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 59 U.S.P.Q.2d 1865 (Fed. Cir. 2001); Biogen, Inc. v. Berlex Laboratories, Inc., 318 F.3d 1132, 65 U.S.P.Q.2d 1809 (Fed. Cir. 2003); Netword, LLC v. Centraal Corp., 242 F.3d 1347, 58 U.S.P.Q.2d 1076 (Fed. Cir. 2001); Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc., 2003 U.S. App. LEXIS 19065 (Fed. Cir., Sept. 15, 2003); Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 65 U.S.P.Q.2d 1865 (Fed. Cir. 2003); Anchor Wall Systems, Inc. v. Rockwood Retaining Walls., Inc., 2003 U.S. App. LEXIS 16535 (Fed. Cir., Aug. 13, 2003); Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003).

6. *See, e.g.,* Golden Blount, Inc. v. Robert H. Peterson Co., ___ F.3d ___, 2004 WL 831106 (Fed. Cir. April 19, 2004), Novartis Pharmaceutical Corp. v. EON Labs Mfr., Inc., ___ F.3d ___, 2004 WL 691734 (Fed. Cir. Apr. 2, 2004), Kinik Co. v. ITC, __ F.3d ___, 2004 WL 583312 (Fed. Cir. Mar. 25, 2004), Premier Networks, Inc. v. Lucent Technologies, Inc., 2004 WL 578396 (Fed. Cir. Mar. 22, 2004) (slip. op.), SuperGuide Corp. v. DirecTV Enter., Inc., 358 F.3d 870 (Fed. Cir. 2004), Springs Window Fashions L.P. v. Novo Indus., L.P., 323 F.3d 989 (Fed. Cir. 2003), Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir. 2004), Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361 (Fed. Cir. 2003), Plant Genetic Systems, N.V. v. Dekalb Genetics Corp., 315 F.3d 1335 (Fed. Cir. 2003), Acco Brands, Inc. v. Micro Security Devices, Inc., 346 F.3d 1075 (Fed. Cir. 2003), Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823 (Fed. Cir. 2003).

7. 517 U.S. 370 (1996).

8. 138 F.3d 1448 (Fed. Cir. 1998).

9. *See* Judge Rader's concurring opinion and Judge Mayer's dissent.

Losing Ground

(continued from page 1)

than a tangential relation to the equivalent in question; or (3) by showing there was some other reason suggesting that the patentee could not reasonably be expected to have described the equivalent in question.[4]

On remand from the Supreme Court in *Festo II*, the Federal Circuit undertook to define further various aspects of a proper *Festo* analysis.[5] For instance, the court held that whether the presumption of estoppel is overcome is a question of law for the district court to decide rather than a question of fact capable of jury determination.[6] Further, the court limited the analysis largely to evidence intrinsic to the patent in question, allowing extrinsic evidence only in the case of a foreseeability determination.[7]

After these decisions, an issue arose as to whether merely rewriting a dependent claim into independent form constituted a "narrowing" amendment that would invoke the *Festo* presumption of surrender. In October 2003, the Federal Circuit considered the issue in-depth in *Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.*[8] In *Deering*, the court held that rewriting a dependent claim into independent form, while also canceling the broader claims from which the rewritten claim depended, presumptively precludes access to the doctrine of equivalents.[9] The court held that "there is no question that the claim was narrowed by the deletion of a broad original claim in favor of a claim that contained the [narrower] Zero Position Limitation."[10] Additionally, the *Deering* court held that the presumption arises as to the narrowed element wherever it appears in the claims, regardless of whether the other claims containing the limitation were ever amended.[11]

One month after *Deering*, the Federal Circuit again addressed application of the *Festo* doctrine where a dependent claim is rewritten into independent form and arrived at a similar conclusion. In *Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc.*, the Federal Circuit relied on *Festo II* and *Deering* in holding that the patentee is presumed to have surrendered the equivalents that may have been encompassed by the cancelled "highly polar solvent" limitation.[12] The applicant had narrowed that limitation to a defined group of solvents and did so by rewriting in independent form a dependent claim containing the narrower limitation. The court ruled that, "[w]hile Apotex was merely rewriting a dependent claim into independent form, the effect on the subject matter was substantial. The dependent claims that were redrafted into independent form did more than simply add an additional limitation; they further defined and circumscribed an existing limitation for the purpose of putting the claims in condition for allowance."[13] In so holding, the Federal Circuit distinguished the scenario in which the dependent claims that were rewritten into independent form "simply add[ed] an additional limitation," a situation the court would face *en banc* the following year in *Honeywell*.

B. The Honeywell Decision

In *Honeywell*, the Federal Circuit held that "an amendment adding a new claim limitation constitutes a narrowing amendment that may give rise to an estoppel" and, further, that "rewriting a dependent claim into independent form, coupled with cancellation of the original independent claim, constitutes a narrowing amendment when the dependent claim includes an additional claim limitation not found in the cancelled independent claim or circumscribes a limitation found in the cancelled independent claim."[14] As discussed in greater detail below, Judge Newman dissented from the majority, opposing the concept that "a limitation that has never been narrowed is subject to the presumption of surrender when a broader claim is cancelled, even when the broader claim did not mention that limitation."[15] Also, in Judge Newman's view, the rule wrongly "imposes an unbounded estoppel, for there is no measure of the yielded territory."[16]

At issue in *Honeywell* was whether Sundstrand infringed two patents directed to an aircraft auxiliary power unit, a small gas turbine engine usually located in the tail section of an airplane and used for starting the primary engines and controlling cabin pressure during flight.[17] Inasmuch as the requirements for compressed air fluctuate widely during flight, the engines claimed in the patents at issue—U.S. Patent Nos. 4,380,893 (the '893 patent) and 4,428,194 (the '194 patent)—included limitations directed to "adjustable inlet guide vanes" to respond to such fluctuations.[18]

During prosecution, the examiner rejected as obvious original independent claims 16 and 32 of the '893 patent and original independent claims 48 and 49 of the '194 patent, none of which contained the inlet guide vane limitation. In contrast, the examiner indicated that dependent claims 17 and 35 of the '893 patent and dependent claim 51 of the '194 patent, each of which further included the inlet guide vane limitation, would be allowable if rewritten into independent form. In response, the applicant cancelled the rejected independent claims and rewrote dependent claims 17, 35, and 51 into independent form. These claims ultimately issued as claims 8 and 19 of the '893 patent and claim 4 of the '194 patent, respectively.[19]

Before the district court, Sundstrand argued that these three claims had been narrowed for reasons related to patentability and that, therefore, prosecution history estoppel barred all equivalents to the inlet guide vane limitation under *Festo I*.[20] The district court disagreed, holding that although the argument had "superficial appeal," the claims had been merely rewritten in independent form, not amended, and thus "Honeywell did not give up an embodiment of the invention with the inlet guide vane" limitation.[21] The case proceeded to trial and a jury found the three claims at issue to be infringed under the doctrine of equivalents.

On appeal, the Federal Circuit first concluded that the addition of a new claim limitation can give rise to a presumption of prosecution history estoppel, just like an

amendment that narrows a preexisting claim limitation, so long as the amendment is made for a substantial reason related to patentability.[22] The court then turned to the specific question of whether rewriting a dependent claim into independent form, coupled with the cancellation of the original independent claim, constitutes a narrowing amendment when the dependent claim includes an additional limitation not found in the cancelled independent claim.

Honeywell argued that prosecution history estoppel cannot apply in such a scenario because it had surrendered its broader claims, but the scope of the rewritten claims themselves had not been narrowed.[23] Relying on the Supreme Court's holding in *Festo II*, the Federal Circuit disagreed, stating that "the proper focus is whether the amendment narrows the overall scope of the claimed subject matter."[24] Thus, the fact that the scope of the rewritten dependent claim remained unchanged would not preclude an estoppel where the overall scope of subject matter claimed in the independent claim had been narrowed for a substantial reason related to patentability.[25] Applying this rule, the appeals court concluded that Honeywell was presumptively estopped from recapturing any equivalents to the inlet guide vane limitation.[26] The court then remanded for a determination of whether the patentee could overcome the presumption of surrender.

Judge Newman dissented vigorously from the majority's opinion, arguing that the majority had changed the law in a manner directly contrary to statute and had restricted equivalency in a manner "far exceeding the holdings of the Supreme Court in *Festo* and *Warner-Jenkinson*."[27] Regarding the first point, Judge Newman argued that the majority's decision was contrary to 35 U.S.C. § 112, ¶ 4, which states that "[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."[28] In her view, restating a dependent claim in independent form does not change its content or scope, and thus there has been no narrowing amendment as required by *Festo*, namely, "it is not a narrowing amendment to go from dependent form to independent form."[29]

Regarding her second point, that the majority's decision far exceeded the bounds of precedent, Judge Newman took issue with the majority's holding inasmuch as it results in a presumptive estoppel "against the entire universe of technology." In *Festo II*, the Supreme Court had established a presumption of surrender of the territory between the original scope of a claim limitation and its scope after a narrowing amendment.[30] The Federal Circuit applied that rule in both *Deering* and *Ranbaxy*, specifically in the context of rewriting a dependent claim into independent form where the amendment in question further limited an already-existing claim limitation. In contrast, in the *Honeywell* scenario, where a new claim limitation is added by the dependent claim rather than an existing claim limitation being narrowed, Judge Newman wrote that the majority had "impose[d] an unbounded estoppel, for there is no measure of the yielded territory."[31] As explained in her dissent, "instead of presuming surrender of the territory between the original scope of the claimed element and the scope of that element after a narrowing amendment—the rule developed in *Festo*—the court now presumes unlimited surrender when an element was not originally claimed at all and therefore presents no outer limit of surrendered territory."[32]

III. Analysis and Implications of the Honeywell Decision

In *Honeywell*, both the majority and dissenting opinions state their arguments confidently, though each seemingly disregards the studied and poignant perspectives of the opposing point of view. For instance, the majority relies heavily on the precedential value of *Festo II*, *Deering*, and *Ranbaxy*, without addressing Judge Newman's fundamental argument that when a dependent claim is restated in independent form, the new independent claim simply states explicitly what was previously incorporated by reference; there is no change in claim scope. On the other hand, Judge Newman discusses at great length the reasons why rewriting a dependent claim into independent form is not a narrowing amendment, but in doing so seems to disregard the fact that *something* was indeed given up by the applicants during prosecution.[33]

Although neither the majority nor the dissent acknowledge their differences explicitly, the primary point of dissension appears to be, to what should the rewritten claim be compared? Judge Newman compares the rewritten claim to itself, finding no change in overall claim scope before and after the amendment, whereas the majority compares the rewritten claim to the original independent claim that was simultaneously cancelled by the applicant. In the words of the majority, "the fact that the scope of the rewritten claim has remained unchanged will not preclude the application of prosecution history estoppel if, by canceling the original independent claim and rewriting the dependent claims into independent form, the scope of subject matter claimed in the independent claim has been narrowed to secure the patent."[34]

Applying Judge Newman's analysis, the dependent claim that the applicant eventually restated in independent form could just have well been written in independent form at the outset, in which case there would have been no amendment at all, and thus, no presumption of estoppel.[35] Judge Newman's point, however, makes clear that the majority's opinion actually was founded not upon the mere act of rewriting a dependent claim into independent form, but rather upon the crucial act of canceling the original independent claim. Although the majority does not make this point explicitly, it is this cancellation that effects the presumptive surrender.

The majority attributes its avant-garde holding to that required by the Supreme Court's opinion in *Festo II*. In that respect, the majority notes that the United States had filed an *amicus curiae* brief urging the Supreme Court to adopt the position that rewriting a dependent claim into independent form cannot give rise to a presumption of surrender.[36] The majority goes on to indicate, without reservation, that the Supreme Court "rejected the position

of the government in this respect, stating that rewriting a dependent claim in independent form creates a presumptive surrender if the amendment is 'made to secure the patent.'"[37] Judge Newman, conversely, takes issue with this point, noting that "[a]lthough the majority attributes its ruling to the Supreme Court, this new leap for inventors is not the Court's work but that of my colleagues."[38]

On this point, it seems that the *Honeywell* majority could have avoided much of Judge Newman's dissent had it not tried to force-fit its decision within the rubric of the *Festo* doctrine. Instead, the majority could have recognized a related, but new form of estoppel called, for purposes of this article, "abandoned claim estoppel." Under abandoned claim estoppel, a patentee would be presumptively estopped from recapturing through equivalents subject matter that was originally claimed but subsequently abandoned during prosecution, such as when a claim is cancelled. A finding of abandoned claim estoppel would be rebuttable in the same manner as a presumptive surrender under *Festo*.

Applying this new form of estoppel to the facts of *Honeywell*, the Federal Circuit could have first held the *Festo* doctrine inapplicable because a dependent claim was simply rewritten into independent form and, thus, there was no narrowing amendment for a substantial reason related to patentability. Next, the court could have achieved the same end result—a presumptive estoppel against the patentee—by applying the new doctrine of abandoned claim estoppel in light of the applicants' claim cancellations. Importantly, this suggested doctrine recognizes that the presumptive surrender in a *Honeywell*-type scenario arises due to the abandonment or cancellation of claimed subject matter during prosecution, which essentially is what the majority in *Honeywell* held, though not in as many words.

The doctrine of abandoned claim estoppel also could have addressed Judge Newman's remaining point directed to the scope of the presumptive estoppel. The *Honeywell* majority held that Honeywell had presumptively surrendered "all equivalents" to the inlet guide vane limitation.[39] However, as pointed out by Judge Newman, the Supreme Court in *Festo II* had "established a presumption of surrender of [only] the territory between the original scope of the claim and its amended scope."[40] This is another instance in which *Festo* seems not to apply to the facts of *Honeywell*; namely, instances in which a new claim limitation was added by the dependent claim, rather than the dependent claim simply narrowing existing limitations as was the case in *Deering* and *Ranbaxy*.

Instead of addressing this issue, the *Honeywell* majority simply states that the estoppel extends to "all equivalents," without any indication as to how such a rule comports with *Festo II*. Judge Newman focuses on that oversight, stating that "the proper focus is the prosecution-induced change to the element at issue."[41] Had the majority accepted the fact that the *Festo* doctrine does not apply to instances where the rewritten dependent claim adds a new limitation, rather than narrowing an existing one, it could have avoided this conflict with the holding of *Festo II*.

How this rule of presumptively denying any equivalents whatsoever affects future patent practice remains to be seen, but one thing is clear: the *Honeywell* decision continues the recent trend of restricting access to the doctrine of equivalents, a trend that is at odds with the interests of patentees. A closer inspection of the court's ruling further emphasizes just how much the court has restricted access to equivalents. As noted previously, the *Honeywell* majority's presumption of estoppel ostensibly arises out of the act of canceling the independent claim rather than the mere ministerial act of rewriting the dependent claim in independent form. Because the court would compare the amended (rewritten) claim to the cancelled claim, future infringement analyses under the doctrine of equivalents might involve a review of the prosecution history to determine the broadest claims that were cancelled during prosecution, and then a comparison of such claims to every issued claim in the patent. Applying the *Honeywell* rule, though taking it to its logical reach, any limitation of the issued claims not found in a cancelled claim would be subject to a *Festo*-like presumption of estoppel. Viewed in this way, this scenario demonstrates just how damaging this new authority is to the interests of patentees.

IV. Where Do We Go from Here?

A. Prosecution Practice in Light of Honeywell

A key practical effect of *Festo* and its progeny is the increased emphasis placed on effective prosecution practice. Today, the astute practitioner must avoid amending claims to secure patentability, and now, in view of *Honeywell*, must also avoid the formerly popular practice of rewriting dependent claims into independent form coupled with cancellation of the corresponding independent claims. Otherwise, the patentee will presumptively surrender all equivalents to the added claim limitation.

As Judge Newman indicates in dissent, the *Honeywell* court's new rule "will simply drive patent applicants away from dependent claims" and "will simply raise the cost and increase the difficulty of patent examination."[42] Dependent claims have been statutorily recognized since 1965, and were in practice decades before then, as a convenient alternative to successive independent claims and as a means for adding clarity and brevity to what oftentimes makes for a daunting read.[43] Judge Newman forecasts that the *Honeywell* decision will result in practitioners avoiding the use of dependent claims, lest they be required during prosecution to rewrite them in independent form and cancel the corresponding independent claims. *Honeywell*, she says, forces such peculiar practice. Moreover, with increased reliance on independent claims will come increased costs, surely to be borne by the patent applicants or their assignees. These points have appeal.

On the other hand, these concerns might not arise at all. The *Honeywell* majority focused its analysis on

comparing what the applicant surrendered in order to secure allowance, comparing the original dependent claim to its cancelled independent counterpart. The notion, implied by Judge Newman, that the result reached by the court would have been different had the applicant originally included solely independent claims may not hold true. It remains to be seen, but if the logic of the *Honeywell* majority is followed, a very likely result would be that, faced with successive independent claims, the court would compare cancelled and allowed independent claims to each other with an eye toward their differences in order to discern that which had been surrendered. Then, it is suspected, the court would presumptively foreclose equivalents to the surrendered limitations. Viewed in this context, drafting a patent application with only independent claims, as suggested by Judge Newman, would not overcome the result of *Honeywell* or the concerns of increased costs and difficulty in examination. Indeed, such a perfunctory distinction – recognized at least implicitly by 35 U.S.C. § 112, ¶ 4, which "assure[s] that claim scope is unrelated to whether the claim is in independent or dependent form"[44]—seems too superficial, too artificial to be the law.

More likely, in our view, a result of *Honeywell*, indeed *Festo*, will be a renewed emphasis on means-plus-function and step-plus-function claim drafting pursuant to 35 U.S.C. § 112, ¶ 6. Means-plus-function format incorporates into the *literal* limitations of the claim the embodiments disclosed in the specification and their equivalents. In order to infringe such a claim limitation, first, the accused structure must be the same as or an equivalent to that disclosed in the specification, and second, the accused and disclosed structures must perform the identical function.[45]

Because Section 112, ¶ 6 requires identical rather than just equivalent function, it is said to be "an application of the doctrine of equivalents in a restrictive role."[46] Nonetheless, it allows one to reach equivalents and, importantly, does so under the rubric of *literal* infringement. Thus, amendments that more narrowly circumscribe the functional aspects of a means-plus-function limitation are not subject to the same type or extent of a *Festo* presumption as are non-means-plus-function limitations. Although such limitations will presumptively impact coverage of means performing equivalent functions, if the claimed function is identically satisfied, equivalent structure to that disclosed in the specification will still be covered without the burden of *Festo*. Importantly, this route for reaching equivalents is not likely to be rendered unavailable by the Federal Circuit, inasmuch as Section 112, ¶ 6 is statutory, not equitable.

One caveat is that equivalent structure in a means-plus-function analysis likely would not include after-arising technology. That is because the means-plus-function analysis is one of literal infringement, and the literal scope of a claim generally fixes upon issuance of the patent. For technology arising after issuance, infringement of a means-plus-function limitation likely exists, if at all, under the common law doctrine of equivalents.[47] Under a common law doctrine of equivalents analysis, "the proper time for evaluating equivalency—and thus knowledge of interchangeability of elements—is at the time of infringement, not at the time the patent was issued."[48]

Thus, for after-arising technology, the patentee may face relying on the doctrine of equivalents and, thus, the prospect of a presumptive estoppel in the event that narrowing amendments were made to the means-plus-function claim during prosecution. But if the technology is after-arising, then the patentee should have a strong argument for rebutting the presumption of surrender, namely, by showing that the equivalent in question would have been unforeseeable at the time of the amendment.[49] Thus, it appears that means-plus-function claim drafting is the best remaining option for ensuring the availability of equivalents to patentees.

However it is accomplished, it is quite clear that the relatively restricted access to the doctrine of equivalents, further restricted by the appeals court in *Honeywell*, will remain a significant point of focus for practitioners. Patent practitioners will need to be particularly vigilant in prosecuting applications. In the words of Judge Newman in *Honeywell*, "Astute practitioners are indeed needed, for little is left of access to equivalency."[50]

B. A Suggested Legislative Solution

In recent years, exemplified in one instance by *Festo*'s rule of presumptive surrender, the Federal Circuit has focused on ensuring that the public is given clear, defined notice of the bounds of patented innovations. The downside of benefiting the public in this regard is that it occurs at the expense of patentees and potential innovators. The Federal Circuit recognizes that there is a balance between encouraging invention and fostering open competition, but recently that balance has tipped heavily in favor of the public. *Festo*, and now *Honeywell*, continue that trend and "further erode[] the ability of inventors to protect their inventions."[51]

This trend has noble goals, but the Federal Circuit has taken it to extremes of late. With the views of the Supreme Court and the Federal Circuit seemingly in place, legislation is needed to more appropriately adjust the balance between the rights of patentees and the public. The authors' colleagues have previously attempted to fashion legislative-like rules to capture the essence of prosecution history estoppel.[52] The exercise was difficult, and the rules devised are not capable of true precision given the large variety of factual situations that can arise in patent prosecution.[53] Indeed, because of the difficulty in drafting an appropriate rule (or statutory language) to guide the application of prosecution history estoppel, it seems unlikely that Congress will enact new legislation for that purpose.

Perhaps there is a better approach than to try to codify the complicated jurisprudence that focuses on prosecution history estoppel. Perhaps a current provision of the Patent Act could be amended to shift the trend back in the direction of patentees; namely, removal of the two-year limit for obtaining a broadening reissue under 35 U.S.C. § 251. Section 251 provides in pertinent part that a patent may be reissued whenever "through error

without any deceptive intention . . . the patentee [has] claim[ed] more or less than he had a right to claim in the patent . . . . No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." It is this last sentence that the authors propose be deleted from the statute.

The policy behind allowing broadening reissues is the recognition that patentees, or their counsel, may fail during prosecution to appreciate the full scope of the invention. Often that failure is not realized until after issuance, when a competitor designs a competing device that falls within the ambit of the specification but outside the scope of the claims. A broadening reissue in such circumstances is permissible if there has been error without deceptive intention. The fact that the error could have been discovered at the time of prosecution does not, by itself, preclude correction through reissuance.[54] Thus, a broadening reissue can be a viable means for patentees to react offensively to technology that is within the scope of the invention at the time the application was filed but beyond the literal reach of the claims. And, thus, it may be a means for reaching technology that the patentee may be otherwise presumptively estopped from reaching under *Festo*.[55]

Under the current Patent Act, the ability of a patentee to secure a broadening reissue is limited temporally to a period of two years following issuance. The rationale for the two-year limit is grounded in the right of the public to rely on the claim language in order to avoid infringement or to design around the claims.[56] But with *Festo*, and now with *Honeywell*, the Federal Circuit has taken the public notice function of patents far beyond where it was when the two-year limit was put in place. Perhaps now is the time to relax that limit. Elimination of the two-year limit on broadening reissues would shift the court's trend back in the direction of inventors and patentees.

It is clear that the primary drawback to removing the two-year limit is that competitors would not be able to rely strictly upon the patent claims, since the claims could be broadened via reissue at any time (assuming reissue is otherwise available). However, by the express terms of Section 251, a reissue patent is always restricted to "the invention disclosed in the original patent." Thus, a patentee may not garner more than was disclosed at the outset, nor may the patentee regain through reissue subject matter surrendered during prosecution, such as by withdrawal or amendment of claims or by arguments made to overcome prior art.[57] Accordingly, though the claims may be left in a state of flux, so to speak, a competitor seeking to avoid infringement or to design around may always review the intrinsic record in order to discern for itself the limits of claim scope available through reissue.[58] Therefore, any uncertainty in the scope of the claims is bounded after all by the specification and prosecution history. Plus, the added uncertainty that would be faced were the two-year limit relaxed is likely no more so than that which existed under the doctrine of equivalents prior to *Festo*.[59]

The proposal to eliminate the two-year limit for broadening reissues would provide only prospective relief for patentees because of the doctrine of intervening rights. Thus, it is particularly useful in the event that an injunction is the primary remedy sought. Even in the instances where damages are of interest, reissue is a viable means for securing claims that literally cover the accused technology only so long as the claims could have been included originally. Of primary importance in view of *Festo* and *Honeywell*, a patentee who otherwise is presumptively estopped from asserting infringement under the doctrine of equivalents may be able to use the reissue process to obtain claims literally covering the infringing technology. Given the imbalanced trend toward favoring the public, it is time for the patent system to give back to its key players, the innovators. Although not necessarily a perfect solution to *Festo*, elimination of the two-year limit on broadening reissues would at least avoid the windfall that currently exists for would-be copyists.

Endnotes

1. Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., Nos. 02-1005, -1082, 2004 WL 1202997 (Fed. Cir. June 2, 2004) (*en banc*).
2. 234 F.3d 558 (Fed. Cir. 2000) (*en banc*).
3. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 741 (2002) (*Festo II*).
4. *Id.* at 740-41.
5. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359 (Fed. Cir. 2003) (*en banc*) (*Festo III*).
6. *Id.* at 1367–68.
7. *Id.* at 1367, 1369.
8. 347 F.3d 1314 (Fed. Cir. 2003).
9. *Id.* at 1325.
10. *Id.* at 1326.
11. *Id.*
12. 350 F.3d 1235, 1240–41 (Fed. Cir. 2003).
13. *Id.* at 1240.
14. *Honeywell*, 2004 WL 1202997, at *7–*8.
15. *Id.* at *12 (Newman, J., dissenting).
16. *Id.* at *19 (Newman, J., dissenting).
17. *Id.* at *1.
18. *Id.* at *1–*2.
19. *Id.* at *4.
20. Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., No. Civ.A. 99-309 GMS, 2001 WL 66348, *4 (D. Del. Jan. 8, 2001).
21. *Id.* at *6.
22. *Honeywell*, 2004 WL 1202997, at *6.
23. *Id.* at *8.
24. *Id.* (citing *Festo II*, 535 U.S. at 736–37).
25. *Id.* at *9.
26. *Id.* at *10 ("In this case, there is a presumptive surrender of all equivalents to the inlet guide vane limitation. . . . Honeywell is presumptively estopped from recapturing equivalents to the inlet guide vane limitation.").
27. *Id.* at *12 (Newman, J., dissenting).
28. *Id.* at *13 (Newman, J., dissenting) (quoting 35 U.S.C. § 112, ¶ 4).
29. *Id.* at *15, *16 ("Rewriting of a claim in accordance with 35 U.S.C. § 112 ¶ 4 can never be a narrowing amendment, because, by statute, rewriting a dependent claim in independent form does not narrow the claim's scope.") (Newman, J., dissenting).
30. *See Festo II*, 535 U.S. at 740; *see also Honeywell*, 2004 WL 1202997, at *19 (Newman, J., dissenting).
31. *Honeywell*, 2004 WL 1202997, at *19 (Newman, J., dissenting).
32. *Id.* at *13 (Newman, J., dissenting).

33. In that regard, Judge Newman disregards the statement by the Supreme Court in *Festo II* that, "Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope." *Festo II*, 535 U.S. at 736. It is difficult to dispute that the overall scope of the patents in *Honeywell* was narrowed when the patent applicant rewrote dependent claims into independent form and cancelled the original independent claims in response to a rejection.

34. *Honeywell*, 2004 WL 1202997, at *9.

35. *See, e.g., id.* at *13, *19 ("This new rule will simply drive patent applicants away from dependent claims and away from the accepted protocol of presenting successively narrowed dependent claims for examination."; "Future applicants may attempt to obtain access to the doctrine of equivalents through avoiding dependent claims.") (Newman, J., dissenting).

36. *Id.* at *8.

37. *Id.* (quoting *Festo II*, 535 U.S. at 736). The majority indicates that, "This is the rule we have consistently applied in our post-*Festo* decisions." *Id.* at *9. However, our research indicates that that may not be entirely true. For example, in Bose Corp. v. JBL, Inc., 274 F.3d 1354, 1359-60 (Fed. Cir. 2001), the applicant had rewritten a dependent claim in independent form and corrected an antecedent basis problem, as to which the Federal Circuit held that "Bose's amendment did not satisfy the 'narrowing amendment' requirement of *Festo* [*I*]." Similarly, it is worth noting that the Federal Circuit, in an unpublished opinion issued just two days before *Festo I*, ruled that "prosecution history estoppel does not bar this claim interpretation because issued Claim 1 was never rejected and was only rewritten in independent form and amended to correct an antecedent basis problem." Vermeer Mfg. Co. v. The Charles Mach. Works, Inc., No. 00-1119, 2000 WL 1742531, at *2 (Fed. Cir. 2000) (per curiam) (unpublished).

38. *Honeywell*, 2004 WL 1202997, at *13 (Newman, J., dissenting).

39. *Id.* at *10.

40. *Id.* at *13 (Newman, J., dissenting).

41. *Id.* at *19 (Newman, J., dissenting).

42. *Id.* at *13 (Newman, J., dissenting); *see also id.* at *19 (Newman, J., dissenting).

43. *See id.* at *14 (Newman, J., dissenting).

44. *Id.* at *13 (Newman, J., dissenting).

45. Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308 (Fed. Cir. 1998).

46. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997).

47. *Chiuminatta*, 145 F.3d at 1310.

48. *Warner-Jenkinson*, 520 U.S. at 37.

49. *See Festo III*, 344 F.3d at 1369 ("Usually, if the alleged equivalent represents later-developed technology . . . or technology that was not known in the relevant art, then it would not have been foreseeable.").

50. *Honeywell*, 2004 WL 1202997, at *19 (Newman, J., dissenting).

51. *Id.* at *13 (Newman, J., dissenting).

52. *See* William M. Atkinson et al., *Was Festo Really Necessary?*, 83 J. PAT & TRADEMARK OFF. SOC'Y 111 (2001).

53. *See id.*

54. In re Wilder, 736 F.2d 1516, 1519 (Fed. Cir. 1984) ("The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.").

55. *Cf.* Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1483 (Fed. Cir. 1998) ("The realm of corrections contemplated within § 251 does not include recapturing surrendered subject matter, without the addition of materially-narrowing limitations, in an attempt to 'custom-fit' the reissue claims to a competitor's product."); In re Weiler, 790 F.2d 1576, 1582 (Fed. Cir. 1986) ("The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application.").

56. *See* In re Fotland, 779 F.2d 31, 33 (Fed. Cir. 1985) ("The purpose of the law that a broadening reissue must be applied for within two years after patent grant is to set a limited time after which the public may rely on the scope of the claims of an issued patent.").

57. *See Hester Indus.*, 142 F.3d at 1480–81.

58. *See Warner-Jenkinson*, 520 U.S. at 32 n.6 ("That [another] rule might provide a brighter line for determining whether a patentee is estopped under certain circumstances is not a sufficient reason for adopting such a rule.").

59. *See, e.g., Festo II*, 535 U.S. at 732 ("If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. In addition the uncertainty may lead to wasteful litigation between competitors, suits that a rule of literalism might avoid. These concerns with the doctrine of equivalents, however, are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.").

Ranbaxy Pharmaceuticals v. Apotex

Redefining Claim Drafting and Patent Prosecution under Festo

BY MARTHA M. RUMORE

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A recent case, *Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc.* (*Ranbaxy*) highlights that the Federal Circuit continues to narrowly apply the principles of the line of judicial decisions, collectively known as *Festo,* to the detriment of patent holders.[1] Generally, *Ranbaxy* shifts the balance struck by patent law and practice between patentees and alleged infringers in favor of the infringers regarding the interpretation of claims. The case had noteworthy ramifications from *Festo,* illuminating the importance of equivalence and forseeability in both claim drafting and claim amendment; perhaps it could be called the daughter of *Festo.*[2]

More specifically, *Ranbaxy* stands for the proposition that a narrowing amendment can occur when a broad claim is cancelled and an original dependent claim is rewritten in independent form. Moreover, inasmuch as the amendment is a narrowing amendment, prosecution history estoppel may be triggered with respect to the subject matter of the cancelled claim, which is not literally covered by the rewritten claim. This article offers commentary on the effects of the *Ranbaxy* decision on claim drafting and patent prosecution post-*Festo.*

Case Review

Ranbaxy involved a battle of the generic companies involving the broad-spectrum antibiotic, cefuroxime axetil. The case is an appeal from the District Court of the District of New Jersey's denial of a preliminary injunction sought by Apotex against Ranbaxy to prohibit Ranbaxy from practicing Apotex's patented method to a "process for preparing amorphous cefuroxime-axetil."

Apotex asserted that Ranbaxy infringed its patent, U.S. Patent No. 5,847,118 ('118 patent) not literally, but under the doctrine of equivalents. The '118 patent was directed to a method of creating the amorphous (non-crystalline) form of the antibiotic. The method involved dissolving the crystalline form under certain conditions using a solvent. In prosecution, the sole independent claim was rejected under 35 U.S.C. § 112, ¶ 2, as indefinite because the examiner questioned how the term "high polarity" was bounded in the claim phrase "highly polar organic solvent." Additionally, the examiner applied an obviousness rejection to U.S. Patent No. 5,013,833 ('833 patent) that disclosed a similar process different in two ways: it used acetone as the solvent, and it added the water and solvent together, whereas the claim first added the solvent, and added the water afterward. The examiner also objected to other claims for being dependent upon a rejected base claim, but stated the claims would be allowable if rewritten in independent form.[3]

In its response to this first office action, Apotex amended the application by canceling all claims and adding new claims including an independent claim, adding a limitation for the solvent: "wherein the highly polar organic solvent is selected from the group consisting of a sulfoxide, an amide and formic acid." That is, the patentee rewrote the dependent claims into a single, new independent claim. Moreover, Apotex, in its discussion of the '833 patent, argued that acetone requires elaborate experimental procedures and that the disclosed invention overcomes these disadvantages through the use of a highly polar solvent. This independent claim was allowed.

District and Federal Court Decisions

In the district court, Apotex moved for a preliminary injunction arguing that the Ranbaxy process which uses acetic acid as a solvent, infringed the claims of the '118 patent under the doctrine of equivalents. The Court determined that Apotex could not meet the preliminary injunction "reasonable likelihood of success" standard, relying on the now vacated original *Festo en banc* opinion.[4] That is, Apotex has either entered a narrowing amendment related to patentability thereby invoking the complete bar of *Festo,* or it had surrendered solvents of the same polarity as acetone, which it found acetic acid was.

On appeal to the Federal Circuit, Apotex argued that the district court erred in finding that there had been a narrowing amendment for "a substantial reason related to patentability." It contended: "....[B]ecause the examiner in the first office action objected to dependent claims 3-7 but stated that they would be patentable if rewritten in independent form, and because the new independent claim is nothing more than three dependent claims combined and rewritten in independent form, there was not a narrowing amendment for a substantial reason related to patentability." The Federal Circuit disagreed, although under a slightly different analysis than the district court, as in the interim the Supreme Court issued its decision. The Supreme Court in *Festo* mentioned estoppel arising upon rewriting a claim into independent form.[5] In a recent case the Federal Circuit had stated that "in deciding whether a narrowing amendment has occurred, 'the correct focus is on whether [the] amendment surrendered subject

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matter that was originally claimed for reasons related to patentability.'"[6]

According to the Federal Circuit, the surrender of equivalents was clear. "While Apotex was merely rewriting a dependent claim into independent form, the effect on the subject matter was substantial. The dependent claims redrafted into independent form did more than simply add an additional limitation; they further defined and circumscribed an existing limitation for the purpose of putting the claims in condition for allowance. The additional language limited "highly polar solvent" to a defined group of solvents: sulfoxides, amides, and formic acid. In so doing, the patentee is presumed to have surrendered the equivalents that may have been encompassed by "highly polar solvent."[7] The court agreed with Ranbaxy that Apotex was unlikely to rebut the *Festo* presumption of claim surrender.[8] Replacing claims are susceptible to estoppel.[9] The fact that the new independent claim contained the identical limitations as the cancelled dependent claims was of no consequence.

Apotex argued that it was not foreseeable that the amendment could constitute surrender of a highly polar organic solvent which is the structural equivalent (i.e., a homolog) of one of the recited solvents. The Federal Circuit did not accept this argument in part because "acetic acid is a foreseeable equivalent to formic acid" and acetic acid has about the same polarity as acetone. The Federal Circuit noted that Apotex itself had stated that the two were "homologs [and thus] are readily known by chemists to exhibit similar properties and are therefore equivalent." The court opined that forseeability relates to the equivalent, not to whether an amendment may result in prosecution history estoppel. Moreover, it stated that if acetic acid were known to be equivalent to formic acid, it would have been foreseeable to literally include acetic acid in the claim.

Relying on *Festo* and *Deering,* the *Ranbaxy* court held that there was a clear surrender of subject matter because the narrower rewritten claim had been substituted for the broader original independent claim.[10] The presumption of surrender only applies to the amended or newly added limitation; there is no surrender of territory as to unamended limitations that were present in the original claim. Thus, when a claim is rewritten from dependent into independent form and the original independent claims is canceled the test applied is "whether [the] amendment surrendered subject matter."[11] The Federal Circuit reasoned that under such circumstances, the surrendered subject matter is defined by the cancellation of independent claims that do not include a particular limitation and the rewriting into independent form of dependent claims that do not include the limitation. According to *Ranbaxy,* equivalents are presumptively not available with respect to that added limitation.

The *Ranbaxy* case definitely reminds us that the doctrine of equivalents is still as confusing as ever and file-wrapper estoppel is alive and well. We can expect to see much in the way of forseeability and unforseeability arguments from patent litigants. Questions remain with regard to what is or is not "foreseeable." Questions remain as to what test is to be applied to determine whether the *Festo* can be rebutted. Is the test whether the patentee could not reasonably be expected to have drafted a claim that would literally have encompassed the alleged equivalents, or are there three separate tests: unforseeability, tangential relation, and other reasons? In any event, the burden has shifted to the patentee.

The patent community can expect the Federal Circuit to narrowly apply *Festo* to the forseeability factor and to broadly apply prosecution history estoppel. While there is general agreement that amended claims should maintain a narrower penumbra than nonamended claims, according to the decision in this case an amendment to a claim collapses the penumbra of the amended claims to zero. The narrowed elements were limited to their literal scope. The decision seems tantamount to the "absolute" bar to equivalence of the original Federal Circuit *Festo* rather than the flexible bar.[12] Further, this case stands for the proposition that rewriting a dependent claim into independent form will create an estoppel-narrowing amendment and that narrowing amendment will be compared to the original claims taken separately, not together. Further, cancellation of a claim may be considered an amendment made for a substantial reason related to patentability, and thus invoke a complete bar to equivalents.

Ramifications: *Honeywell v. Hamilton*

On June 2, 2004, the Court of Appeals for the Federal Circuit in *Honeywell International, Inc. v. Hamilton Sundstrand Corp.* (*Honeywell*),[13] following the *Ranbaxy* decision, determined that the rewriting of dependent claims into independent form coupled with the cancellation of the original independent claims, constitutes a narrowing amendment, when the dependent claim includes an additional claim limitation not found in the cancelled independent claim or circumscribes a limitation found in the cancelled independent claim, thereby creating a presumption of prosecution history estoppel. In *Honeywell,* the court vacated the lower court judgment of infringement and remanded the case for determination of whether Honeywell can rebut the presumption of surrender under *Festo.*[14]

Honeywell had argued that prosecution history estoppel cannot occur where a dependent claim is merely rewritten into independent form. Honeywell contended that, although it surrendered its broader independent claims, there was no presumption of surrender because the scope of the rewritten claims themselves was not narrowed. The Federal Circuit disagreed, holding that "...[T]he fact that the scope of the rewritten claim has remained unchanged will not preclude the application of prosecution history estoppel if, by canceling the original independent claim and rewriting the dependent claims into independent form, the scope of the subject matter claimed in the independent claim has been narrowed to secure the patent."[15]

Of interest in *Honeywell v. Hamilton* is Judge Newman's dissent opining that the decision restricts equivalency, far exceeding the holding of *Festo.*[16] Judge Newman states that rewriting a claim in accordance with 35 U.S.C. § 4,[17] can never be a narrowing amendment because, by statute, rewriting a dependent claim in

independent form does not narrow the claim's scope. According to Judge Newman, "Astute practitioners are indeed needed, for little is left of access to equivalency."[18]

Claim Drafting and Prosecution Strategies

A. Drafting for Argument Not Amendment.

The decisions in *Ranbaxy* and *Honeywell* highlight the need for patent practitioners to review claim drafting and prosecution practices in an effort to avoid the need for narrowing amendments. Each claim word must be carefully chosen to consider the forseeability test. Claims should not be overbroad in view of the art unless plausible arguments to overcome the art can be formulated.[19] Amending claims should be avoided if possible; potentially useful techniques include examiner interviews and posing more substantive arguments to overcome prior art. Greater resistance should be given to Examiner amendments. Furthermore, arguments should be consistent with those made in co-pending applications to avoid introducing new bases upon which prosecution history estoppel may arise.

1. Filing More Independent Claims

One option is the filing of more independent claims, especially if the typical drafting approach is that none of the independent claims is clearly narrower than other independent claims. The purpose of this approach is to reduce the likelihood that the examiner will reject a claim, and consequently reduce the likelihood of claim amendment. As rewriting dependent claims in independent form may trigger a loss of equivalents, avoiding dependent claims can provide access to the doctrine of equivalents. Unfortunately, one consequence will be increased costs, since excess independent claims carry a heavier fee than excess dependent ones. Another drawback may be a lengthening of examination, inasmuch as the use of the dependent form adds organization to the claims and makes them easier to understand.

2. Filing More Claims of Varying Scope

Another option is the drafting of more claims of varying scope and utilization of means-plus-function claims, including different characterization of the claim elements using differing terminology but not having any graduation in scope. Means-plus-function claims are defined under 5 U.S.C. § 112 to expressly include equivalents and therefore, can be considered broader from an equivalents standpoint. Other strategies patent practitioners may utilize include reciting "laundry lists" of equivalents or resorting to broad generic terminology.

The past practice of simply drafting a very broad independent claim which upon rejection is cancelled, and subsequently rewriting the other claims in independent form is no longer acceptable in view of the potential loss of equivalents for the subject matter. In view of *Ranbaxy* and *Honeywell*, claims must be precise—broad, but not so broad as to fail to distinguish over prior art, thereby requiring narrowing amendments. In other words, there is increasing pressure upon a patent practitioner to get it right the first time, and avoid the possibility of narrowing amendments.

3. Avoid Amendments

Practitioners should be less willing to amend and more willing to appeal or state disagreement with the examiner for the record. The avoidance of preliminary amendments is also warranted as these voluntary amendments are not a safe harbor from *Festo*. Preliminary amendments are not treated any differently than other amendments and are, therefore, likely to be assumed as being submitted for reasons related to patentability. On the other hand, these amendments may be easier to characterize as not related to patentability when they occur before the first office action.

4. Utilize Continuation Applications

Yet another option is to consider pursuing broader claims from a narrowed claim in continuation applications. According to *Festo* "estoppel attaches because the patentee conceded or at least abandoned the right to appeal." A continuation is not a concession and is cheaper and may be shorter than the appeal process. Via continuation, a patentee could continue the prosecution of the broader claims from an application in which narrower claims are allowed in order to secure territory that the patentee does not wish to surrender. If a double patenting rejection is made, then the continuation can be maintained via a terminal disclaimer. If broader claims finally issue the patentee can make clearer, what, if any, subject matter was ultimately surrendered.[20]

B. Amending Carefully

Despite your best efforts, the claims may need to be amended. In view of the above-mentioned case law, amendments and/or arguments are more critical than ever to preserving or forfeiting the equivalents. If the claims must be amended then amend judiciously and only to the minimal extent necessary to avoid the rejecting art.[21] Avoid gratuitous amendments or those made for style or other nonsubstantive reasons. The broadest and most general language should be utilized in crafting amendments. Some suggestions include splitting composition ranges, avoiding run-on claims with no clear separation of claim elements, as well as use of relative terms (e.g., "substantially and about"). Claims should be drafted to keep the elements distinct, as this will prevent estoppel to the unamended claims. Further, if the elements are not clearly separated, a court may become confused resulting in a loss of equivalents. Splitting ranges (e.g., from "between A and B" to "at least A amount and no more than B amount") clarifies when amending which end of the range is being amended. Otherwise, equivalents on both ends of the range could be forfeited, even if the prior art only addresses one end of the range.[22] Additionally, the patent practitioner must be cautious in providing explanations for claim amendments.

Any claim amendments should be undertaken from the perspective of one skilled in the relevant art, not from the perspective of the inventor.[23] Depending upon the time and resources available, technical research in the field of the invention and thorough prior art searches, at the time of amendment in addition to the time of filing, may be warranted to avoid excluding foreseeable equivalents.

Perhaps, in certain circumstances, estoppel may be avoided by amending a dependent claim to expressly include all

the elements of the independent claim rather than amending an independent claim or adding a new claim. However, when placing a dependent claim in independent form, do not amend the independent claim to add the limitations of the dependent claim as this will be interpreted as an amendment for reasons of patentability. Under *Ranbaxy*, claim cancellation has taken on greater significance. Certainly, this case highlights the fact that the cancellation of a claim coupled with the addition of a new claim may evoke estoppel if the new claim is considered to be a replacement for the cancelled claim. In some circumstances, it may be better to add a claim element or limit to a claim rather than amending a claim to specifically address the examiner's rejection.[24]

Conclusion

Determining how prosecution history estoppel limits claim scope under the doctrine of equivalents has been troublesome in practice. How the most recent *Festo* decision is ultimately interpreted and refined by the lower federal courts and the Federal Circuit remains to be seen. At this junction, we will have to stay tuned and see if the most recent decision marks the end of this fifteen-year-old case.[25] However, the decision rendered in *Ranbaxy* applying the Court's *Festo* decision heightens the risk of loss of equivalents due to claim amendment. *Ranbaxy* demonstrates that the Federal Circuit's 2003 decision represents an attempt to place some limitations on a patentee's ability to rebut the presumption of surrender.

Ranbaxy expands the applicability of prosecution history estoppel in patent infringement actions, substantially curtailing a patentee's bases for obtaining a judicial finding of infringement under the doctrine of equivalents. According to *Ranbaxy*, a narrowing amendment can occur when a broad claim is cancelled and an original dependent claim is rewritten in independent form. Further, according to this case, such narrowing amendment may trigger prosecution history estoppel with respect to the subject matter within the scope of the claim that was cancelled but not literally covered by the rewritten claim. The protection against the "unscrupulous copyist" is nearly gone when the copyist merely changes an element to an equivalent of a claim limitation that was narrowed during prosecution.26 Now, more than ever, patent counsel should be vigilant in drafting and prosecuting claims.

Endnotes

1. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 68 U.S.P.Q.2d 1321 (Fed. Cir. 2003). On September 26, 2003, the Federal Circuit rehearing the *Festo* case on remand from the United States Supreme Court, set forth a three-prong test for estoppel: The first question is determining whether the amendment narrowed the literal scope of the claim. If the amendment was not narrowing, then prosecution estoppel does not apply. If the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial reason relating to patentability. If the patentee successfully establishes that the amendment was not for a reason of patentability, then prosecution history estoppel does not apply. If, however, the Court determines that a narrowing amendment has been made for a substantial reason relating to patentability, then the third question addresses the scope of the subject matter surrendered by the narrowing amendment. At that point *Festo* imposes the presumption that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation. The presumption is rebuttable via three factors: (1) The alleged equivalent would have been unforeseeable to one skilled in the art at the time of the narrowing amendment; (2) The rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question; or (3) There was "some other reason" suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent.

2. 350 F.3d 1235, 69 U.S.P.Q.2d 1086 (Fed. Cir. 2003).

3. *Id.* at 1238.

4. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 122 S. Ct. 1831, 1841 (2002).

5. *Id.* at 1840.

6. Deering Precision Instruments L.L.C. v. Vector Distribution Systems, Inc., 347 F.3d 1314 (Fed. Cir. 2003).

7. *Ranbaxy*, 350 F.3d at 1241.

8. For Apotex to overcome the *Festo* presumption that it has surrendered equivalents it had to show: (1) the equivalent was unforeseeable at the time of the application; (2) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

9. Prosecution history estoppel, also known as file history or file-wrapper estoppel is a limiting doctrine that holds that where an inventor narrows a claim element during the prosecution of a patent application by making an amendment or argument in support of patentability he cannot later invoke the doctrine of equivalents to recapture what the claim element would have otherwise covered. The patentee is estopped or "locked in" by the amendment or argument.

10. *Ranbaxy*, 350 F.3d at 1241 (*quoting Deering*, 347 F. 3d at 1325).

11. *Id.* at 1240.

12. Festo v. Shoketsu Kinzoku Kogyo Kabushiki, 234 F.3d 558, 56 U.S.P.Q.2d 1865 (Fed. Cir. 2000) (en banc) (holding that prosecution history estoppel acted as a complete bar to the doctrine of equivalents and limiting copier's liability to literal infringement of the claims).

13. No. 02-1005, -1082, slip op. (Fed. Cir., June 2, 2004) (en banc).

14. 535 U.S. 722 (2002), *remanded to* 344 F.3d 1359 (Fed. Cir. 2003).

15. *See Honeywell*, at 16.

16. *Id.* (Newman, J., dissenting).

17. 35 U.S.C. § 4 states that a claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

18. *See Honeywell*, at 14.

19. *See* Steven J. Lee & Patrick J. Birde, *Advanced Claim Drafting and Amendment Writing for Chemical Inventions*, 768 PLI/Pat 211 (Nov. 2003).

20. *See generally* Brian S. Mudge & Fred Grasso, *Prosecuting Patents Under The Scrutiny of Festo's Rebuttable Presumption*, 9 INTELL. PROP. TODAY, 2002, at 38–39; EDWARD G. POPLAWSKI & ROCHELLE K. SEIDE, PATENT PRACTICE IN THE AFTERMATH OF FESTO & VORNADO (Practicing Law Institute 2002).

21. *See* Mudge & Grasso, 9 INTELL. PROP. TODAY, at 38.

22. Teresa S. Rea, *Preparation and Prosecution of Patent Applications After Festo in the Biotechnology and Chemical Arts, in* EDWARD G. POPLAWSKI & ROCHELLE K. SEIDE, PATENT PRACTICE IN THE AFTERMATH OF FESTO & VORNADO 36–37 (Practicing Law Institute 2002).

23. *Id.* at 39.

24. *See* Gerry Gressel, *Claim Drafting and Claim Amendment to Reduce the Festo Effect*, 8 INTELL. PROP. TODAY, 2001, at 25.

25. However, the parties will now have to return to another proceeding at the district level.

26. Graver Tank Manufacturing Co. v. Linde Air Products Co., 399 U.S. 605, 607 (1950).

Why Dilution May Offer a Solution to the Problem of Unauthorized Fan Memorabilia in Europe

BY ANGELA FOX

Angela Fox

Two years on, the dust has finally settled on the European Court of Justice's groundbreaking decision in *Arsenal Football Club PLC v Matthew Reed.*[1] In *Arsenal*, the court ruled, albeit indirectly, on a most fundamental question: When is it proper for a competitor to use another's registered trademark? In answering, the court boldly reverted to first principles in an attempt to cast an infringement net wide enough to catch all uses that interfere, or may interfere, with a trademark's ability to distinguish one trader's goods from others. What has emerged, however, is a test of notorious ambiguity that is of questionable propriety in cases where dilution is the real damage and that has already sown judicial discord at the highest levels.[2] Nowhere is this clearer than in the arena of celebrity brand merchandising,[3] and more recent developments invite analysis of whether a different, dilution-based rationale may offer a better solution to the problem of unauthorized fan memorabilia in Europe.

Setting the Scene

The history of *Arsenal* is by now well-rehearsed, but a brief synopsis may help to set the scene. The defendant, Matthew Reed, ran a highly successful stall outside the grounds of the well-known English soccer team, Arsenal Football Club, selling scarves and other articles of clothing which bore the team's name. The claimant club had registered ARSENAL as a trademark for clothing and claimed a right to automatic relief for trademark infringement under Section 10 (1) of the United Kingdom Trade Marks Act 1994 (Act).[4] Under that provision, a defendant infringes if he uses a mark identical to a registered mark in the course of trading in goods identical to those for which the mark has been registered. It is not necessary to prove a likelihood of confusion.

Although the criteria of Section 10 (1) were met on the *Arsenal* facts, the English High Court nevertheless doubted that the unauthorized use of a team name on fan memorabilia could infringe. In the view of the judge, Laddie J., a finding of trademark infringement required that the unauthorized use be perceived as an indicator of trade origin.[5] By contrast, a celebrity name on scarves sold to fans appeared to communicate something different altogether—namely, that the purchaser was a supporter of the person, group or team so named. The High Court therefore asked the ECJ to rule on whether origin-indicating use, or so-called trademark use, was a prerequisite to a finding of infringement under Article 5 (1) (a)[6] of the 1988 Directive on Harmonization of Trade Mark Laws in the Member States,[7] the basis in European law for Section 10(1). Had it answered in the affirmative, the ECJ would have confirmed a long line of pre-directive English authority, as well as settling a controversy running almost since the implementation of the directive in the U.K. in 1994.[8]

Ultimately, however, the ECJ took the opposite view. Absolute protection for distinctive signs, it intoned, was a crucial element of the system of undistorted competition which the Treaty of Rome had been intended to foster.[9] The essential function of distinctive signs was to indicate origin to consumers, and the law must protect against the erosion of that function caused by unauthorized use. The exclusive right conferred under Article 5 (1) (a) must therefore apply to all cases where the use of another's sign *"affects or is liable to affect the function of the trade mark, in particular its essential function of guaranteeing to consumers the origin of the goods."*[10] If an unauthorized use of a registered mark affected or was liable to affect the trademark's ability to guarantee origin, then a finding of infringement under Article 5 (1) (a), whose implementation into all European Union member states was mandatory, would be automatic unless a defense could be proved.

In so finding, the ECJ ruled that the test for whether use of an identical mark infringed was not how the use was intended to function or how it was perceived. Questions of trademark or nontrademark use were therefore irrelevant. Instead, the measure of infringement was how the unauthorized use might affect the ability of the registered mark to function as a trademark. Since the most basic function of a trademark is to indicate trade origin, the ECJ singled out erosion of the capacity to distinguish as the most fundamentally detrimental effect caused by unauthorized use.[11] That erosion could take the form of immediate confusion as to source. Equally, however, it could develop more incrementally over time, where unauthorized use takes unfair advantage of the reputation and success of a registered mark and gradually weakens its distinguishing power.[12] In this recognition of an incremental species of damage under Article 5 (1) (a), the ECJ spoke the language of dilution.[13]

It took a trip to the English Court of Appeal to finally dispose of the factual issues in *Arsenal*. However, as a result of the case's high profile, the legal test laid down by the ECJ is now well-known even if courts differ on how to apply it: where identical marks and goods are concerned, unless a specific defense applies, there will

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be an automatic finding of infringement if that use might affect the trademark's ability to guarantee origin, either immediately or over time.

The Problem with Arsenal

For such a clean distillation of the law, however, the *Arsenal* test is uncomfortable to apply. Within a day, its broad ambiguity had permitted the House of Lords to interpret it completely differently in a counterfeiting case, *R. v. Johnstone*,[14] creating legal uncertainty in the United Kingdom that remains unresolved. The irresistible temptation of the courts to drop anchor swiftly, perhaps too swiftly, on the effect of *Arsenal* is understandable, however, as without judicial moorings the *Arsenal* test would be at sea.

The *Arsenal* test is so problematic because it is difficult to imagine any circumstances in which unauthorized use of a registered mark for identical goods would not affect or be liable to affect the ability of the trademark to guarantee origin. This is so even where defenses would clearly apply.[15] For example, affixing another's mark to genuine repackaged goods is allowed under Article 7 of the Directive where the goods were first put on the market within the European Union by the trademark owner or with his consent, provided there are no legitimate reasons to oppose the further sales such as shoddy re-packaging that creates a risk of contamination or may mar the trademark owner's image.[16] Likewise, stating honestly and accurately that a wing mirror is a spare part for, for example, a FORD MONDEO car will also not infringe, in accordance with Article 6 (1) of the directive[17]

Even where the use is honest, the goods unimpaired, and the packaging of high quality, uncontrolled use by third parties may still affect a trademark's ability to guarantee origin. A parallel importer who advertises a chic brand for sale in cheap market stalls may subtly damage a trademark's carefully polished, upscale image, thus gradually depleting its attractive force and its ability to guarantee that the goods bearing it are indeed exclusive and sophisticated. Confusion as to source is unlikely since the goods are genuine; but nevertheless, over time the trademark's image may be undermined and the ability of the trademark to guarantee origin will weaken, the aura that originally attracted its custom having been lost. Likewise, the vendor of spare parts who advertises wing mirrors in shabby packaging as spare parts for FORD MONDEO cars is not acting contrary to honest practices and will not confuse customers since his claim is honest. Nevertheless, the shoddy packaging may gradually undermine the image of the car manufacturer, to whom the public may erroneously and even subconsciously attribute the poor packaging quality and ultimately any shortfalls in the quality of the parts. Again, over time, the trademark's image may be damaged, its attractiveness weakened, and its ability to draw in custom as a guarantee of trade origin may decline.

The risks associated with these legally permitted unauthorized uses would seem to suggest that the Article 6 (1) and Article 7 defenses themselves undermine the Treaty aim of providing absolute protection for distinctive signs. The ECJ attempted to resolve this problem by explaining that *"certain uses for purely descriptive purposes"* are *"excluded from the scope of Article 5 (1) of the Directive because they do not affect any of the interests which that provision aims to protect, and do not therefore fall within the concept of use within the meaning of that provision."*[18] For the reasons explained above, however, even descriptive use by others can affect the ability of a trademark to guarantee origin in the long term, which is the central interest that Article 5 (1) aims to protect. Where European law permits such use, therefore, it is arguably not because the use is not capable of causing damage, but rather because the public interest in permitting the use outweighs the potential detriment.

Purely Descriptive versus Nonpurely Descriptive Merchandising

Purely descriptive celebrity merchandising demonstrates the point. Successful and popular figures, groups and teams often inspire items like books and posters which are either about the figure or group or depict them. There is no sensible way to market such items other than to identify the subject matter by name. Such activities may be termed purely descriptive merchandising because the use of the celebrity's name or image accurately and necessarily describes the product to which it is applied, which has no independent value or use apart from its connection with the celebrity. Where the celebrity's name is also a registered mark, it is easy to imagine how purely descriptive merchandising activities may affect a trademark's ability to fulfill its functions. Widespread unauthorized use of a celebrity's name or image on posters, books, decals and the like would erode any trade connection buyers might reasonably make between the goods and the celebrity because the public would not be able to rely on the goods emanating from, or under the control of, a single source that is responsible for their quality. Under the *Arsenal* test, such use of a registered trademark for goods identical to those for which the mark was protected would automatically infringe, unless the merchandiser could successfully prove that the mark would be seen as an honest and accurate descriptor under Article 6 (1) of the directive.[19]

This issue was not before the ECJ in *Arsenal*, which concerned items of clothing rather than mere information or image carriers such as books or posters. Whether and when an Article 6 (1) defense would shield the honest use of registered trademarks directly to describe characteristics of fan memorabilia has yet to be decided.[20] However, despite the ruling in *Arsenal*, it is highly unlikely that purely descriptive merchandising would in fact infringe. It is in the public interest that the names of celebrities, whose fame arouses the attention and interest of a following, be available freely for use to describe commercial items naturally springing from that fame and following, which could not sensibly be described in any other way. Therefore, even though such use is clearly capable of affecting the ability of the trademark to

guarantee trade origin, the benefits of permitting the use outweigh the potential detriment. Publishing books on and posters of celebrities are legitimate commercial activities that not only thrive on, but sustain, the celebrities' fame. These activities could not be carried out without reference to signs which are more than just registered trademarks—they are also celebrities' names or likenesses.

In *Arsenal*, no Article 6 (1) defense was advanced, but even if it had been raised it is unlikely to have affected the outcome in the absence of any clear descriptive link between the trademark and the goods to which it was applied. There was no such link in *Arsenal*, because the merchandise at issue was nonpurely descriptive in nature. Nonpurely descriptive merchandising uses a celebrity's trademarked name not to describe content or subject matter of, for example, a book or poster, but rather to enhance the value of another article whose primary purpose is something other than to carry information or images. Nonpurely descriptive merchandise commonly includes items such as commemorative plates, bookmarks, caps, t-shirts, and, in the case of *Arsenal*, football scarves.

The distinction between purely descriptive and nonpurely descriptive merchandising is that, while a book about a celebrity has no independent value or usefulness apart from its connection with the celebrity, a scarf bearing the celebrity's name is still an article of clothing with an independent usefulness, whose value has simply been enhanced by the affixing of the famous name. The ECJ's ruling in *Arsenal* considered only nonpurely descriptive merchandising, and appears to preclude an Article 6 (1) defense in such cases because it held that the defense applies only when *no* interest of the trademark owner is affected by the use. The ECJ appeared to find—as a matter of fact—that the unauthorized application of a celebrity's trademarked name to articles of clothing *can* affect trademark function by taking unfair advantage of the high profile and fame attained by the celebrity brand owner.[21] That fact, once found, would lead inevitably to an automatic finding of infringement, the result ultimately reached by the court of appeal.

Even supporters of the ECJ's decision in *Arsenal* question the court's *vires* to comment on such questions of fact. Nevertheless, unauthorized nonpurely descriptive merchandising is certainly capable of affecting the guarantee function of a trademark in the same way as purely descriptive merchandising, and is indeed more likely to do so given the much broader scope for commercial application of the mark. It is arguably less clearly in the public interest that such activities should go unchecked in the face of an identical registered trademark, since the use is not so directly descriptive. Moreover, the ECJ's views, now expressed, are likely to be strongly influential. Even where a merchandiser prominently advertises his goods as unofficial, there is still likely to be a finding of infringement under Article 5 (1) (a) where there is a risk that the origin function of the trademark may be impaired, for example where end users are unaware of that notice and may erroneously believe that the goods emanate from the trademark owner, thus wrongly attributing to him any poor quality and inflicting the resulting repercussions on his future sales.

Despite the ECJ's dilution-laced remarks, it was ultimately the potential for origin confusion in cases of nonpurely descriptive merchandising that persuaded the court of appeal to find that the use in *Arsenal* was capable of affecting the trademark's guarantee function.[22] Even though confusion as to origin is not an express prerequisite for infringement under Article 5 (1) (a), the automatic remedy thereby afforded is reasoned by virtue of a presumption that confusion is likely.[23] It is difficult, however, to accept that origin confusion will be likely in every instance of nonpurely descriptive merchandising. For example, a merchandiser may not only announce at the point of sale that the goods are unofficial, but may stitch labels on the products notifying the end user. Additionally, in many fields the public is used to merchandise being sold from a variety of unofficial sources and does not expect them all to emanate from the same source. To paraphrase Laddie J., they understand that what they are buying is a "badge of loyalty" and do not care whether it comes from an official source or not.[24] In cases of soccer merchandising in the United Kingdom, the teams themselves have encouraged this sophisticated level of public understanding by actively promoting their own merchandise as official and warning fans that proceeds from the purchase of unauthorized merchandise do not support the club.[25] Although the court of appeal was not ultimately persuaded that such evidence avoided a risk of damage to the trademark's guarantee function, the facts will clearly play an important role in similar cases in the future.

Where the facts may be so pivotal, a finding of infringement based on a presumption of confusion jars. Yet, in *Arsenal* the ECJ and the court of appeal both found, as a matter of fact, that nonpurely descriptive merchandising can sometimes be damaging. The types of damage that uncontrolled and unauthorized third-party use can inflict are disparate, however, ranging from outright confusion as to source to a more generalized, incremental weakening of distinctiveness or commercial attractiveness. Moreover, where a trademark is also a famous name there may be a public interest in permitting the use, especially where purely descriptive merchandising is concerned. Given these factors, it is argued that the nature of the alleged damage should be taken into account in determining how infringement is assessed in merchandising cases. Where that damage is in the nature of confusion, the basis for a finding of infringement should properly be Article 5 (1) (a), which presumes a likelihood of confusion. However, where the facts suggest that confusion is unlikely but the use nonetheless affects trademark function in intangible but harmful ways, dilution may offer a better solution.

The Dilution Solution?

Until *Arsenal,* the dilution rationale in Europe had been thought to exist only under Article 5 (2) of the directive.[26] Article 5 (2) is an optional provision whereby

EU member states may implement a dilution principle into their national laws on trademark infringement. Where implemented, it expressly provides a cause of action for infringement where an identical or similar mark is used in connection with goods or services which are not similar to those for which an earlier mark is registered, and where the earlier mark has a reputation and the use without due cause of the later mark would take unfair advantage of, or be detrimental to, the distinctive character or repute of the earlier mark.

On its express wording, Article 5 (2) did not appear to apply to cases where an identical mark was used for goods that were identical or similar to those for which the mark was registered. This was a serious disadvantage for celebrities, who were likely to have registered their names as trademarks for the most popular categories of merchandise. Where a celebrity's well-known name was also his or her registered trademark, unauthorized third-party use on nonpurely descriptive merchandise for which the mark was already protected was thought not to infringe under Article 5 (2). Prior to *Arsenal*, it was also widely assumed that such activities would not infringe under Article 5 (1) (a), because such use was not "trademark use" intended to denote origin, and was therefore not properly within the scope of a provision based on a presumption of confusion. Before the ECJ's ruling in *Arsenal*, therefore, it was unclear whether a celebrity in such circumstances would have any remedy for trademark infringement.

The ECJ's interpretation of Article 5 (1) (a) may have been swayed, therefore, by the apparent absence of a true dilution-type remedy covering identical and similar goods. Brand owners who prudently sought the full protection conferrable through registration for all types of fan merchandise might be positively disadvantaged if they could not rely on Article 5 (1) (a) against nonpurely descriptive merchandisers, since Article 5 (2) appeared on its face to be limited to cases where such protection did not exist. This outcome might be avoided if Article 5 (1) (a) could be construed to permit relief even in cases where a likelihood of confusion could not reasonably be presumed.

In order to achieve this, the ECJ circumvented the presumption of confusion on which Article 5 (1) (a) was based by defining confusion as a species of damage to trademark function.[27] It then added more flesh to the bones by defining other species of damage which could be just as undermining, identifying in particular the taking of unfair advantage of an earlier mark's reputation, and the general weakening of the trademark that might follow.[28] The end result was a dilution rationale under Article 5 (1) (a) that would allow celebrities who enjoyed trademark protection for the relevant goods to act against unauthorized, nonpurely descriptive merchandisers on the basis that such activities involved taking a free ride on the back of an earlier, well-known trademark, which the ECJ appeared to regard as inherently unfair.

The ECJ's reasoning appears to have been stretched by its determination to make the means justify the end. It is hard to understand, for example, how Article 5 (1) (a) can reasonably encompass cases that cannot, on their facts, reasonably presume a likelihood of confusion, when that likelihood remains an express requirement under Article 5 (1) (b), which provides for infringement where there is only identity of marks and similarity of goods, or similarity of marks and identity or similarity of goods, and there exists a likelihood of confusion.[29] The ECJ may have taken the view that where there is identity of marks and goods, the law should protect against a broader range of damage than where there are differences between marks or goods. However, the ECJ did not address this point and it is therefore unclear whether it even considered it.

The Dilution Solution, Revisited

Despite its difficulties, the immediate success of the ECJ's reasoning in *Arsenal* cannot be doubted. By moving beyond the presumption of a likelihood of confusion and into the realms of likely damage to trademark function, the ECJ avoided the unpalatable result that registered trademark protection might actually limit the ability of a mark owner to act against use by another that could damage his brand without actually causing confusion.

Yet, had *Arsenal* reached the High Court just two years later than it did, later developments in the law of dilution may have supplied a less problematic result. Contrary to widespread expectations, in its recent decisions in *Davidoff & Cie SA v Gofkid Ltd.*[30] and *Adidas-Salomon AG v Fitnessworld Trading Ltd.* [31] the ECJ ruled that Article 5 (2) is not in fact restricted to cases where an identical or similar mark is used for goods that are dissimilar to those for which the earlier mark with a reputation is registered, despite the express wording of the provision. Article 5 (2) infringement can therefore be found even where an earlier mark is registered for the same or similar goods in respect of which the unauthorized use is made.

In these cases, the ECJ reasoned that the European legislature could not have intended to confer on registered marks with a reputation greater protection against the use of an identical or similar mark for dissimilar goods than it did against use for identical or similar goods.[32] Article 5 (2) was therefore construed as an umbrella provision, protecting all registered trademarks with a reputation against use without due cause of the same or a similar mark for *any* goods or services, wherever that use might take unfair advantage of or cause detriment to the distinctive character or repute of the registered mark. As with Article 5 (1) (a), there is no need for a likelihood of confusion, merely evidence of a sufficient mental association between the marks on the part of the relevant public. Where a celebrity's trademarked name is used on unauthorized, nonpurely descriptive merchandise, it is hard to imagine that such a connection could not be proved. It is in fact the presumption that the public will make the connection that encourages the merchandiser to apply the mark at all.

Following the ECJ's rulings in *Davidoff* and *Adidas*, the dilution remedy for identical and similar goods, whose apparent absence may have encouraged the labored reasoning in *Arsenal,* has now been firmly established.

Now, in cases of nonpurely descriptive merchandising, brand owners are not tied to bringing their case under legislative provisions that are either expressly or impliedly based on a presumption of a likelihood of confusion. Where a merchandiser applies a well-known team name that is also registered as a trademark to a scarf or commemorative plate, there is no need for the team to show that the purchasers or ultimate recipients might be confused as to the origin of the goods. It can sue as the owner of a registered mark with a reputation if it merely shows that the use is without due cause, that there is a connection in the public mind between the registered mark and the unauthorized use, and that the use takes unfair advantage of, or is detrimental to, the distinctive character or repute of the trademark. A finding of infringement under Article 5 (2) rather than 5 (1) (a) in a case where dilution is the real damage seems right, unless there is also a reasonable basis on which to presume confusion.[33]

In cases where the real complaint is dilution, applying Article 5 (2) rather than 5(1)(a) to cases of nonpurely descriptive merchandising is not without its problems. In particular, the implementation of Article 5 (2) was optional for the EU member states. Of the pre-enlargement members, data compiled in 1998 indicates that at least Austria and Spain had not yet implemented it into their national laws at that time.[34] Although later national laws in both countries appear to have adopted the provision,[35] it is not known to what extent all the ten new member states who joined the EU on May 1, 2004, did so, or to what extent new member states who may join in the next few years, such as Bulgaria and Romania, will. In countries that choose not to implement Article 5 (2), Article 5 (1) (a) or unfair competition may form the only basis for action against dilutive use of a registered mark in nonpurely descriptive merchandising. Furthermore, Article 5 (2) imposes a steeper test for those who would pray it in aid, as there is more to prove than under Article 5 (1) (a). Article 5 (1) (a) requires only unauthorized use of a registered mark for the registered goods, but Article 5 (2) requires that the unauthorized use be without due cause, that the registered mark have a reputation, and that the unauthorized use take unfair advantage of or be detrimental to the distinctive character or repute of the registered mark. Specifically, a claimant must prove the additional factors of reputation and dilutive effect in the form of either unfair advantage or detriment.

The difficulty of the test under Article 5 (2), however, is no reason to dismiss it in favor of Article 5 (1) (a) where dilution is the real essence of a claim. Although Article 5 (2) is limited to cases where a registered trademark has a reputation, it is strongly arguable that only trademarks that have acquired that extra dimension through commercial success should receive extraordinary protection against blurring or tarnishment, which do not interfere in commerce with the same immediacy as confusion.[36] Indeed, in the case of celebrity trademarks, merchandising is only really likely where there is a reputation, since reputation is what encourages the supply and demand of celebrity-related merchandise. Support for such reasoning can be found in the English law of passing off, where it is only reputation that enables celebrities to found a cause of action against false claims that a celebrity endorses a particular product or service.[37] It is true that Article 5 (2) as interpreted by the ECJ requires the use to be perceived as more than mere decoration.[38] However, the fact that trademarked celebrity names are dual-purpose "distinctive-descriptors" that identify the celebrity at the same time as denoting origin makes it likely that such a mark will be seen as something more than mere ornament.[39]

That not all member states of the EU now or in the future may have implemented Article 5 (2) is a more serious problem, and one that only legislative action at the national or community level can address. At community level, an obligation to implement Article 5 (2) expressly and in full could, by a directive, be imposed on member states. At the national level, in contemplating whether the time has come to recognize dilution as a species of trademark infringement as well as a basis for an unfair competition claim, member states and those joining in future may well be influenced by the fact that *Arsenal* already intrudes the recognition of such a claim into their national laws, whether they wished to recognize it or not. Only time will tell.

End Thoughts

The ripples from the *Arsenal* decision continue to spread. In an effort to soften the feared impact against purely descriptive merchandising, the United Kingdom Patent Office recently issued a practice direction indicating that nondistinctiveness objections will be raised against trademark applications for known celebrity names in respect of goods for which use of the name would be purely descriptive.[40] In fact, true purely descriptive merchandising should be shielded from infringement by Article 6 (1), and the practice direction threatens to result in well-intentioned but misguided objections being raised to trademark applications for celebrity names. Nevertheless, the Patent Office's cautious approach is understandable in the light of the significant impact of *Arsenal* wherever infringement is claimed in respect of the use of identical marks for identical goods. Uncertainty over whether Article 6 (1) really will shield proper, purely descriptive merchandising use will linger until this issue, too, is resolved by the ECJ.

Arsenal is widely seen as a coup for celebrity brand owners, and it is. It places them in an enviably strong position where their marks are registered for the most common types of fan memorabilia, and ring-fences their right commercially to exploit their names and images. However, the law on dilution in Europe has developed in important ways since *Arsenal* was decided, and nonpurely descriptive merchandising infringement now fits more comfortably within the dilution rationale of Article 5 (2) than the ill-fitting source confusion of Article 5 (1) (a). That fewer marks might ultimately be protected need not disappoint the celebrity brand owners most in need of extended protection, as they are most likely to have the

reputation that causes the merchandisers to follow them, and which provides the basis for action under Article 5 (2). For the others, in the absence of reputation and dilution, infringement of celebrity marks should be assessed based on whether confusion is likely or can reasonably be presumed. The ECJ must now set, as much as it has also extended, the boundaries of celebrity trademark protection in Europe.

Endnotes

1. Case C-206/01, [2003] R.P.C. 9.

2. The English Court of Appeal and House of Lords interpreted the ECJ's guidance in *Arsenal* differently in separate cases on consecutive days, in *Arsenal Football Club Plc v. Reed (No. 2)* [2003] R.P.C. 39 and *R. v. Johnstone (Robert Alexander)* [2003] F.S.R. 42.

3. Nick Walker and Richard Penfold, *Arsenal v Reed*—The Final Decision?," INTA BULLETIN, Vol. 58, No. 11, at 10.

4. Section 10 (1) Trade Marks Act 1994: "A person infringes a registered mark if he uses in the course of trade a sign which is identical with the trade mark in relation to goods or services which are identical with those for which it is registered."

5. Arsenal Football Club Plc v. Reed *(No. 2)*, [2003] E.T.M.R. 36 at 880.

6. Article 5 (1) (a) reads, "The registered trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade:

(a) any sign which is identical with the trade mark in relation to goods or services which are identical with those for which the trade mark is registered."

7. First Council Directive of 21 December 1988 to Approximate the Laws of the Member States Relating to Trade Marks (89/104/EEC).

8. In particular, between the judgment of the Scottish Court of Sessions in Bravado Merchandising Services Ltd v. Mainstream Publishing (Edinburgh) Ltd., [1996] F.S.R. 205 and the English High Court in British Sugar Plc v. James Robertson & Sons Ltd., [1997] E.T.M.R. 118.

9. Referring to the tenth recital in the preamble to the Directive, "Whereas the protection afforded by the registered trade mark, the function of which is in particular to guarantee the trade mark as an indication of origin, is absolute in the case of identity between the mark and the sign and goods or services;..."

10. *Arsenal,* ECJ, note 1 *supra* ¶ 51.

11. *Id.*

12. *Id.* ¶ 50.

13. The idea that dilution was not relevant under Article 5 (1) was indirectly supported by the ECJ's ruling in *Sabel BV v. Puma AG,* (C251/95) [1998] E.T.M.R. 1 at 9, which confirmed that a mere mental association without a likelihood of confusion could not found an infringement action under Article 5 (1) (b) of the Directive.

14. *See* note 2 *supra.*

15. "Like it or not, unfair competition is now a part of English law," Norman, H., "Time to Blow the Whistle on Trade Mark Use," IPQ 2004, 1, 1 – 34, at 33.

16. Article 7 reads:

"(1) The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

(2) Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market."

17. Article 6 (1) of the Directive states, "The trade mark shall not entitle the proprietor to prohibit a third party from using, in the course of trade,

(a) his own name or address;

(b) indications concerning the kind, quality, quantity, intended purpose, value, geographical origin, the time of production of goods or of rendering of the service, or other characteristics of goods or services;

(c) the trade mark where it is necessary to indicate the intended purpose of a product or service, in particular as accessories or spare parts;

provided he uses them in accordance with honest practices in industrial or commercial matters."

Ambiguity about whether the use is descriptive is enough to take the user outside a descriptiveness defense (*Newton Chambers & Co. Ltd. v Neptune Waterproof Paper Co. Ltd.* [1998] RPC 283 at 311 – 312 and *AB Volvo v Heritage (Leicester) Ltd.* [1999] RPC 809 at 823*).*

18. *Arsenal,* ECJ, note 1 *supra* at ¶ 54.

19. See note 17 *supra.*

20. Lord Walker of Gestingthorpe in *R. v. Johnstone* (note 2 *supra,* at 45–46) observed, "A trademark owner may well have other grievances, such as a breach of copyright or performing rights in a recording which is honestly sold by reference to the name of the artist recorded. However, as long as such a recording is clearly labelled in such a way that there can be no doubt as to the fact that the trademark refers to the identity of the artist recorded, and not to the trade origin of the compact disc, for example, trademark law should not interfere."

21. *Arsenal,* ECJ, note 1 *supra* at ¶ 61.

22. [2003] E.T.M.R. 73.

23. CYCLING IS... Trade Mark [2002] R.P.C. 37 at 743.

24. [2001] E.T.M.R. 77 at 880.

25. *Id.*

26. Article 5 (2) reads: "Any Member State may also provide that the proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade any sign which is identical with, or similar to, the trade mark in relation to goods or services which are not similar to those for which the trade mark is registered, where the latter has a reputation in the Member State and where the use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark."

27. *Arsenal,* ECJ, note 1 *supra* ¶ 48.

28. *Id.* ¶ 50.

29. Article 5 (1) (b) reads: "The registered trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade: ...

(b) any sign where, because of its identity with, or similarity to, the trade mark and the identity or similarity of the goods or services covered by the trade mark and the sign, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association between the sign and the trade mark."

30. [2003] E.T.M.R. 42.

31. [2004] E.T.M.R. 10.

32. *Id.* at 542 and 136, respectively.

33. In fact, as of May 5, 2004, the United Kingdom Trade Marks Act 1994 was amended to take the *Davidoff* and *Adidas* rulings into account, making it express that action may be taken under Section 10 (3) TMA 1994, which implements Article 5 (2) of the Directive, against unauthorized use in respect of any goods or services [the Trade Marks (Proof of Use, Etc.) Regulations 2004].

34. National tables of implementation in D. Tatham and W. Richards, ECTA GUIDE TO E.U. TRADE MARK LEGISLATION (London, Sweet & Maxwell, 1998).

35. The author wishes to thank Richard Atzwanger of Beer & Partner Patentanwälte KEG for helpful advice on the position in Austria.

36. In a similar vein, the Federal Trademark Dilution Act of 1995 in the United States confers dilution protection only on famous marks.

37. Irvine v. Talksport Ltd. (Nos 1 and 2), [2003] E.M.L.R. 26, [2003] EWCA Civ 423 CA

38. *Adidas, supra* note 33 at 41.

39. In *R. v Johnstone* (*supra* note 2), Lord Walker discusses that dual purpose in his speech at 45–46.

40. Practice Amendment Notice 5/04.

The Hatch-Waxman Act: When Is Research Exempt from Patent Infringement?

BY PRADIP K. SAHU AND K. SHANNON MRKSICH

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Numerous institutions conduct research on pharmaceutical and medical devices: some conduct pioneering research, others improve existing technology, and still others make generic equivalents of existing products. Which of these research activities are exempt from a patent infringement suit under the Hatch-Waxman Act? To make that determination, it is important to examine the scope of the exemption and see how it has evolved over the years.

Below, we trace the history of the Act to its common law foundation and examine the case law leading up to its implementation. Next, we look at the cases interpreting what remains of the common law experimental use defense after passage of the Act. Finally, we consider the cases interpreting the statutory exemption created by the Act and discuss what, if any, safe harbors still exist for scientific researchers.

The Common Law Experimental Use Exception

To understand the exemption provided by the Act, one needs to recognize its common law origins. The experimental use defense to patent infringement was formally recognized almost two hundred years ago in *Whittemore v. Cutter.*[1] In that case, Justice Story stated that, "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[2] Several months later, Justice Story refined this idea in *Sawin v. Guild,*[3] reaffirming his position that it would not be infringement to make an invention "for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[4] Moreover, Justice Story opined that there must be "an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery."[5] Both *Whittemore* and *Sawin* introduced two core concepts of the experimental use defense: "philosophical" endeavors and "intent." While the common law theory has been refined in modern patent law, these core concepts remain essentially the same.

The CAFC's Landmark 1984 Ruling Regarding the Experimental Use Exemption

One of the most important CAFC decisions that addressed the common law defense is *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*[6] In this case, the generic drug manufacturer Bolar intended to bring to market a generic version of a patented drug that was manufactured and sold by Roche. Bolar began conducting clinical tests required for FDA approval before the subject patent's expiration date. When Roche became aware of Bolar's activities, it sued for infringement. After considering the common law use exception and Bolar's intent, the district court held that Bolar's activities did not infringe Roche's patent because its use of the patented drug was experimental, was for federally mandated testing, and was *de minimis.*

The CAFC reversed on appeal, relying primarily on 35 U.S.C. § 271(a), which stated that mere "use" of a patented invention, without either manufacture or sale, is actionable. Citing *Pitcairn v. U.S.*[7] as controlling law, the CAFC reasoned that experiments that are in keeping with the legitimate business of an alleged infringer are not exempt from infringement.[8] The CAFC concluded that Bolar's use was solely for business reasons and not strictly for philosophical inquiry. As such, the experimental use exception did not apply.

The court did note that the term "use" was never defined in the patent statute, and its meaning had become a matter of judicial interpretation. It discussed several such interpretations in its decision and came to the conclusion that some types of experimental use could be exempt from infringement. The court ended its analysis by stating that Congress had before it a bill labeled the "Drug Price Competition Act of 1983" and the "Patent Term Restoration Act of 1983," and Congress was the appropriate place to debate the issue. The CAFC declared, "[w]here Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation...We will not rewrite the patent laws here."[9] The industry paid heed, and focused its efforts on legislation rather than litigation.

The Resulting Legislation: The Drug Price Competition and Patent Term Restoration Acts

The industry's lobbying efforts were well-timed. In the late 1970s, the U.S. economy was in recession and the Carter administration needed to create more jobs.

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They reasoned that if the patent term were lengthened to compensate for the time lost for regulatory review, companies would be more willing to invest in research and development of new products. Despite their efforts, legislation stalled. The Reagan administration continued to promote the legislation, and eventually the chair of the House Health Subcommittee, Henry Waxman, began promoting the bill as an opportunity to improve the country's healthcare system. To that end, he touted the social benefits that could result from restoring the patent terms to certain pharmaceutical inventions and allowing companies to prepare to market generic drugs before the corresponding pioneer patents expired. Senator Orrin Hatch joined in, stating that enactment of the bill would be a ground-breaking compromise in the public interest in which the public receives the best of both worlds—cheaper drugs today and better drugs tomorrow. However, it was not until after the CAFC handed down the *Roche* decision when Congress was able to rally behind what is now known as the Hatch-Waxman Act.

The Act can be divided into three main categories. The first part relates to drug price competition. Specifically, the legislation provides for an Abbreviated New Drug Application (ANDA) to be implemented by the U.S. Food and Drug Administration (FDA). Briefly, the ANDA provisions allow makers of generic drugs to apply for regulatory approval of their drugs if (1) the drug hasn't been patented, (2) the patent term of the subject drug has expired, (3) the patent will expire before the generic goes on the market, or (4) the patent is invalid or not infringed.

The second part of the Act relates to patent term restoration. Briefly, this section provides that inventors of pioneer drugs may have their patent terms extended by an amount of time equal to one-half of the FDA's investigational new drug period. The maximum term of extension is five years, but the effective market exclusivity may not exceed fourteen years.

The third part of the Act, relates to the research exemption to patent infringement. Specifically, 35 U.S.C. § 271(e)(1) states,

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

This part of the Act has been the subject of much controversy. In the context of *Roche*, it would appear that the main reason that Section 271(e)(1) was enacted was so that generic drug manufacturers could enter their products into the marketplace as soon as the corresponding pioneer patents expire. However, because of the ambiguous language of the statute and equally unclear legislative history, there has been considerable debate as to the scope of this statutory exemption as discussed below.

The Common Law Experimental Use Defense after the Hatch-Waxman Act

A. Embrex v. Service Engineering

After *Roche* and the passage of the Act, few cases have discussed the common law experimental use exception. In *Embrex v. Service Engineering,*[10] the CAFC considered and soundly rejected the defendant's common law experimental use and *de minimis* use defenses to patent infringement. While such defenses were still available, the CAFC indicated that they were extremely narrow in scope and could not be used to escape liability for infringement simply by cloaking infringing activities in the "guise of scientific inquiry."[11]

Particularly noteworthy is Judge Rader's concurring opinion, which foreshadowed the opinion he wrote for the majority in *Integra Lifesciences I, Ltd. v. Merck KgaA,*[12] discussed below. Rader wrote, "Since its inception, this court has not tolerated the notion that a little infringement—*de minimis* infringement—is acceptable infringement or not infringement at all. . . Rather, the statute accommodates concerns about *de minimis* infringement in damages calculations [only]."[13] He further stated that neither the patent statute nor any Supreme Court precedent gave any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation or idle curiosity.

Rader relied on *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*[14] to validate that intent was not an element in infringement actions. He closed by stating,

> [The Supreme Court's Warner-Jenkinson decision] precludes any further experimental use defense, even in the extraordinarily narrow form recognized in Roche. Of course, even if the experimental use excuse retains some lingering vitality, the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable, as occurs in the court's resolution today . . . I would lay to rest permanently [the defendant's] infringement excuses which find no support in the Patent Act.[15]

B. Madey v. Duke

The CAFC again discussed the common law exception more recently in *Madey v. Duke.*[16] In that case, Madey, a researcher at Duke University, owned patents covering a new laser device. He left Duke without licensing or assigning any rights to the inventions. After he left, Duke continued to use his inventions without permission, and the suit followed.

The district court granted summary judgment in favor of Duke University, stating that Duke researchers were using the patented laser for basic scientific research that was not commercial in nature; therefore, it fell under the common law experimental use exemption. The CAFC disagreed, noting that the district court improperly focused on whether Duke is a nonprofit institution when it decided that Duke's research was not commercial in

nature. The CAFC reasoned that since academic institutions frequently conduct research without regard to commercial value, the focus instead should be on Duke's legitimate business objectives.

Judge Gajarsa wrote for the court, "Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[17] The court reasoned that Duke's business includes educating students as well as conducting research, which increases the status of the institution and lures lucrative research grants. Thus, the CAFC characterized Duke's research as a part of its business. As such, the common law experimental use exemption did not apply. *Madey* appears to signal an end to the common law experimental use exception to patent infringement.

The Courts' Interpretations of Section 271(e)(1)

Just as the courts have limited the scope of the common law exception, they also have recently begun to restrict the scope of the statutory exemption. This was not always the case. Initially, the courts appeared to have interpreted Section 271(e)(1) rather broadly, beginning with *Eli Lilly and Co. v. Medtronic.* [18]

A. Eli Lilly and Co. v. Medtronic

In one of the first cases to define the scope of the Act, Lilly sued Medtronic for infringement of its two patents covering implantable cardiac defibrillators. Medtronic defended their activities based on the experimental use shield of Section 271(e)(1). The district court sided with Lilly, stating that Section 271(e)(1) did not apply to medical devices.

Relying on a combination of legislative intent and *Roche,* the CAFC reversed the district court's decision. They noted that Congress explicitly stated that Section 271(e)(1) would "have the net effect of reversing the holding of *Roche*."[19] They further noted that *Roche*'s holding was rather broad: "the unlicensed use of a patented invention for testing and investigation, even though strictly related to obtaining FDA approval for a substitute, was an infringement under 35 U.S.C. Sec. 271(a)."[20] In reconciling Congress's intent and the holding of *Roche*, the CAFC used Justice Scalia's reasoning in *United States v. Fasto*[21] to conclude that *Roche*'s interpretation of §271(e)(1) was repealed by implication by the newly enacted statute. That is, Congress meant to allow testing and investigation of a patented invention if strictly related to obtaining approval for a substitute, regardless of the product involved.

On appeal, Justice Scalia, writing for the Supreme Court, noted that the statute and legislative history were both ambiguous, and found that the CAFC's interpretation appeared to be closer to what Congress intended. To that end, the high court recognized that medical devices fall within the purview of Section 271(e)(1) and, thus, broadened the scope of the statutory research exemption.

B. Intermedics v. Ventritex

Soon after the Supreme Court's ruling, the Northern District of California lent its interpretation to Section 271(e)(1) in *Intermedics v. Ventritex*.[22] Well before Intermedics' patents on a medical device expired, Ventritex began preparing to commercialize an allegedly infringing device. The district court found for Ventritex, reasoning that the timing of preparations for commercialization was irrelevant. They focused on whether a party's uses were *de minimis* and whether the party reasonably believed that their use would contribute to the generation of relevant information for the FDA. The district court further noted the protection of Section 271(e)(1) wasn't negated even if some of the uses either failed to generate information or generated more information than necessary to secure FDA approval. *Intermedics* thus broadened the scope of Section 271(e)(1) in terms of both the timing and the extent of the allegedly infringing activities.

C. Telectronics v. Ventritex

Later in *Telectronics v. Ventritex,*[23] the Federal Circuit catalogued the types of activities exempt under Section 271(e)(1). In that case, Telectronics sued Ventritex for patent infringement based on their manufacture, sales and marketing of an allegedly infringing device. Ventritex defended that their activities were exempt under Section 271(e)(1): their manufacture and sales were limited to their clinical trials and their marketing was necessary to raise funds to support the clinical trials and further manufacture. The CAFC agreed that Ventritex's activities were exempt, either because they were reasonably related to FDA approval or were simply "dissemination of the data developed for FDA approval."[24] The CAFC noted that Congress was aware that some fund raising and related marketing activities were necessary to enable competitors to enter the market after a controlling patent expired. *Telectronics* thus further broadened the scope of activities permitted under Section 271(e)(1).

D. Amgen v. Hoechst Marion Roussel

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*,[25] the District Court of Massachusetts further defined the limits of the exemption. Amgen sued Hoechst for manufacturing and using their patented erythropoietin product to develop a competing product. Hoechst intended to sell their product after the expiration of Amgen's patents. The district court opined that the statutory phrase "solely for uses reasonably related" to FDA approval does not prevent companies from engaging in activities for purposes other than FDA approval. That is, the court found that certain ulterior *motives* or alternate *purposes* do not preclude the Section 271(e)(1) exemption, if a party reasonably believes that there was a decent prospect that "the *use* in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product."[26] (Emphasis added.) In *Amgen*, the court found that such activities included

exporting the patented product to evaluate manufacturing processes, testing to comply with European and Japanese standards, making an amount of the product in excess of that required for the FDA approval process, and characterizing the product. Moreover, the district court held that the aforementioned activities would be exempt even if the results were eventually discarded or abandoned for reasons unrelated to FDA approval. *Amgen* further broadened the scope of exempt activities.

E. Nexcell Therapeutics v. AmCell

The district court in Delaware took a similarly broad view of Section 271(e)(1) in *Nexcell Therapeutics Inc. v. AmCell Corp.*[27] In this case, AmCell was planning to seek FDA approval for the clinical use of a magnetic cell-separating device that used Nexcell's patented antibodies. The district court found AmCell's activities exempt under Section 271(e)(1), which included recruiting clinicians to participate in FDA studies to evaluate the device, displaying the device at a conference, advertising the device in medical journals and providing to FDA-approved clinicians the device and reagent kits with the patented antibodies. In an unusual litigation move, Nexcell asked the FDA to comment on whether AmCell's activities were reasonably related to FDA approval. The FDA responded by stating that "the ultimate construction and application of § 271(e)(1) lies with the court . . ." and that "there is no reason to assume any direct correlation between [the] FDA's evaluation of AmCell's submissions and the appropriate construction of section 271."[28] Nonetheless, in finding for AmCell, the district court specifically stated that "a large degree of deference to activities conducted in furtherance of FDA-approved clinical trials is appropriate,"[29] because it will not always be clear to a party exactly what kinds of information and what quantities are necessary. Thus, *Nexcell* broadened the scope of the statutory exemption a bit more.

F. Integra Lifesciences v. Merck

The most recent decision addressing the statutory exemption to patent infringement, and the one that has been said to reverse the broadening trend, is *Integra Lifesciences I, Ltd. v. Merck KgaA.*[30] Merck hired researchers at Scripps to perform "the necessary experiments to satisfy the biological bases and regulatory (FDA) requirements for the implementation of clinical trials"[31] on a series of peptidyl compounds that inhibited angiogenesis. Scripps began *in vivo* and *in vitro* experiments "to evaluate the specificity, efficacy, and toxicity of [several drug candidates] for various diseases, to explain the mechanism by which these drug candidates work, and to determine which candidates were effective and safe enough to warrant testing in humans."[32] Ultimately, Scripps identified one of these peptidyl candidates for clinical development. Unfortunately for Merck and Scripps, Integra owned five patents that covered the peptidyl candidate. When Integra became aware of the allegedly infringing use of their patented compounds, they offered a license to Merck. License negotiations failed and litigation ensued. The district court found Merck liable for infringing four of Integra's patents, finding that the safe harbor of Section 271(e)(1) was not available to Scripps and Merck between 1994 and 1998.[33] The CAFC affirmed with respect to the Section 271(e)(1) exemption, with Justice Newman dissenting.

1. The Majority Opinion

The majority opinion reviews the history of the Hatch-Waxman Act, *Roche*, and *Eli Lilly;* explains the scope of Section 271(e)(1); and clarifies what constitutes premarket approval activity. According to the majority, in enacting the legislation, the House Committee considered that the premarket activity would be "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute."[34] They further note that the House intended that "all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference [with the patent holder's rights] is *de minimus* [sic]."[35]

The majority felt that the Scripps-Merck experiments were conducted to identify the candidates to subject to future clinical testing, not to supply information to the FDA. Thus their answer to the question: "[Does] the §271(e)(1) safe harbor reach back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval"36 was a resounding no. The focus of the entire statutory exemption to patent infringement is to provide information to the FDA, and the express objective of the Act was to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of the corresponding pioneer drug patent. Since the Scripps' research was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds, it did not fall within the narrow scope of Section 271(e)(1).

The majority recognized that Section 271(e)(1) was being interpreted quite broadly and appear to believe that the results were not what Congress envisioned. They theorized that the implications of the continued broadening of Section 271(e)(1) could mean that holders of research tool patents would lose the benefits of patent protection. As such, the majority decided that extension of Section 271(e)(1) by the courts under the circumstances of *Integra* would be unwarranted.

2. The Dissent

In her dissent, Newman *sua sponte* evoked the common law experimental use exception to patent infringement,[37] stating that it should apply to all of the activity conducted by Scripps and Merck before 1998. She believed that the true issue of the case should have been "whether, and to what extent, the patentee's permission is required in order to study that which is patented."[38] The dissent makes an intriguing distinction between conducting research *on* a patented invention and *using* a patented invention to conduct research. Not surprisingly, the dissent's views on the common law use exemption have been well received by certain groups in the academic and

research communities. Accordingly, it is quite possible that the ideas espoused by Newman may resurface in future legislation or litigation to redefine the scope of statutory and common law exceptions to infringement.

Conclusion

The range of activities that are considered reasonably related to FDA approval for generic substitutes of patented drugs or medical devices seems to remain rather broad. As a practical matter, it appears that the Section 271(e)(1) defense will be available only to those planning to market a generic version of a medical device or drug upon the expiration of the corresponding patent. It remains to be seen if this exemption is still an available defense for nongeneric companies, as it was for all of the above defendants. For those involved in basic research and the search for improvements and substitutes for patented medical and biotech inventions, if the safe harbor of Hatch-Waxman is not available, other measures such as licensing, litigation, or acquisition should be considered in the interim. By recognizing the limitations to the Section 271(e)(1) defense, attorneys and their clients will be able to develop successful strategies that will respect the rights of patent holders and leave them less vulnerable to suit.

Endnotes

1. 29 F. Cas. 1120 (1813).
2. *Id.*
3. 21 F. Cas. 554 (1813).
4. *Id.* at 555.
5. *Id.*
6. 733 F.2d 858 (1984).
7. 547 F.2d 1106 (1976).
8. *Id.* at 1125–26.
9. 733 F.2d 858, 865.
10. 216 F.3d 1343 (2000).
11. *Id.* at 1348.
12. 331 F.3d 860 (2003).
13. 216 F.3d 1343, 1352.
14. 117 S. Ct. 1040 (1997).
15. 216 F.3d 1343, 1352.
16. 307 F.3d 1351 (2002).
17. *Id.* at 1360.
18. 496 U.S. 661 (1990).
19. 872 F.2d 402, 406 (1989), citing H.R.Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 27.
20. 872 F.2d 402, 406.
21. 484 U.S. 439 (1988).
22. 775 F. Supp. 1269 (1991), affd, 991 F.2d 808 (1993).
23. 982 F.2d 1520 (1992).
24. *Id.* at 1524.
25. 3 F. Supp. 2d 104 (2002).
26. *Id.* at 108.
27. 199 F. Supp.2d 197 (2002).
28. *Id.*
29. *Id.* at 204.
30. 331 F.3d 860 (2003).
31. *Id.* at 863.
32. *Id.*
33. After 1998, the defendants formally filed an Investigational New Drug Application with the FDA for the infringing compound.
34. *Id.* at 866, citing H.R.Rep. No. 857, at 8, reprinted in 1984 U.S.C.C.A.N. at 2692.
35. *Id.* at 865, citing H.R.Rep. No. 857, at 8, reprinted in 1984 U.S.C.C.A.N. at 2714.
36. *Id.* at 865–66.
37. The majority pointed out in a footnote in its opinion what it considered the flaws in Newman's analysis: "In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in Madey v. Duke Univ... However, the common law experimental use exception is not before the court in the instant case. The issue before the jury was whether the infringing pre-clinical experiments are immunized from liability via the 'FDA exemption,' i.e., 35 U.S.C. § 271(e)(1). The district court did not instruct the jury on the common law research exemption with respect to the Merck's infringing activities. On appeal, Merck does not contend that the common law research exemption should apply to any of the infringing activities evaluated by the jury. Neither party has briefed this issue to this court. Moreover, during oral arguments, counsel for Merck expressly stated that the common law research exemption is not relevant to its appeal. Judge Newman's dissent, however, does not mention that the Patent Act does not include the word 'experimental,' let alone an experimental use exemption from infringement...Nor does Judge Newman's dissent note that the judge-made doctrine is rooted in the notions of de minimis infringement better addressed by limited damages." *Id.* at 864.
38. *Id.* at 872.

Recent Decisions of the Board of Patent Appeals and Interferences in Biotechnology Cases

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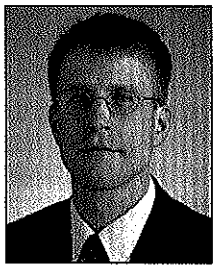
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Introduction

We have conducted a study of recent decisions of the Board of Patent Appeals and Interferences in an effort to better understand the implications of appeals of biotechnology-related patent applications.[1] In a review of more than one hundred recent board decisions in the area of biotechnology (broadly construed), we found that the rate of reversal of rejections was much higher than we had anticipated. Most of these cases involved appeals of rejections of claims based on obviousness or lack of enablement. Many cases involved method claims with functional language reminiscent of the claims at issue in the recently decided *Amgen v. Hoechst Marion Roussel*,[2] in which the Federal Circuit affirmed that claims with arguably broad functional limitations did not violate the enablement requirement.

Two cases involved claims to nucleotide or amino acid sequences. One of these cases reversed a rejection for lack of enablement for claims covering fragments of a protein, and the other case reversed rejections for lack of enablement and written description for claims to variant nucleotide sequences sharing percent sequence identity to a disclosed sequence. While these cases are nonprecedential, they provide insights to overcoming rejections that have become routine for nucleic acid molecule and protein claims. In reversing the examiner, the board relied on the structure/function information about the sequence included in the application and available in the art. Thus, when drafting applications, it is advisable to provide as much structure/function information as possible. If necessary, structure/function information may also be provided during prosecution. We are optimistic that in view of these recent decisions, examiners will adopt a more reasonable approach when examining sequence claims.

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Methodology

In order to identify appeals related to biotechnology and pharmaceutical subject matter, we identified the subject class and subclass numbers for subject matter examined by Art Unit 1600. We then screened the publicly available board decisions at www.uspto.gov/web/office/ dcom/bpai/bpai.htm for appeals of applications that had been assigned these subject classification numbers. This procedure identified a number of cases with subject matter having these classification numbers. We continued by studying decisions involving biotechnology or pharmaceutical subject matter, in addition to several cases with chemical subject matter. Approximately 127 such decisions were rendered between early 2002 and March 2004, and we reviewed the statutory basis or bases for rejection(s) and whether those rejections were reversed by the board.

Statistical Overview

Of these 127 cases, ninety involved rejection of claims for anticipation under 35 U.S.C. § 102 or obviousness under 35 U.S.C. § 103: three cases had rejections of claims under 35 U.S.C. § 102, seventy-three cases had rejections of claims under 35 U.S.C. § 103, and fourteen cases had rejections of claims under both 35 U.S.C. § 102 and 35 U.S.C. § 103. In the following analysis, we categorized a case as reversed if the Section 102 and/or Section 103 rejections were reversed as to at least some of the claims that were at issue, so that after the decision was rendered, at least some of the claims in the case no longer had standing rejections under 35 U.S.C. §§102 or 103. Of the three cases with rejections under only 35 U.S.C. § 102, one rejection was reversed and two were affirmed. Of the fourteen cases with rejections under both 35 U.S.C. §§ 102 and 103, ten were reversed and four were affirmed, a reversal rate of 72 percent. Of the seventy-three cases with rejections only under 35 U.S.C. § 103, sixty-eight rejections were reversed and five were affirmed, a reversal rate of 93 percent.

Among the 127 cases, thirty-six involved rejections for failure to meet either the written description or enablement requirement of 35 U.S.C. § 112, ¶ 1. Two cases involved a rejection based on the written description requirement; one of these rejections was reversed. Six cases involved rejections based on both the written description and enablement requirements; all six of these rejections were reversed. Twenty-eight cases involved rejections based on the enablement requirement; twenty-seven of these rejections were reversed, a reversal rate of 96 percent.

Two Appeals Involving Sequence Identity Claims and Fragment Claims

We note that only six decisions of the Board of Patent Appeals and Interferences have been published and made precedential (as indicated by information available at http://www.uspto.gov/web/offices/dcom/bpai/ prec.htm). None of the 127 decisions we studied have been officially published or made precedential, so they are not binding on examiners. However, several of these decisions were significant because they reversed rejections of the types of claims that are commonly found in cases involving nucleotide or amino acid sequences.

Often, where the invention is a particular protein or nucleic acid, the invention is claimed by reference to an exemplary protein or nucleic acid that has a specific amino acid or nucleotide sequence. Typical claims to such inventions are drawn to proteins or nucleic acids that share a particular percentage of sequence identity to the exemplary sequence ("sequence identity claims") or to proteins or nucleic acids that are a fragment of the exemplary sequence ("fragment claims"; collectively, "sequence claims"). Examiners typically reject such claims and only allow claims to the exact exemplary sequence or at most to claims having 95 percent and higher sequence identity. Claims limited to an exact nucleotide or amino acid sequence could be easily circumvented and thus are of little value to inventors and investors. Typically, rejections of sequence identity claims and fragment claims are made based on the written description requirement and/or the enablement requirement of 35 U.S.C. § 112, ¶ 1.

Ex parte Sun[3] involved sequence identity claims. The application at issue in *Ex parte Sun* described a *Zea mays* homolog of WEE1, a protein involved in cell cycle regulation. The claims at issue were similar to claim 31:

> 31. An isolated WEE1 nucleic acid comprising a member selected from the group consisting of:
>
> (a) a polynucleotide that encodes a polypeptide of SEQ ID NO:2;
>
> (b) a WEE1 polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1;
>
> (c) a polynucleotide comprising the coding sequence set forth in SEQ ID NO:1; and
>
> (d) a polynucleotide complementary to a polynucleotide of (a) through (c).

The rejection in this case was based on both the written description and enablement requirements. The examiner cited a prior art reference as teaching that a particular region of the protein was critical for function and concluded that alterations to this region could affect the function of the protein. The examiner argued that one of skill in the art would not be able to predict the structure and function of a WEE1 polynucleotide having at least 80 percent identity to the coding region of SEQ ID NO:1.

The board, considering the written description rejection, quoted *In re Herschler*[4] as stating that "[t]he claimed subject matter need not be described *in haec verba* to satisfy the description requirement" and emphasized that the relevant analysis was whether the claim limitations were described so that one of skill in the art would recognize that the applicants had invented that subject matter. The board discussed *The Regents of Univ. of Calif. v. Eli Lilly and Co.*,[5] and *Enzo Biochem, Inc. v. Gen-Probe, Inc.*,[6] stating that:

> [T]he written description requirement can be met by 'showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[7]

Here, the board noted, the specification provided examples of how to screen for WEE1 activity and also provided a polynucleotide comprising the sequence of SEQ ID NO:1 and a polynucleotide that encoded the polypeptide of SEQ ID NO:2. The board stated that a specific teaching of a species with 80 percent sequence identity and WEE1 function was not dispositive of whether the written description requirement had been met. The board noted that those of skill in the art were aware that most WEE1 variations occurred at the amino terminal end of the protein, while the central region and carboxy-terminal region contained protein kinase domains and substrate recognition regions. Accordingly, the board reasoned:

> [T]hose of ordinary skill in the art would have recognized from reading the disclosure that the inventors had invented the isolated wee1 having the specific nucleotide and amino acid sequences and variations of these sequences with mutations in described specific areas of Wee1, while avoiding the introduction of mutations in other regions. This teaching, coupled with the ability to test for functional mutants with the assays provided for in the specification, supports appellants' position that the inventors sufficiently described and were in possession of the invention as claimed, at the time of filing of the patent application.[8]

The board concluded that the examiner had not established why one of ordinary skill in the art would be unable to recognize that applicants had invented the claimed subject matter and reversed the written description rejection.

With regard to the enablement rejection, the board stated that the examiner had "the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention."[9] The first step in the analysis was to determine whether the examiner had met this burden, and the board reiterated the factors to be considered in analyzing

enablement, which were discussed in *Ex parte Forman*[10] and *In re Wands*.[11] Here, the examiner had provided an analysis of these factors, and a key factor cited by the examiner was the failure of the specification to disclose "any specific structural or functional characteristics of any isolated nucleic acid comprising a polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1." Moreover, the examiner argued, Applicants had provided no definitive evidence that introducing such a polynucleotide into a plant would alter a plant's phenotype. The examiner concluded that the art was unpredictable, citing a reference teaching that transformation of *Arabidopsis* with wild-type cell cycle regulatory protein Cdc2a "unexpectedly did not affect the development of transgenic plants," although transformation with a mutant Cdc2a did produce the expected phenotype.

The board, noting that the analysis of the enablement requirement "dovetail[ed]" here with the analysis of the written description requirement, observed that the specification taught how to screen for WEE1 activity and also disclosed a polynucleotide encoding a polypeptide of SEQ ID NO:2 and the polynucleotide sequence set forth in SEQ ID NO:1. The board noted that the specification described the level of skill in the art and taught regions of the gene that could be altered without affecting substrate recognition. The specification also taught that the central and carboxy end of the protein contained the protein kinase and substrate recognition domains of the protein and were relatively conserved, while most of the variations in WEE1 amino acid sequences were found at the amino terminal end.

The board found that the examiner had not established that these teachings were insufficient to enable the claimed polynucleotide. In making this finding, the board particularly noted the teachings of the specific coding sequence, the teachings on how to test for WEE1 activity, and the teachings of areas of the gene that could be altered. The board noted that here, the examples "indicate successful expression of [the *Zea mays* homolog of WEE1] in *E. coli* as evidenced by the successful inhibition of cyclin-dependent protein kinase." Moreover, "in view of the success described in the specification" and the state of the art as it related to the transformation of seeds and plant cells as outlined in the specification, the Examiner had also not established that these teachings would be insufficient to enable the transformation of cells, plants, and seeds.[12] Accordingly, the board also reversed the rejection of the claims for lack of enablement.

In *Ex parte Vogelstein*,[13] the claims were drawn to a method involving the use of "a portion," or fragment, of the p53 gene. The claims at issue were claims 4 and 12:

> 4. A method of supplying wild-type p53 gene function to a cell which has lost said gene function by virtue of a mutation in a p53 gene, comprising: introducing a portion of a human wild-type p53 gene into a human cell which has lost said gene function such that said portion is expressed in the cell, said portion encoding a part of human wild-type p53 protein which is required for non-neoplastic growth of said cell, whereby wild-type p53 gene function is supplied to the cell.
>
> 12. The method of claim 4 wherein said portion corresponds to a region of the p53 gene in the cell which contains the mutations.

The examiner rejected these claims for lack of enablement by the specification. The board noted that the p53 gene is a tumor suppressor and that the specification disclosed a method of supplying wild-type p53 function to a cell containing a p53 mutation. The specification taught that the wild-type p53 gene might remain in a cell extrachromosomally or might recombine with the endogenous p53 mutant gene to correct the defect in the mutant; vectors suitable for such embodiments were known in the art.

The examiner rejected all the claims for lack of enablement, stating that undue experimentation would be required to practice the invention, but had conceded that a similar method using a full-length p53 gene was enabled.

The examiner pointed to the unpredictability of the art, including the uncertainty in predicting whether any portion of a gene would exhibit wild-type activity, the lack of guidance provided concerning the importance of amino acid residues "outside the 132-309 region which affect protein folding and/or p53 activity," the lack of working examples using a portion of the p53 gene, and the unpredictability of therapeutic gene delivery *in vivo*, and concluded that undue experimentation would be required to practice the invention.

Applicants argued that, as disclosed in the specification, most mutations that inactivate the p53 gene occur between codons 132 and 309, and that one of skill in the art would expect that at least this portion of the gene would be required to supply wild-type gene function. Applicants also pointed to a prior art reference as teaching that deletions of the N-terminal and C-terminal portions of the protein were not required for DNA binding, and since DNA binding is the mechanism by which wild-type p53 operates, those of skill would have understood that portions of p53 would not require C-terminal or N-terminal amino acids to be functional.

The board noted that the examiner has the burden of showing that a claimed invention is not enabled, citing *In re Wright*.[14] Here, the board concluded that the examiner had not met that burden. The board noted that this application resulted from a restriction requirement in which the fragment claims were held to be patentably distinct from claims to a similar method of supplying wild-type p53 function using a full-length wild-type p53 gene. The board emphasized that the examiner had conceded that claims using the wild-type p53 gene were enabled. Accordingly, as the board noted, the issue was whether even though a method using the full-length gene was enabled, it would "requir[e] undue experimentation to practice the same method using a part of the p53 gene that encode[s] a functional portion of the p53 protein."[15] The board pointed to the information provided concerning the importance of the middle half of the p53 gene (i.e., codons 132 to 309) and the prior art teaching regarding the unimportance of the N- and C-terminal regions:

> Thus, the experimentation required by the instant claims would appear to be limited to determining how many of the

amino acids between positions 41 and 131, and how many of the codons between positions 310 and the C-terminal 393, could be deleted without adversely affecting the function of p53. We agree with Appellants that this experimentation would not appear to be undue. At most, the skilled artisan would be required to make and test a series of deletion mutants of p53. This experimentation might be tedious, but it would not seem to be undue.[16]

The board noted that the art cited by the examiner in support of the unpredictability of the art involved point mutations rather than the deletions at issue here and thus was not relevant. Accordingly, the board reversed the enablement rejection.

Thus, in both of these cases, the board focused on the fact that information was provided about conserved and nonconserved regions or about regions important for function. In view of the similarities between these cases, we recommend that applications include as much structure/function information about the protein as possible. Structure/function information includes sequence alignments to other sequences of known function, results of Pfam analysis, the identity and location of functional domains or sequence motifs, and the location and effect of known mutations. If necessary, structure/function information may also be provided during prosecution. We are optimistic that in view of these decisions, examiners will have a more reasonable approach during examination of sequence claims.

Other Reversals of Rejections under Section 112, Paragraph 1

Many of the other cases involving enablement rejections were drawn to methods and had language reminiscent of that at issue in *Amgen v. Hoechst Marion Roussel*[17] (see example claim in footnote 2). Typical statements by the board in reversing rejections for lack of enablement were: the examiner failed to establish a *prima facie* case of nonenablement; the examiner did not provide any evidence or factual analysis to support his or her position; and the fact that the claims may encompass inoperative embodiments is not enough, by itself, to show nonenablement (often citing *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*,[18] for the holding that claims can encompass inoperative embodiments and still meet the enablement requirement). The board often explicitly reviewed and critiqued the examiner's analysis of the *Wands* factors. A significant percentage of opinions cited data presented in the specification or provided in declarations as supporting a finding of enablement, although the majority of opinions did not specifically mention data or working examples.

Examples of representative claims for which enablement rejections were reversed include the following:

> A method of treating an autoimmune disorder comprising administering to a patient in need of such treatment an amount of an agent that binds CD23, and thereby blocks the interaction of CD23 with a ligand to which CD23 binds in vivo, sufficient to effect such treatment.[19]

> A method of treatment selected from the group consisting of (a) preventing or treating atherosclerotic vascular disease in a mammal; (b) hormone replacement therapy in a peri- or postmenopausal female mammal; and (c) treating hypertension in a mammal, which comprises administering to the afflicted mammal an amount of prostacyclin or prostacyclin analog in combination with one or more of an estrogen and a progestin, in amounts effective to ameliorate or prevent the appearance of the symptoms thereof, wherein said amounts are synergistically effective and the amounts of prostacyclin, prostacyclin analog, estrogen or progesterone are individually ineffective or marginally effective.[20]

> A method of altering the phenotype of a bird, comprising introducing avian somatic tissue-specific stem cells into an egg containing a bird during in ovo incubation, said cells containing and capable of expressing at least one DNA molecule in an amount effective to cause a change in the phenotype of the bird.[21]

> A pharmaceutical composition, comprising: at least one enzymatic nucleic acid molecule having a ribonucleotide at a catalytically critical site, at least one deoxyribonucleotide and at least on nucleic acid analog; and a pharmaceutically acceptable carrier.[22]

> A yeast cell stably transformed with an expression vector comprising: (a) an insert encoding a mammalian receptor comprising seven hydrophobic transmembrane segments, extracellular and intracellular loops, an extracellular amino terminal region, and a carboxyl terminal cytoplasmic region; and (b) a control region capable of being recognized by polymerases of the yeast cell for expression of said polypeptide in said yeast cell; and wherein after expression, said polypeptide is incorporated into a cell membrane of said yeast cell and said polypeptide is capable of binding a ligand of said mammalian receptor.[23]

An Enablement Rejection Is Affirmed

The enablement rejection was not reversed in *Ex parte Evans et al.*[24] The following claim was representative:

> An isolated Drosophila melanogaster knirps-related receptor polypeptide [Knrl] having the sequence set forth in Figure 2.

In making this enablement rejection, the examiner noted that the specification taught that Knrl shared about 45 percent sequence identity with the DNA binding domains of other steroid receptors, but other portions of the molecule only shared less than 15 percent sequence identity. Knrl had no known ligand. The specification stated that the knrl receptor's homology to other steroid receptors suggested that its function could be ligand-dependent, yet the knrl carboxyl terminus differed from other receptors, making it "difficult to predict a potential ligand."[25] The board noted that the specification was very similar to a reference authored by one of the inventors, with several striking omissions. These omissions included the statement that "[e]xperiments directly addressing the developmental role of the knrl gene must await isolation of loss-of-function alleles" and the statement that knrl might not be an essential gene. Moreover,

the specification stated that the gene contained "an open reading frame capable of encoding 647 amino acids, beginning with . . . nucleotide 1499 and ending . . . at position 2460," which as the board noted only contained 961 nucleotides and was therefore incapable of encoding 647 amino acids. The board also noted that the asserted utility was for "assays and methods relating to screening for materials which modulate the claimed receptor"[26] and that, contrary to the applicants' assertions, "no 'other purposes' [were] described in the specification."[27]

Other Observations and Practice Tips

In some cases—both those with obviousness rejections and Section 112, Paragraph 1 rejections—applicants submitted declarations to support their arguments. A number of board opinions emphasized that the decision of whether to enter a declaration into the record after a final rejection is at the discretion of the examiner and is not appealable to the board. Rather, such a decision can only be the subject of a petition to the commissioner for administrative relief under 37 C.F.R. 1.181.[28] Similarly, the refusal of the examiner to enter amendments after final cannot be appealed to the board and may only be the subject of a petition to the commissioner.[29]

As discussed earlier, most of the cases we reviewed were appeals of claim rejections under 35 U.S.C. § 103 ("obviousness rejections"). These cases are very fact-specific, so rather than examining specific claims, we here discuss observations gathered from our review of these decisions. Typically, the reversals of obviousness rejections were on the basis that the Examiner had not established a *prima facie* case of obviousness. Other statements frequently made by the board in reversing these rejections were: that the references provided only an invitation to experiment; that there was no motivation or suggestion to combine the references; and/or that the references did not teach a reasonable expectation of success. In concluding that the references did not teach a reasonable expectation of success, some opinions emphasized the unpredictability of the art.

In several cases, the board acknowledged that the elements of the claimed invention were present in the cited references, but that the references could not render the claims obvious without further guidance as to which elements to select from among the many possibilities presented. Another articulation of this idea was that the combination of references did not flow logically from their having been individually taught in the prior art.

In only a few cases, the board stated that the examiner had mischaracterized a reference or that the reference did not teach the limitation as asserted by the examiner. Another notable holding was the one in *Ex parte Lanzara*:[30]

> While we agree with the examiner that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art," In re Boesch, 617 F.2d 272, 276...(CCPA 1980) [citations omitted], our reviewing court has found an exception to this general rule where "the parameter optimized was not recognized to be a result effective variable," In re Antonie, 559 F.2d 618, 621 . . . (CCPA 1977).

Conclusion

In view of the percentage of successful appeals in biotechnology-related cases—over 90 percent for obviousness rejections as well as for written description and enablement rejections—applicants facing final rejection should consider filing an appeal. However, as always, applications should include as much supporting data as possible and sequence claims should be supported by ample structure/function information, as exemplified by the successful appeals in *Ex parte Sun* and *Ex parte Vogelstein*.

Endnotes

1. The authors gratefully acknowledge the assistance of Dr. Noah Hoffman, without whose contribution this study would not have been possible. Dr. Hoffman, a Python programmer, wrote a program that enabled the authors to identify biotech-related board decisions. He also has assisted the authors with projects involving the identification of consensus sequences and projects involving sequence alignment. *See* http://www.unc.edu/~nghoffma or e-mail noah_hoffman@med.unc.edu.

2. 314 F.3d 1313 (Fed. Cir. 2003). For example, claim 1 of U.S. Pat. No. 5,955,422 is: "A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture."

3. No. 2003-1993 (Bd. Pat. App. Int. Jan. 20, 2004).

4. 591 F.2d 693, 700 (C.C.P.A. 1979).

5. 119 F.3d 1559, 1568 (Fed. Cir. 1997).

6. 296 F.3d 1316 (Fed. Cir. 2002).

7. Slip op. at 6, citing *Enzo*, 119 F.3d at 1324; emphasis added by the board.

8. Slip op. at 10.

9. Slip op. at 12, citing *In re Wright*, 999 F.2d 1556, 1561–62 (Fed. Cir. 1993).

10. 230 USPQ 546, 547 (Bd. Pat. App. Int. 1986).

11. 858 F.2d 731, 737 (Fed. Cir. 1988).

12. Slip op. at 15.

13. No. 2002-0779 (Bd. Pat. App. Int. Dec. 30, 2002).

14. 999 F.2d 1557, 1561–1562 (Fed. Cir. 1993).

15. Slip op. at 4.

16. Slip op. at 7, citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

17. 314 F.3d 1313 (Fed. Cir. 2003).

18. 750 F.2d 1569 (Fed. Cir. 1984).

19. *See Ex parte Bonnefoy*, No. 2000-1783 (Bd. Pat. App. Int. Sept. 27, 2002).

20. *See Ex parte Garfield and Chwalisz*, No. 2001-0982 (Bd. Pat. App. Int. Jan. 30, 2003).

21. *See Ex parte Petitte et al.*, No. 1999-1223 (Bd. Pat. App. Int. Aug. 22, 2002).

22. *See Ex parte Usman et al.*, No. 2002-1251 (Bd. Pat. App. Int. Nov. 27, 2002) (reversing both enablement and written description rejections).

23. *See Ex parte Marullo et al.*, No. 2001-1436 (Bd. Pat. App. Int. Jan. 30, 2003).

24. No. 1999-1361 (Bd. Pat. App. Int. Jan. 31, 2001). While this case was not decided during the same time frame as the other cases we originally reviewed, the disposition of this case governed the disposition of *Ex parte Evans et al.*, No. 2003-1608 (Bd. Pat. App. Int. Feb. 11, 2004).

25. Slip op. at 3.

26. Slip op. at 4.

27. Slip op. at 4–5.

28. *See, e.g., Ex parte Evans*, No. 2003-1608 (Bd. Pat. App. Int. Feb. 11, 2004.

29. *In re Berger*, 279 F.3d 975, 984–85 (Fed. Cir. 2002).

30. No. 2001-1437 (Bd. Pat. App. Int. Jan. 7, 2003).

From the Chair

(continued from page 3)

• Section officers spoke on FTC report on programs sponsored by the FTC, the University of California, Berkeley, and the ABA Section of Antitrust Law.

• Preparing Section trip to China, July 2004.

Meetings, CLE, and Publications

• Monthly *Chair's Bulletin* on current Section news and IP developments.

• Quarterly *IPL Newsletter* with substantive articles.

• Young Lawyers program, "Practical Tips on Enforcing and Defending Patents," September 2003.

• Joint program (with AIPPI): "Trying an IP Case in Foreign Countries—Five Mini-Trials," October 2003.

• 2003 Supplement to "Patent Litigation Strategies Handbook" (with BNA Books).

• 2003 Annual Report of Section activities, December 2003.

National CLE Conference (with Law Education Institute), January 2004.

• Copyright Office Day meetings with U.S. Copyright Office officials, January 2004.

• IPL Midwinter Meeting for Section leadership, January 2004.

• Trademark Office Day meetings with Trademark Office officials, March 2004.

• 19th Annual Intellectual Property Law Conference, April 2004.

• Young lawyers program, "Practical Tips on Intellectual Property Law," April 2004.

• 11th Annual Summer IPL Conference in Toronto, June 2004.

• Preparing IP Valuation Survey and Primer.

• Preparing for ABA teleconference on the Federal Trademark Dilution Act.

Diversity and Young Lawyers Initiatives

• Jointly administered the American Intellectual Property Law Education Foundation (AIPLEF), awarding the Sidney B. Williams, Jr. Intellectual Property Law Scholarships and the Jan Jancin Scholarship Award (with AIPLA).

• Adopted a Section Fellows program for young lawyers.

• Joined Judicial Intern Opportunity Program for minority law students (with the Section of Litigation).

• Women in IP law breakfasts at the Midwinter Meeting and Summer IPL Conference.

• Program on the value of diversity in the IP marketplace at the Summer IPL Conference.

• Participated in ABA Women's Leadership Summit Meeting, May 2004.

The IPL Section sincerely appreciates the support of the association in its activities and is pleased to submit this report of its work this year.

Respectfully submitted,
Robert W. Sacoff
Chair, Section of Intellectual Property Law
August 2004

Summer IPL Conference Recap

The 11th Annual Summer IPL Conference was held June 16–20 at the Four Seasons Hotel in Toronto, Ontario Canada. This year's conference was presented in cooperation with the Canadian Bar Association, the National Intellectual Property Law Association, and the Intellectual Property and Entertainment Committee of the International Bar Association Section of Business Law.

More than 300 attendees enjoyed a week of excellent CLE programming. This year's CLE programs featured an international flair with presenters from the United States, Canada, and the United Kingdom. Programs covered recent issues in patent, domain name, copyright, anti-counterfeiting, and trademark law. There were also presentations on open source software, ethics, and intellectual property valuation.

Attendees, their spouses, families, and guests enjoyed tours of the Art Gallery of Ontario, Stratford Theatre, and the historical and literary flavors of Toronto; a visit to Niagara Falls; and a cruise of Toronto Harbor.

The Royal Ontario Museum was the site of the Welcome Reception where mounties greeted attendees at the museum's entrance. Guests were treated to museum tours and tastes of Canadian cuisine hand-delivered by hockey players and Hudson Bay Trappers. Other activities at the conference included an evening of laughs at the Second City, a local art gallery crawl, and the Section's annual golf and tennis tournaments. The bike tour along Toronto Harbor took riders to the new trendy Distillery region.

The Section was fortunate again to hold a business session at the Summer Conference where Section members debated resolutions prepared at the committee level. The business session is an excellent opportunity for Section members to hear many of the country's top intellectual property lawyers debate Section policy and current issues in intellectual property law.

The Section's Thursday luncheon featured hockey legend and recently elected federal Member of Parliament for Canada Ken Dryden. Friday's luncheon featured an impressive Women's Advocate Panel comprised of Karen Mathis, Julie Mazza, and Kathryn Barrett Parks. Marylee Jenkins organized and moderated this panel. Continuing the Section's recognition of diversity, the Women in Intellectual Property Law Advocate Group hosted a breakfast and the Committee on Minorities and Women in the Profession hosted a cocktail reception.

Sidney B. Williams Awards

The American Intellectual Property Law Education Foundation (AIPLEF) presented scholarship awards to two of the eight recipients of this year's Sidney B. Williams Scholarships. AIPLEF was formed to increase the diversity of lawyers joining the IP bar. The Sidney B. Williams, Jr. Scholarship Program was named in honor of Sidney B. Williams, Jr., a corporate and law firm intellectual property lawyer for more than 30 years. Mr. Williams was the first African-American quarterback for a Big Ten school while earning a degree in chemical engineering. He played briefly for the National Football League's New York Giants and in the Canadian Football League before attending law school and becoming a patent lawyer. He was also the first African-American lawyer to (1) chair a committee of AIPLA, (2) become a member of the AIPLA Board of Directors, (3) become Secretary of AIPLA, (4) chair the National Council of Intellectual Property Law Associations, and (5) serve as a Council member and the Financial Officer for the American Bar Association Section of Intellectual Property Law. Mr. Williams also served as the first president of the National Inventors Hall of Fame.

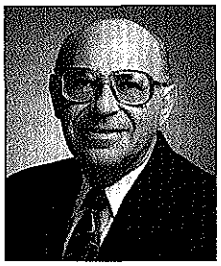
We were pleased that two recipients of the scholarships were present: Stephanie Harris and Tashica T. Williams. Many of us had the pleasure to speak with these two outstanding women at the conference. Stephanie holds a Bachelor of Science degree from the Morgan State University. She participated in an engineering rotational internship program at Motorola, Inc. in Plantation, Florida, where she worked in Motorola's intellectual property department. She also became a patent examiner in 2001 at the USPTO and will be attending law school this fall at Howard University School of Law. Tashica holds a Ph.D. in chemistry from California Institute of Technology in Pasadena, California. While a graduate student, Tashica mentored undergraduate researchers and was an instructor for minority high school students. She will enter Boalt Hall Law School this fall.

Special thanks to all of the moderators, speakers, cosponsors, and hosts of this year's Summer IPL Conference.

Be sure to mark your calendars now for the 2005 Summer IPL Conference to be held June 22–26, 2005 at The Palace Hotel in San Francisco. Once again we will provide high-quality CLE programming, interesting tours, and an opportunity to network with both old and new friends. We look forward to seeing you there!

I²P Group News

BY SAMSON HELFGOTT, INTERNATIONAL ACTIVITIES COORDINATOR



Samson Heffgott

A number of interesting items have come up with respect to I²P Group (International Intellectual Property Group), which are of interest to the entire membership.

PCT Reform Update

Over the last few years, PCT reform has made great strides in streamlining and improving the PCT system. Initially this initiative was driven by workloads within patent offices, especially the PCT workload within the European Patent Office. However, thereafter, with user involvement much of the direction of the Reform was addressed to making the PCT system more user-friendly and cost-effective.

The initial change, which benefited both patent offices and users, was to extend the time of Chapter I to thirty months to eliminate the patent office backlogs when the only purpose of entering Chapter II was for delay. Thereafter, the new EISPE System merged search and examination so the written opinion was provided along with the search report in Chapter I.

Numerous other changes have been implemented including the elimination of the designation system, reductions in signature requirements, and other formality improvements.

The change in the PCT articles permitting Chapter I to extend to thirty months required a treaty modification; all other changes have been limited to rule changes in order to permit faster implementation of these reforms.

At the beginning of the reform process there was great enthusiasm for change. This enthusiasm seems to have slowed, and combined with increased concerns on the part of developing countries for "global patent treaties," further progress on reforms has been limited. Simple matters such as finalizing language for rectification of obvious errors, restoration of the right of priority, missing parts requirements, and other items that should have been considered noncontroversial have been stalled with further discussions and rewrites.

Although the EPO itself has proposed a "fast-track" approach to expedite further PCT reform, this proposal has not found a consensus of approval. As a result, further progress on PCT reform may slow over the next few meetings.

At the same time, there has been continuous conceptual discussion of further possibilities for expanding the PCT scope. While none of these possibilities have reached the stage of review for approval, in concept, continued study of these areas has been favored. Recently, the suggestion of having multiple searches conducted simultaneously in patent offices having specialized language competence has found favorable backing and is being proposed for the next meeting. The possibility of utilizing the PCT *after* the international phase as a resource for centrally making changes in bibliographic information, such as name change, address change, etc., also has met with favorable approval for further study.

Accordingly, it appears that further PCT reform will proceed, albeit on a slower path, in the hope of expanding the scope and capabilities of PCT. Ultimately, to the extent harmonization of substantive laws is achieved in some areas relating to search and examination, it will also aid in improving the use of PCT and permit the results of PCT to be used in a more cost-effective way.

Nevertheless, while improvements have taken place and while discussions are still ongoing for further expanded use of PCT, for the time being it is believed that the great advances of the recent past may not be continued in the immediate future.

Further concern is that other reforms to be pursued may go beyond simple rule changes and require treaty changes; the difficulty of which has also held back further progress.

Trilateral Activities

Over the last few years, the trilateral meetings between the USPTO, the JPO, and the EPO have been successful in correlating activities among these organizations. The meetings have produced coordinated activities in computerization areas, exchange of search and examination activities, reduction of flow of paperwork, and other areas. It has also given the three offices the opportunity to exchange views on fees, budgets, workloads, for a better appreciation of the work of other offices.

With the slowdown in progress on harmonization talks, the trilateral have also begun discussions of their own to work toward harmonization.

At the November 2003 Trilateral Conference, the three offices agreed that a discussion of a limited list of items relating to the grant of patents would improve the prospects for progress. This "first package" of provisions for discussions at the inaugural Trilateral Working Group meeting, included prior art, grace period, novelty, and inventive step/nonobviousness. Discussions focused on proposals from each office based on the current proposed SPLT Text.

Various articles and rules contained in the draft SPLT relating to these areas of the "first package" were discussed in a meeting of the Trilateral Working Group on Patent Law Harmonization in February 2004. None of the three patent offices could commit to a particular position since none was previously agreed upon within their respective governments. The discussions reached a consensus that they could take back to their

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constituencies, rather than an actual agreement that could be put into place.

Progress was made in a number of areas where it appeared general consensus was possible. For example, in connection with the definitions of prior art, form of availability and date of availability general agreement seemed possible. Agreement also seemed possible in connection with other items, such as how to deal with erroneously published applications, what constitutes applications for prior art, and whether to include third-party rights. Likewise, agreement appears possible on a definition of novelty and a definition of what is an item of prior art.

In other areas, there was at least an appreciation of issues that must be addressed by each of the three offices, and an indication of what might or might not be areas of compromise.

One of the major areas of concern that appears to be critical for many aspects of compromise relates to the treatment of secret prior art. While each of the offices currently has different understandings of and applications of such secret prior art, all of the offices felt that it would be worthwhile to explore a compromise position of utilizing such prior art on the basis of "enlarged novelty." First, it is necessary to come up with an adequate definition of "enlarged novelty." For example, the EPO alleges that their current approach is not "strictly photographic novelty" but that they already include subject matter inherent to the disclosure of the prior application. The JPO currently considers as "novelty" variations and equivalents of subject matter disclosed, as long as the variation or equivalents have the same contribution with the subject matter of the prior application. Of course, the USPTO cites such prior application for both novelty and nonobviousness purposes.

It appears that to the extent a workable compromise can be reached on what is "enlarged novelty," this might be acceptable and not only will address the prior art issue but will be effective for use in other areas requiring compromise.

Another area of concern relates to the grace period. While general agreement that such grace period would only relate to disclosures made by or on behalf of the inventor, the extent of time for such grace period, whether twelve months or six months, was still an issue. Also, still open is the issue of the use of declarations at the time of filing.

In February, the trilateral agreed to suggest the reduced package to WIPO for the next meeting of the SCP. However, with the failure of the SCP to address the reduced package, the Trilateral met again at the end of May 2004 to reevaluate the situation relating to harmonization considering the current stall in discussions at WIPO. It was also agreed that there would be a meeting of the Trilateral Working Group on harmonization before the next PCT General Assembly in order to come up with a proposal for the General Assembly relating to harmonization. To the extent that the General Assembly would be favorably inclined toward such proposal the Trilateral felt that they could again proceed with WIPO discussions.

World's Three Major Intellectual Property Offices Streamline Trademark Registration Process

The Department of Commerce's United States Patent and Trademark Office (USPTO), the European Office for the Harmonization in the Internal Market (OHIM), and the Japan Patent Office (JPO) recently reached agreement on a list of identifications and classifications for goods and services that will be accepted in trademark applications filed in the three offices. Having a consistent list for all three offices will make trademark registration easier and faster in the United States, Europe, and Japan. Representatives from the USPTO, OHIM and JPO, known as the Trademark Trilateral Partnership group, have been working for more than two years on this project.

Trademark examination will be faster for filers who use designations from the list to describe and classify their goods or services because examiners in each of the three offices will know immediately that the identification of the goods or services comes from the approved list. The initial list includes more than seven thousand entries, and thousands more will be added as new designations of goods and services are agreed to by the offices.

South Africa Proposes Patent Amendment Bill to Address Genetic Resources and Traditional Knowledge

The proposed amendment bill seeks to introduce into the South African Patents Act provisions to compel applicants for patents in those cases where an invention entails the use of genetic or biological resources, or where an invention is based on indigenous or traditional knowledge, to disclose this fact in the patent application. It also seeks to compel applicants for patents in those cases where a patent aims to protect an element of indigenous or traditional knowledge or of "heritage," to obtain the prior and informed consent of the owners of the traditional knowledge. Furthermore, it provides for sanctions in cases of noncompliance with these provisions.

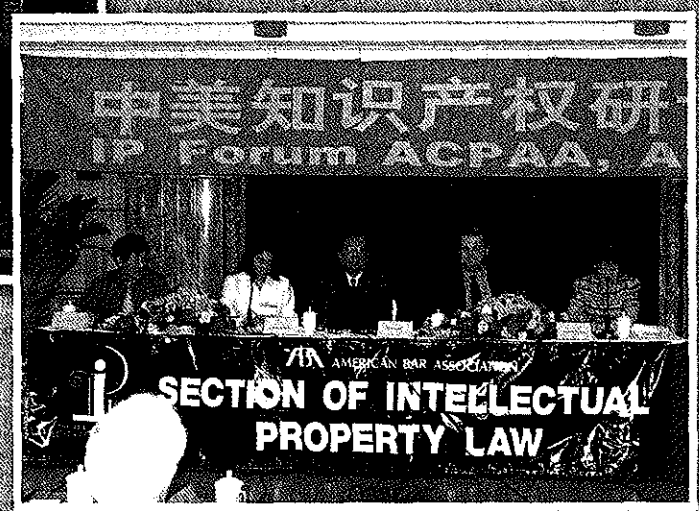
In the explanatory memorandum published with the bill, the problem being addressed by the bill is that genetic and biological resources are being patented without the knowledge or consent of the states to which these resources belong, and without the knowledge or consent of the indigenous peoples from whom the knowledge was derived and who, through their knowledge, have made a contribution to the invention.

The proposed bill has been published for public comment.

Ten Countries Join the European Union

As of May 1, 2004, ten countries, including much of Central and Eastern Europe, have joined the European Union. These are Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovenia, and Slovakia.

ABA Section of Intellectual Property Law Trip to the People's Republic of China



ABA Section of Intellectual Property Law members visited China recently, where they met with local officials and learned more about IP law in China. The trip was a huge success. Many thanks to the primary organizer of the event, Elizabeth Chien-Hale, Chair, Committee #109—Cooperation with Foreign Patent Offices. Thanks also to Jones Day; All-China Patent Agents Association; Jeekai & Partners; and Lehman, Lee & Xu.

Visitors heard reports from a broad range of IP agencies, including the central agencies and courts in Beijing (China's capital), the local agencies in Shanghai (a centrally governed municipality) and Guangzhou (a provincial capital), and met many IP professionals, judges, and company representatives during numerous social events.

In addition to talking to the local trademark enforcement agency in Guangzhou, the local economic development officials also invited visitors to wear a different hat and discuss how IP professionals can facilitate bringing U.S. companies to China.

The trip included:

• Meetings at the State Intellectual Property Office and the Trademark Office of the State Administration for Industry and Commerce.

• Visits to the People's Supreme Court, the National Copyright Administration of China, the Shanghai Intellectual Property Administration (patent enforcement agency), and the Guangzhou Administration for Industry and Commerce (trademark enforcement agency).

The following speakers participated in a day-long IP seminar: Mr. Gao Lulin, president of the All-China Patent Agents Association; Judge Zhang Lumin of Beijing Higher People's Court; and Mr. XIE Guomin, senior legal director of Sina.com. The Litigation Panel included Albert Jacobs, Greenberg & Traurig; Rob Lindefjeld, Jones Day; Lyle Vander Schaaf, White & Case; and Benjamin Bai, Jones Day. The IP Commercialization Panel included Adam Ross, U.S. Embassy, Beijing; Steven Ludwig, Sterne, Kessler, Goldstein & Fox; Holly Li, McGlew and Tuttle; and Emil Chang, Law Office of Emil Chang.

Many thanks again to Elizabeth Chien-Hale, trip participants, and the law firms and organizations that hosted our delegation. We look forward to continued involvement and developing relationships that further the growth of international IP law

Recent Developments in Intellectual Property Law

BY JOHN C. GATZ, REPORTER

John C. Gatz

Patents

Claim Construction

SuperGuide Corp. v. DirecTV Enterprises, Inc., 69 U.S.P.Q.2d 1865 (Fed. Cir. 2004). The district court held that "regularly received television signal" refers to the format of television signals that were regularly received by televisions as of 1985, and that because no televisions existed as of that date that could receive digital signals, the term as understood by one of skill in the art necessarily excludes digital technology. The Federal Circuit, however, performed a closer analysis of the intrinsic record and found that the claim language does not limit the disputed phrases to any type of technology or specify a particular type of signal format, such as analog or digital. The "regularly received television signal" received by the mixer is referred to in the specification as "video data." "Regularly received television signal" therefore refers not to signals directly received by the RF section and sent directly to the television, but rather to the video data received by the mixer. It appears indisputable that it was known to those skilled in the art during the pendency of the patent application that video data could be communicated in either analog or digital format. Moreover, the specification of the patent reveals that the applicants were aware of the existence of analog and digital signals. For example, the specification describes examples of transmitting digital signals, such as those conveyed to a microprocessor and from digital sound files. Had the applicants intended to limit the disputed claim terms to "analog" technology, they could have easily done so by explicitly modifying the disputed claim language with the term "analog." The Federal Circuit found nothing in the patent that precludes the mixer of the claimed invention from receiving video data in digital format. The Federal Circuit found no reason to limit the scope of the claimed invention to analog technology when "regularly received television signals" (i.e., video data) is broad enough to encompass both formats and those of skill in the art knew both formats could be used for video.

Liquid Dynamics Corp. v. Vaughan Co., 69 U.S.P.Q.2d 1595 (Fed. Cir. 2004). Because the district court incorrectly construed a claim term, the Federal Circuit vacated and remanded the district court's granting of summary judgment of non-infringement. The district court construed the term "substantial helical flow" to require a perfect helical flow. The Federal Circuit disagreed. The term "substantial" is a modifier that implies "approximate" rather than perfect. This is supported by the plain language of the disputed claim. The plain language does not require perfectly helical flow nor a flow that returns to the center after one rotation. This claim language is not contradicted by anything in the written description, the figures, or the prosecution history. The district court erred in relying on the written description and some of the figures, which showed a perfectly helical flow. The district court failed to differentiate between "helical" and "substantially helical." Because the claim uses the language "substantially helical," it covers all flow patterns that are generally spiral and that fill much of the tank's volume. While the Federal Circuit found that the patentees submitted evidence that might convince a reasonable jury that the alleged infringer's systems generate flows that are generally helical, the prosecution history indicates that the patentees may have surrendered rights to any flows that are not "substantially helical." Thus, to prove infringement, the patentees will have to overcome the presumption that any flow other than a substantially helical one infringes under the doctrine of equivalents.

Liebel-Flarsheim Co. v. Medrad, Inc., 69 U.S.P.Q.2d 1801 (Fed. Cir. 2004). The Federal Circuit reversed and remanded the district court's summary judgment of noninfringement of four patents. Regarding the first two patents, the Federal Circuit reversed based on the district court's claim construction as requiring a pressure jacket. The plain language of the claims does not state that the opening must be formed in a pressure jacket. The district court found the claim language ambiguous and, thus, turned to the embodiments described in the specification. The Federal Circuit disagreed, finding that the term "opening" was not ambiguous, and looked instead to the common usage of the term "opening." Furthermore, the Federal Circuit rejected the argument that merely because all of the embodiments described in the specification required a pressure jacket that the claims were limited to including a pressure jacket. There is nothing in the specification that contains a clear disavowal of embodiments lacking a pressure jacket. The prosecution history also supports such a broad reading of the claims. During the prosecution, the

John Gatz is a member of the firm of Jenkens & Gilchrist in Chicago. Contributors to this department include: Patents—Julio Garceran, Lucent Technologies, Inc.; and John C. Gatz and Cynthia K. Thompson, Jenkens & Gilchrist, Chicago; Trademarks—Patrick J. Gallagher and Laura J. Borst, Fulbright & Jaworski LLP, Minneapolis; Dana C. Jewell, Fulbright & Jaworski LLP, Dallas; and Katherine M. DuBray, Fulbright & Jaworski LLP, Washington, D.C.; Copyrights—Timothy Kowalski, Jenkens & Gilchrist, Chicago; Zachary Smolinski, Panduit Corporation; and Michael N. Spink, Brinks, Hofer, Gilson & Lione, Ann Arbor, Michigan.

applicants replaced claims that included references to a pressure jacket with claims that did not include such a limitation. Also, both patents contained claims that expressly added the limitation of a pressure jacket.

The Federal Circuit also addressed the district court's interpretation of the term "physical indicia related to" a physical property of the syringe. The district court found that the phrase "related to" as requiring the physical indicia to be the actual syringe properties that can be directly used computing the various syringe properties without reference to some other source of information. The Federal Circuit reversed, stating that both the plain language of the claims and the prosecution history do not support such a reading. There did not need to be a direct relationship between the physical indicia and the syringe properties.

Chef America, Inc. v. Lamb-Weston, Inc., 69 U.S.P.Q.2d 1857 (Fed. Cir. 2004). The sole issue in the appeal was whether a claim term requires dough to be heated to a certain temperature or whether the claim only specifies the temperature at which the dough is to be heated. The Federal Circuit held that it is the former. The plain language of the claim requires that the dough is heated to the specified temperature. Nothing suggests that what is to be heated is the air inside the oven and not the dough itself. The Federal Circuit found that the claim required this construction even though it produced a non-sensical result (that the dough would be burnt). If claims are susceptible to only one reasonable interpretation, even if it is nonsensical, the claim must be construed as written. There is nothing in the claims, specification or prosecution history to refute this construction. Also, there was no attempt by the patentee to argue that the claim was drafted incorrectly or was a draftsman's mistake. Thus, the claim requires that the dough is to be heated to a specific temperature.

Claim Construction/Laches and Estoppel

International Rectifier Corp. v. IXYS Corp., 70 U.S.P.Q.2d 1209 (Fed. Cir. 2004). There were a number of disputed claim terms between the patentee International Rectifier Corp. (IR) and IXYS Corp. (IXYS). The first term in dispute was "polygonal," which the district court construed to require that the shape of the region "be generally but not perfectly polygonal." The district court also noted that "[t]he 'corners' of the polygonal regions may take the form of spherical junctions (i.e., round) after processing, and are not necessarily formed by straight lines intersecting at a point to form a well defined angle." Both IR and IXYS agree that the ordinary and customary meaning of the term "polygon" is "a closed plane figure bounded by straight lines." The parties, however, dispute the district court's relaxation of requiring straight lines and well-defined angles. The patent specification is consistent with the ordinary dictionary definition of the word "polygon." IR did not point to a disavowal or disclaimer of this scope and did not contend that the patentee acted as his own lexicographer. Moreover, neither party argued that anything in the prosecution history affects the disputed claim term scope. IR argued that those of ordinary skill in the art and informed by the patent specification would understand "polygonal" to encompass shapes with curved corners. While IR is correct that the meaning of claim terms must be considered from the perspective of one of ordinary skill in the art, that does not mean that the inventor's choice of words may be ignored. The district court was not free to attribute a new meaning to the term "polygonal" or to excuse the patentee from the consequences of its own word choice.

The Federal Circuit also reversed the district court's construction of the term "annular." Because factual issues exist as to whether IXYS's devices include the "polygonal" and "annular" limitations of the claims, as properly construed, the Federal Circuit vacated in part the district court's grant of partial summary judgment in favor of IR that IXYS's devices infringe claims.

The last disputed term was "adjoining." The definition of the term "adjoining" is "touching or bounding at some point or on some line: near in space." Because there was no express disavowal or limit on the scope of the claim term, the Federal Circuit gave the term "adjoining" its ordinary and customary meaning. Since IXYS devices include a buffer layer, the Federal Circuit stated that no reasonable jury could conclude that the IXYS products infringe some of the claims because they are not adjoining. Therefore, the Federal Circuit reversed the district court's summary judgment order in favor of IR on selected claims, and remanded with instructions to enter a judgment of non-infringement of these claims in favor of IXYS.

The district court granted summary judgment in IR's favor on the laches and estoppel defenses based on IXYS's assertion of the attorney-client privilege to withhold facts considered by the district court to be material to the analysis of these claims. IXYS claimed that this was in error because it did not rely on these facts to support its equitable defenses. IXYS pointed to a number of allegedly undisputed facts that it contended supports the claims of laches and estoppel. The Federal Circuit agreed with IXYS that it was entitled to present its claims of laches and estoppel based on the non-privilege evidence, and the Federal Circuit therefore vacated the district court's grant of summary judgment in IR's favor on these defenses and remanded for further proceedings consistent therewith.

Claim Construction/Prosecution History Estoppel

Microsoft Corp. v. Multi-Tech Systems, Inc., 69 U.S.P.Q.2d 1815 (Fed. Cir. 2004). The Federal Circuit addressed the issue of whether certain claim limitations were restricted to communications over a telephone line or whether they may encompass communications over a packet-switched network. The Federal Circuit held that the claims were so restricted. Turning first to the plain language of the claims, only one claim explicitly requires using a telephone line. As the claims must be interpreted in light of the specification, the specification repeatedly describes the systems as communicating

directly over a telephone line. First, the "Summary of the Invention" section describes the overall inventions, and is not limited to describing a preferred embodiment. This narrow reading of the claims is also supported by the prosecution history. The Federal Circuit held that a statement made during the prosecution history of one patent was relevant to the understanding of the scope in a second patent stemming from the same parent. This is true even though the statement was made after one of the other patents in the case had issued. The Federal Circuit found that any statement of the patentee in the prosecution of a related application is relevant to claim construction.

The Federal Circuit then turned to other claim terms, revising the district court's construction of three of them. Because the plaintiff had stipulated noninfringement if the construction of the first term was affirmed, the final judgments of the district court were affirmed.

Claim Construction/Willful Infringement

Golight, Inc. v. Wal-Mart Stores, Inc., 69 U.S.P.Q.2d 1481 (Fed. Cir. 2004).The patent is directed to a wireless, remote-controlled, portable search light. The construction of the phrase "horizontal drive means for rotating said lamp unit in a horizontal direction" in the patent was in dispute. The issue was whether this phrase implicitly requires the searchlight to be able to rotate through 360 degrees. The other independent claims in the patent explicitly recited that the rotation of the lamp unit can be in a horizontal direction through at least 360 degrees.

Wal-Mart Stores, Inc. (Wal-Mart), the accused infringer, acknowledged that such a limitation does not expressly appear in the claim, but nevertheless contended that the claim scope cannot exceed what is supported by the patent specification. Specifically, Wal-Mart argued that the patentees only described a searchlight capable of rotation through 360 degrees and, thus, the claims must be limited to the same. The Federal Circuit saw no clear definition or disavowal of claim scope in the patent specification that would limit the claim to horizontal rotation through 360 degrees. Patentees are not required to include within each of their claims all of these advantages or features described as significant or important in the patent specification. Thus, the Federal Circuit was unpersuaded by Wal-Mart's contention that the patent specification must import the requirement of rotation through 360 degrees into the claim.

In arguing against willful infringement, Wal-Mart stated that it presented undisputed evidence that no one at Wal-Mart had knowledge of the patent until this lawsuit. The Federal Circuit stated that there was no admissible evidence that Wal-Mart took appropriate action after receiving a cease-and-desist letter to establish a reasonable belief that it was not infringing the patent. While Wal-Mart argued that it obtained a letter from the manufacturer assuring that its products did not infringe, this letter was not admitted into evidence at trial and was rejected by the district court as "crudely drafted" and "cursory." There was evidence that Wal-Mart continued to sell off its remaining inventory even after it had learned of its possible infringement. Based on this evidence, the district court's finding of willful infringement was not clearly erroneous. The Federal Circuit affirmed the district court's rulings that Wal-Mart has willfully infringed the claim, and that Golight Inc. was entitled to its attorney fees.

Claim Indefiniteness/Claim Construction

Bancorp Services, L.L.C. v. Hartford Life Ins. Co.. 359 F.3d 1367 (Fed. Cir. 2004). The patent at issue provides a system for administering variable life insurance policies, including those containing stable value-protected investments, by "tracking the book value and market value of the policies and calculating the credits representing the amount the stable value protected writer must guarantee and pay should the policy be paid out prematurely."

The district court held all of the independent claims of the patent invalid for indefiniteness because each of those claims used the term "surrender value protected investment credits," which the court held was "fatally indefinite." The court found the term to be so unclear as to render the patent claims invalid because the term "surrender value protected investment credits" was not defined in the patent, or made clear by either the patent or the extrinsic evidence.

The Federal Circuit previously held that a claim is not indefinite merely because it "poses a difficult issue of claim construction" and should only be found invalid for indefiniteness if it is "insolubly ambiguous." As patents enjoy a statutory presumption of validity under 35 U.S.C. § 282, the Federal Circuit restricts findings of indefiniteness only to those cases where "reasonable efforts at claim construction prove futile." Whenever the question of indefiniteness in a litigation setting is a close call, the decision should be made in favor of the patentee.

The Federal Circuit agreed with Bancorp Services, LLC (Bancorp) that the meaning of the term "surrender value protected investment credits" was reasonably discernible and that the asserted patent claims were therefore not invalid for indefiniteness. Although the entire term at issue was not defined in the patent, and Bancorp did not enter into evidence any industry publication that defined the term, the individual components were found to have well-recognized meanings, and the reader could infer the meaning of the terms: "surrender value," "protected investment," and "credit." Thus, the Federal Circuit concluded the term "surrender value protected investment credits" was reasonably definite.

Damages/Patent Misuse

Monsanto Co. v. McFarling, 70 U.S.P.Q.2d 1481 (Fed. Cir. 2004). Monsanto Co. (Monsanto) manufactures ROUNDUP herbicide. Homan McFarling (McFarling) operates a farm in Mississippi. McFarling executed a Technology Agreement with Monsanto on buying ROUNDUP READY soybean seed in 1998. McFarling saved bushels of seed from his 1998 crop and replanted them in 1999. He also saved soybeans from the 1999 crop and replanted them in 2000. Monsanto

moved for summary judgment on the infringement claim under the '605 patent, the breach of the Technology Agreement claim, and all of McFarling's affirmative defenses. The Federal Circuit affirmed the breach-of-contract claim on liability only.

McFarling argued that Monsanto committed patent misuse because Monsanto has impermissibly tied an unpatented product to a patented product. In evaluating a patent-misuse defense, the key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the patent scope with anticompetitive effect. McFarling effectively argued in different words that he should be granted a compulsory license to use the patent rights in conjunction with the second-generation ROUNDUP READY soybeans in his possession after harvest. The Federal Circuit declined to hold that Monsanto's right to exclude from the patented invention by itself is a tying arrangement that exceeds the patent scope. Because the '435 patent would read on all generations of soybeans produced, the Federal Circuit held that the restrictions in the Technology Agreement prohibiting the replanting of the second generation of ROUNDUP READY soybeans do not extent Monsanto's rights.

The Federal Circuit agreed with McFarling that the liquidated damages clause in the Technology Agreement is invalid and unenforceable under Missouri law as it applies to McFarling's breach of replanting of saved seed. Missouri law distinguishes between liquidated damages clauses, which are valid and enforceable, and penalty clauses, which are neither. For a damage clause to be valid as fixing liquidated damages: (1) the amount fixed as damages must be a reasonable forecast for the harm caused by the breach; and (2) the harm must be of a kind difficult to accurately estimate. The Federal Circuit concluded that the multiplier in the Technology Agreement is not valid because at the time of contracting, it was not a reasonable estimate of the harm that Monsanto would likely suffer. The multiplier in the Technology Agreement also violated the anti-one-size rule because it specifies the same measure of damages in the event of breach of several different restrictive provisions of the contract that lead to different types of damage. The Federal Court vacated the damages award and remanded for determination of actual damages.

Declaratory Judgment Jurisdiction

Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc., 70 U.S.P.Q.2d 1577 (Fed. Cir. 2004). The question was whether the facts alleged, under all the circumstances, show that there is a substantial controversy between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. For a declaratory judgment, there must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity that could constitute infringement or concrete steps taken with the intent to conduct such activity. As a threshold matter, in analyzing whether a case or controversy exists, Sierra Applied Sciences, Inc. (Sierra) argued that the Federal Circuit should treat Sierra's various power supplies as unitary technology. The district court separately considered its jurisdiction over the various power supplies, but did not consider its jurisdiction over the Coleman and Billings devices. The Federal Circuit believed that the record demonstrated that Sierra has developed three distinct, technologically different power supplies—the 2kW power supply, the Coleman 150kW power supply, and the Billings 150kW power supply—and that jurisdiction must be separately considered as to each. With respect to the Billings 150kW power supply, Sierra needed to show both immediacy and reality, but it failed to show either. As for immediacy, the record contained no evidence that the Billings 150kW power supply was built and operational until about one year after the complaint was filed.

Doctrine of Claim Differentiation

NOMOS Corp. v. BrainLAB USA, Inc., 69 U.S.P.Q.2d 1853 (Fed. Cir. 2004).. The Federal Circuit decided whether the structure of a means-plus-function limitation required a fixation device. The Federal Circuit affirmed the district court's decision that it did. The specification describes an ultrasound probe that includes a fixation device that secures the probe to the table. The specification consistently states that the probe is to be disposed on or secured to the treatment table. Although a dependent claim included a limitation adding the fixation device, the Federal Circuit found the patentee's argument of claim differentiation unavailing. First, the Federal Circuit stated that this is a guide, not a rigid rule. Second, the Federal Circuit stated that when the claim will only bear one interpretation, claim differentiation does not override this interpretation. Due to this construction, the Federal Circuit upheld the district court's finding of noninfringement, stating that the accused device is not the same nor an equivalent of the corresponding structure of this limitation.

Doctrine of Equivalents

Gaus v. Conair Corp., 70 U.S.P.Q.2d 1380 (Fed. Cir. 2004). In the specification of the patent, Dr. Gaus criticized prior art in which the protective device relied on the fluid coming in contact with the voltage-carrying portions of the system and indicated that his invention avoids the resulting problem, an electric shock to the user. Likewise, Dr. Gaus described his invention as requiring the protective circuitry to function regardless of the operating state of the apparatus, something that the prior art device cannot do. Dr. Gaus thus made it clear that it is essential to his invention that the pair of probe networks be separate from the voltage-carrying components of the appliance. Having disavowed coverage of devices in which the two components are not separate and in which the protective cut-off mechanism is not triggered until the water reaches the electrical operating system, the patentee cannot reclaim that surrendered claim

coverage by invoking the doctrine of equivalents. Accordingly, the district court should have granted Conair Corporation's motion for judgment of noninfringement as a matter of law.

Double Patenting

Bristol-Myers Squibb Co. v. Pharmachemie B.V., 70 U.S.P.Q.2d 1097 (Fed. Cir. 2004). The Federal Circuit reviewed the issue of whether the district court correctly concluded, as a matter of law, that the 1973 restriction requirement was applicable to the 1977 application and therefore resulted in the 1978 divisional application. The district court held that it was and that the patent therefore cannot be applied as a reference against the '927 patent for double-patenting purposes. Pharmachemie, B.V., however, argued that the 1973 restriction requirement was not in effect at the time of the filing of one of the divisional applications that matured into the '927 patent, and that the '927 patent therefore was not filed as a result of that restriction requirement. The Federal Circuit found that the continuation application filed in 1977 began a new proceeding in which all of the original claims were once again presented for examination. In 1977, when the examiner issued the restriction requirement for that application, she did not reinstate or even advert to the 1973 restriction requirement. In fact, the 1977 restriction requirement was different from, and inconsistent with, the 1973 restriction requirement. The record thus did not support the inference that any of the various restriction requirements automatically carried forward, in part or in whole, from one application to the next. For that reason, the Federal Circuit did not sustain the district court's summary judgment order, which was based on the court's conclusion that the 1973 restriction requirement continued in effect in the continuation application that was filed in 1977.

Enablement/Written Description

Chiron Corp. v. Genentech, Inc., 70 U.S.P.Q.2d 1321 (Fed. Cir. 2004). The applications in this case satisfy the enablement requirement only if one skilled in the art, after reading their disclosures, could practice the invention claimed in the '561 patent without undue experimentation. Moreover, the prior application must enable one of ordinary skill in the art to practice the full scope of the claimed invention. Whether the earlier applications enable the claims of the '561 patent is determined as of the filing date of each application. A patent cannot enable technology that arises after the date of application. The law does not expect an applicant to disclose knowledge invented or developed after the filing date. In sum, the district court erred to the extent that it attempted to create an obligation for Chiron scientists to enable nonexistent technology in the 1984 filing. In the context of the 1984 application, the district court and the Federal Circuit need not rely on enablement to support the jury's verdict. The jury may have found that the 1984 application does not provide any support for the new matter, chimeric antibodies, claimed in the '561 patent. Because chimeric antibody technology did not even exist at the time of the 1984 filing, the record conclusively supports that the Chiron scientists did not possess and disclose this technology in the 1984 filing. Thus, the '561 patent cannot claim priority based on the 1984 application because it fails to comply with the written description requirement.

Findings of Fact

Golden Blount, Inc. v. Robert H. Peterson, 70 U.S.P.Q.2d 1624 (Fed. Cir. 2004). In the district court's Findings of Fact and Conclusions of Law, its entire infringement analysis for literal infringement, contributory infringement, induced infringement and infringement under the doctrine of equivalents is presented in six short and conclusory paragraphs. For example, with respect to literal infringement, the only discussion in the entire district court opinion is as follows: "Applying the claim construction referred to in the Conclusions of Law, this Court finds there is [literal infringement of the asserted claims]." There is nothing to explain how the limitations of the claims as construed compare to the allegedly infringing device. In the absence of any findings, the Federal Circuit cannot determine whether the district court had any evidence to support its conclusions, nor is the Federal Circuit able to determine whether the district court applied appropriate legal standards. After a bench trial, a district court must put forth the findings of fact relied on to justify its actions. While Rule 52(a) does not require elaborate, detailed findings on every factual issue raised, the district court opinion must include as many of the subsidiary facts necessary to disclose the steps by which the district court determined factual issues and reached its ultimate conclusions. The Federal Circuit thus concluded that the district court's judgment as to literal infringement, contributory infringement, induced infringement, and infringement under the doctrine of equivalents is insufficient under Rule 52(a). The Federal Circuit vacated those portions of the district court's opinion and remanded those issues to the district court for specific factual findings. Furthermore, because the Federal Circuit vacated the district court's judgment with respect to all aspects of infringement, the Federal Circuit also vacated and remanded the district court's judgment with respect to willfulness, the exceptional nature of the case, and damages.

Infringement

International Rectifier Corp. v. Samsung Elec. Co., 70 U.S.P.Q.2d 1124 (Fed. Cir. 2004). Tracking the language of 35 U.S.C. § 271(a), the permanent injunction at issue prohibited Samsung Electronics Co. (Samsung) from making, using, offering for sale or selling in or importing into the United States the components devices or products infringing any claim of the patent. Based on both the language of the permanent injunction and Section 271(a), neither applies to conduct outside of the United States. Samsung fabricated IXYS-designed devices at Samsung's foundry in South Korea. Samsung sold these devices to an IXYS subsidiary in Germany.

At least some of IXYS's completed devices were sold by IXYS to its customers in the United States. The district court imputed IXYS's conduct to Samsung, concluding that there was an agreement between Samsung and IXYS for IXYS to import the devices into the United States. The district court concluded that Samsung cannot accomplish indirectly through IXYS that which Samsung is prohibited by the injunction from doing directly. The Federal Circuit disagreed with the district court's conclusions. None of the cases cited by the district court purports to extend the scope of liability under the Patent Act beyond the territorial boundaries of the United States. The district court's "subversion by agreement" theory is tantamount to conspiracy to infringe a patent, a theory that has no basis in law. Even if a legal basis were apparent, the district court's finding of an agreement to subvert the injunction is not supported by any evidence, let alone the clear and convincing evidence required in a contempt proceeding. While there is evidence of a fabrication agreement between Samsung and IXYS, that agreement pertains only to the manufacture and delivery of IXYS-designed devices outside the United States. Moreover, there is no evidence that Samsung exercises any control over IXYS or participates in any activities of IXYS following delivery. Because it is undisputed that Samsung conducted no activity in the United States in violation of the agreement and because no evidence supports the district court's finding of an agreement to subvert the injunction, the Federal Circuit found the district court's determination that Samsung's extraterritorial activities violated the injunction to be an abuse of discretion.

Dynacore Holdings Corp. v. U.S. Philips Corp., 70 U.S.P.Q.2d 1369 (Fed. Cir. 2004). There is nothing in the IEEE 1394 standard implying that compliant networks will meet the "equal peers" limitation that is central to every claim in the patent at issue. To the contrary, the requirements of the IEEE 1394 standard suggest that most if not all compliant networks will not meet the "equal peers" limitation. Dynacore Holdings Corp. (Dynacore) has not pointed to even a single network that both complies with the IEEE 1394 standard and meets the "equal peers" limitation, nor has Dynacore presented anything other than speculation that such a network might actually exist. Dynacore has raised little other than a theoretical possibility or metaphysical doubt, which is insufficient to create a genuine issue of material fact.

Interference

In re Sullivan, 70 U.S.P.Q.2d 1145 (Fed. Cir. 2004). In an interference involving issues of priority and patentability, the Board of Patent Appeals and Interferences (Board) terminated an interference in light of a concession on priority by Sullivan. The Board recommended that the examiner consider the patentability issues presented in Sullivan's preliminary motions. Sullivan argued that the Board's action was "void ab initio" because the original declaration of the interference was allegedly unlawful. Whether or not the original interference was erroneously declared, however, the Board subsequently redeclared the interference, in the exercise of discretion under 35 U.S.C. § 135(a) and 37 C.F.R. § 1.640(b)(1). The Board noted that a claim amendment entered simultaneously with the redeclaration of the interference may obviate Sullivan's 135(b) motion. To establish that the Board lacked jurisdiction, Sullivan must demonstrate not that the original declaration was improper, but rather that the redeclaration of the interference was somehow unlawful. On the record, the Federal Circuit did not conclude that the Board's actions in redeclaring the interference was arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or otherwise not in accordance with law. Additionally, the Federal Circuit rejected Sullivan's argument that, because the Board had jurisdiction not only over the issue of priority but also over the patentability issues, the Board was required to address patentability even after it had rendered a decision on priority.

Interference/Written Description

Noelle v. Lederman, 69 U.S.P.Q.2d 1508 (Fed. Cir. 2004). The dispute involved intellectual property directed to a monoclonal antibody. An interference was declared by the PTO between the issued claims of Lederman's patent and Noelle's patent application. Noelle was designated the junior party and Lederman was designated the senior party. Claim 1 of Lederman's patent and Claim 52 of Noelle's application were directed to the "human" form of the antibody. Claims 42 and 51 of Noelle's application were directed to the "mouse" and "genus" forms of the antibody, respectively. The Board of Patent Appeals and Interferences (Board) determined that the human and genus claims in Noelle's later application failed to comply with the written description as of the date Noelle filed its earlier patent application. The Board found that the claims covering the genus and human antibodies constituted new matter because they lacked adequate written description in Noelle's earlier patent application. The Board determined that a person of ordinary skill in the art would not have been reasonably likely to isolate the human antibody given Noelle's claimed invention of the mouse antibody.

Whether a specification complies with the written description requirement of 35 U.S.C. § 112, ¶1, is a question of fact. The test to determine if an application receives the benefit of an earlier filed application is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application. An earlier application that describes later-claimed genetic material only by a statement of function or result may be insufficient to meet the written description requirement. The Federal Circuit has held that a description of DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." The Federal Circuit has also held that one may comply with the written description requirement by depositing the biological material with a public depository.

The Federal Circuit has held that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. The Board was correct in determining that the human and genus claims were anticipated by the prior art and Noelle conceded that without the earlier filing date of his patent application, the claims were indistinguishable from this prior art.

To determine whether the two parties claim the same patentable invention, the PTO has promulgated a "two-way" test, which has been approved by the Federal Circuit. The Board determined that one skilled in the art lacked a reasonable expectation of success of obtaining Lederman's claimed "human" subject matter when provided with Noelle's "mouse" subject matter and using the Noelle screening techniques.

The parties agreed that one of ordinary skill in the art would have been motivated to obtain the human antibody if the mouse antibody were available. The parties disagreed, however, as to whether the prior art would provide a reasonable likelihood of success in so doing. Therefore, the issue before the Federal Circuit was whether substantial evidence supports the Board's determination that one of ordinary skill in the art would not have had a reasonable expectation of success of isolating the other party's invention given the disclosures found in the claims. The Federal Circuit concluded that there was substantial evidence to support the Board's decision that found no interference-in-fact between Noelle's claims and Lederman's claims. The Federal Circuit affirmed the decision of the Board rejecting selected claims of Noelle's patent application, and granting Lederman's preliminary motion of no interference-in-fact.

Invalidity and Inherency

Toro Co. v. Deere & Co., 69 U.S.P.Q.2d 1584 (Fed. Cir. 2004). The alleged infringers, Deere & Co. (Deere), moved for summary judgment that a claim of the '168 patent was anticipated by the '516 patent. The district court found that the '516 patent did not inherently read on or teach the parameters necessary to perform the aeration claimed in the '168 patent. The Federal Circuit found several errors in the district court's analysis.

First, the district court did not expressly construe one of the limitations of the claim. The lack of claim construction left the precise scope of this limitation unclear and, thus, made it impossible to know what the invalidating reference must disclose to invalidate the claim. Second, the district court failed to address whether practicing the '516 invention necessarily featured or resulted in a limitation of the claim. The Federal Circuit, however, found that Deere failed to make the requisite factual showing for inherency.

Third, the district court incorrectly held that to prove the '516 patent inherently disclosed this limitation, it had to be known by those skilled in the art. Instead, the prior art need only necessarily perform the function, the fact that it does so can be unknown at the time. The Federal Circuit found that district court erred in finding that no reasonable factfinder could invalidate the claim of the '168 patent based on the '516 patent. The Federal Circuit vacated the holding that the '168 patent was valid, affirmed the denial of summary judgment of invalidity for anticipation and the grant of summary judgment of infringement of the '168 patent.

Jurisdiction

Gen-Probe Inc. v. Vysis Inc., 70 U.S.P.Q.2d 1087 (Fed. Cir. 2004). The Federal Circuit vacated the district court's findings of noninfringment and invalidity based on the lack of jurisdiction. In 1998, the '338 patent issued to Vysis Inc. (Vysis) and shortly thereafter, a Vysis employee orally informed an employee of Gen-Probe Inc. (Gen-Probe) that it might be infringing the '338 patent. Gen-Probe then obtained a license to the '338 patent and began paying royalties. Gen-Probe later filed a declaratory judgment lawsuit, alleging noninfringement and invalidity. Gen-Probe, however, continued to pay the royalties due on the license. The Federal Circuit stated that because Gen-Probe obtained a license to the patent and continued to pay the licensing fee, Gen-Probe could not have a reasonable apprehension of suit when it initiated the declaratory judgment action.

The Federal Circuit distinguished this case from a prior case, where the alleged infringer had ceased paying royalties and had materially breached the licensing agreement. The Federal Circuit also found that the district court erred in relying on the actions of Vysis that occurred before the consummation of the licensing agreement. Although Vysis had sent letters regarding possible infringement, upon entering into the licensing agreement, Vysis promised not to sue. Thus, the license insulated Gen-Probe from an infringement suit. For these reasons, the Federal Circuit found that it lacked jurisdiction and vacated the district court's findings.

Jury Instructions

Sulzer Textil A.G. v. Picanol N.V., 358 F.3d 1356 (Fed. Cir. 2004).The issue considered was the nature and extent to which district courts are required to give jury instructions in patent cases in which claim constructions are made prior to trial and followed by the parties during the trial. In such cases, the Federal Circuit found that district courts must inform jurors both of the court's claim construction rulings on all disputed claim terms and of the jury's obligation to adopt and apply these meanings of disputed claim terms during deliberations.

The Federal Circuit distinguished its prior case of *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997), where the claim terms were not disputed by the parties at any point in the proceedings and were understood to have their plain meaning. Here, however, the meanings of several claim terms were in dispute and were only resolved by the district court's *Markman* rulings. Despite the district court not complying with this requirement, the Federal Circuit found that the error was not prejudicial.

Another issue addressed in *Sulzer* was that the district court misstated the patentee's burden by stating that the patentee must show that the accused infringer "has *manufactured* its weaving machines using a process which includes all steps of [the claims]." This instruction was incorrect because the patent claims are not directed to manufacturing weaving machines, but to the methods of operating the same. The parties also agreed that the claims are not directed to the process of manufacturing machines. The Federal Circuit stated, however, that "it is not enough to merely show that a jury instruction is erroneous, it must also be shown that the erroneous jury instruction was prejudicial. After reviewing the trial proceedings in their entirety, the Federal Circuit concluded that the reference in the jury instructions to the manufacture of the machines was an error that was apparent and not prejudicial.

Jury Instructions/Claim Construction

Norian Corp. v. Stryker Corp., 363 F.3d 1321 (Fed. Cir. 2004). The patent at issue is directed to repairing bones or teeth with certain rapidly setting calcium phosphate compositions. The patentee moved for a new trial on the issue of obviousness, contending that its case was prejudiced because the jury was allowed to hear evidence of its admitted misstatements to the examiner concerning the teachings of another prior art reference. Norian Corp. attempted to use the summary judgment granted by the district court before trial, which held that inequitable conduct had not been established. The admitted misstatement was made by the patentee's counsel who admitted at trial that he had discovered, in preparing for trial, that during prosecution relating to the other reference he had made "a factual misstatement as to its teaching."

In addition to the jury hearing this admission, the district court instructed the jury that the "presumption of validity varied with the jury's view of whether the examiner believed the applicant's misstatements or otherwise did not 'properly focus on the prior art.'" The Federal Circuit found this instruction was not proper. However, at trial, the patentee did not object to this instruction and the lack of an objection weighed into the Federal Circuit's decision on prejudice. The Federal Circuit stated that in the absence of objection to the jury instruction, and in view of the patent prosecution, the error was not deemed to be prejudicial or the trial unfair.

The jury also found that the claims were invalid based on anticipation by an abstract from an IADR technical conference. Both parties agreed that the invention was described in the abstract, but there was a dispute to whether the abstract was prior art. The district court granted the patentee's motion for judgment as a matter of law, on the ground that there was not clear and convincing evidence that the abstract was actually available at the IADR technical conference. In reaching its conclusion, the district court cited the evidence that (1) Dr. Chow, a co-author of the abstract who testified that he had attended the IADR meeting and had taken along a copy of the abstract to be given to a meeting organizer, could not recall whether he attended the presentation and could not recall whether copies of the abstract were actually available to hand out; and (2) Dr. Tagaki, another co-author who testified that he had attended the presentation, was not questioned about the availability of the abstract. The Federal Circuit noted that although there was testimony that it was the general practice at IADR meetings for presenters to hand out abstracts to interested attendees, the lack of substantial evidence of actual availability of the abstract supported the district court's conclusion.

The district court also granted a motion for summary judgment of noninfringement, holding that the kit contained a spatula, and the patentee's claims did not recite a spatula, and the claims could not be infringed as a matter of law because the claims used the language "consisting of." The Federal Circuit disagreed because the claims recite chemicals that have no interaction with the spatula and, thus, the spatula is irrelevant to the invention. Thus, the Federal Circuit reversed the summary judgment of noninfringement.

Means-Plus-Function

Summit Tech., Inc. v. Nidek Co., Ltd., 363 F.3d 1219 (Fed. Cir. 2004). The jury found willful infringement, that the patent was valid, and awarded the patent owner damages. The district court overturned the jury's verdict finding because there was no substantial evidence to support the jury's verdict of infringement.

The parties disputed whether substantial evidence supports the jury's finding that Nidek Co. (Nidek) infringed the "beam dimension control means" limitation of the patent. The Federal Circuit found that based upon evidence presented at trial the pulses delivered to the surface do not have substantially the same energy per unit area as required by this limitation, but instead have a Gaussian-shaped energy density distribution. The Federal Circuit also found that the patentee could not prove infringement of the term "means for focusing" and, thus, failed to provide evidence to support the jury's verdict.

Obviousness

Ruiz v. A.B. Chance Co., 68 U.S.P.Q.2d 1686 (Fed. Cir. 2004). A.B. Chance Co. argued that the district court clearly erred in utilizing hindsight to find that a person of skill in the art would have been motivated to combine the prior art teachings. While the Federal Circuit warns against employing hindsight, its counsel is just a warning. That warning does not provide a rule of law that an express, written motivation to combine must appear in prior art references before a finding of obviousness. Stated differently, the Federal Circuit has consistently stated that a court or examiner may find a motivation to combine prior art references in the nature of the problem to be solved. This form of motivation to combine evidence is particularly relevant with simpler mechanical technologies. In this case, the record shows that the district court did not use hindsight in its obviousness analysis, but properly found a motivation to combine because the two references address precisely the same problem of underpinning existing structural formations.

Patent Term

Pfizer, Inc. v. Dr. Reddy's Lab., Ltd., 359 F.3d 1361 (Fed. Cir. 2004). The patentee obtained federal registration of an anti-hypertensive, anti-ischemic drug product whose active ingredient is amlodipine, as the besylate salt. In obtaining the registration, Pfizer, Inc. (Pfizer) submitted clinical data obtained using both amlodipine besylate and amlodipine maleate. The besylate salt was selected by Pfizer for ease of tableting. The seventeen-year term of the patent ended on February 25, 2003, but was extended to July 31, 2006 as authorized by the Hatch-Waxman Act.

In December 2001, the defendant filed a new drug application proposing to market amlodipine as the maleate salt based on the data provided to the U.S. Food & Drug Administration (FDA). Dr. Reddy acknowledged that amlodipine maleate is covered by the claims of the patent, but argued that the term extension applies only to the besylate salt because that is the registered product. The Federal Circuit, in reversing the district court, found that the terms of the Hatch-Waxman Act extend the patent term for the registered uses of the drug product, including the salt esters.

The Arnold Partnership v. Jon Dudas, 362 F.3d 1338 (Fed. Cir. 2004). The patent recites compositions comprising hydrocodone and ibuprofen, as well as methods of treating pain with those compositions. Because the two components of the drug had only been available separately, the FDA required a New Drug Application (NDA) before clearing Vicoprofen for the market. The patent is due to expire in 2004 and Arnold filed an application with the PTO for patent-term restoration under 35 U.S.C. § 156 to compensate for the regulatory-review period. The PTO denied the application solely because Vicoprofen did not comply with the "first commercial marketing" requirement of Section 156(a)(5)(A). The PTO found the patent was ineligible for patent-term extension because both hydrocodone and ibuprofen had been marketed previously either alone or in combination with other active ingredients. The district court affirmed the PTO's denial of an extension.

If both active ingredients have been previously marketed in any combination, the new drug containing these ingredients cannot come under the extension provisions of 35 U.S.C. § 156. Based on this reasoning, the Federal Circuit affirmed the decision of the district court. "Even though a drug may contain two or more active ingredients in combination with each other, for the purpose of patent extension that drug is defined through reference to only one of those active ingredients; the other active ingredient or ingredients are merely 'in combination' with this first active ingredient."

Preemption/Claim Construction

Globetrotter Software Inc. v. Elan Computer Group Inc., 70 U.S.P.Q.2d 1161 (Fed. Cir. 2004). Globetrotter Software Inc. (Globetrotter), the patentee, was accused of patent misuse. Ken Greer (Greer), the chief executive officer of Elan Computer Group Inc. (Elan) at the time, alleged that Rainbow Technologies, Inc. (Rainbow) was negotiating to purchase all of the outstanding shares of Elan not already owned by Rainbow. At the time, Rainbow also distributed Elan's allegedly infringing software. While these negotiations were pending, Globetrotter sent an e-mail and two letters to Rainbow alleging infringement of its patents.

The first issue was whether the district court properly granted summary judgment on Greer's state law claims for tortious interference with prospective economic advantage and unfair competition. Greer asserted state law claims of tortious interference with prospective economic advantage and unfair competition, based on the allegations of patent infringement in Globetrotter's e-mail and letters sent to Rainbow. The Federal Circuit has held that federal patent law preempts state law tort liability for a patent holder's good-faith conduct in communications asserting patent infringement and warning about potential litigation. State law claims, such as Greer's, can survive federal preemption only to the extent that those claims are based on a showing of "bad faith" action in asserting infringement.

In the district court, Greer made no effort to establish that the claims asserted by Globetrotter with respect to its patents were objectively baseless, either because those patents were obviously invalid or plainly not infringed. With respect to one of the patents, Greer conceded at oral argument that the only proof of objective baselessness was the fact that the district court granted summary judgment of noninfringement on this patent. The Federal Circuit, however, concluded that Globetrotter's claim of infringement on this patent was not objectively baseless, and in fact reversed the grant of summary judgment. Thus, the district court properly granted summary judgment dismissing Greer's state law claims for tortious interference with prospective economic advantage and unfair competition.

In the summary judgment motion, some of the claims involved the phrase "license file means limitation." Both parties' expert reports and other evidence on summary judgment were both highly technical and confusing. The Federal Circuit stated that "[i]t is not our task, nor is it the task of the district court, to attempt to interpret confusing or general testimony to determine whether a [claim] has been made out, particularly at the summary judgment stage." Because the testimony proffered by Globetrotter raised issues of material fact, the district court's grant of summary judgment of noninfringement was vacated.

The Federal Circuit also reviewed the claim construction of the term "prevent limitation." The claim construction of the prevent limitation as applied by the district court in its grants of summary judgment of noninfringement was incorrect. The district court's claim construction in its *Claim Construction Order,* however, was correct.

Although the Federal Circuit vacated the district court's grant of summary judgment, it noted that a full trial is not necessarily required in this case. The district court retains the discretion to reopen the record for clearer, more specific expert testimony from the parties and to

entertain a new summary judgment motion based on that evidence under the proper claim construction.

Prosecution History Estoppel

SmithKline Beecham Corp. v. Excel Pharm., Inc., 69 U.S.P.Q.2d 1712 (Fed. Cir. 2004). SmithKline Beecham Corp. (Glaxo) amended claims during prosecution to recite hydroxypropyl methyl cellulose (HPMC) and overcome the lack of enablement rejection. HPMC was the only sustained release mechanism disclosed in the patent application. Excel Pharmaceuticals, Inc. (Excel) proposed a formulation that did not include HPMC, but rather included polyvinyl alcohol (PVA). Glaxo accused Excel of infringement under the doctrine of equivalents.

The present record did not address the foreseeability of PVA at the time of the narrowing amendment. Thus, this record did not address whether Glaxo has rebutted the presumption of surrendered equivalents. On remand, the district court may address whether PVA is a foreseeable sustained release agent or an unforeseeable technology. Because a material issue of fact remains to be resolved, Excel was not entitled to summary judgment of noninfringement as a matter of law.

Glaxo Wellcome, Inc. v. Impax Lab., 69 U.S.P.Q.2d 1705 (Fed. Cir. 2004). Glaxo Wellcome, Inc. (Glaxo) amended claims during prosecution to recite hydroxypropyl methyl cellulose (HPMC) and overcome the lack of enablement rejection. HPMC was the only sustained released mechanism disclosed in the patent application. Impax Laboratories, Inc. (Impax) proposed a formulation with a release agent of hydroxypropyl cellulose (HPC). Glaxo accused Impax of infringement under the doctrine of equivalents.

The record showed that at the time the amendments were made, no known hydrogels other than HPMC had been tested with bupropion hydrochloride to achieve sustained release. The record, however, contains considerable evidence that suggests Glaxo could have described the sustained release compound HPC at the time the claims were amended, if not earlier. In this regard, the record showed that both HPMC and HPC were known as sustained release hydrogel-forming polymers in the art of pharmaceutical formulation. The record also showed that Glaxo submitted references to the Patent Office in an Information Disclosure Statement that describe HPC, HPMC, and numerous other polymeric compounds as extended-release drug formulations. These references suggest that Glaxo was aware of these potential hydrogel equivalents at the time of submitting the patent claims and later amended those claims to recite only HPMC. Accordingly, Glaxo has not rebutted the presumption that prosecution history estoppel bars a finding of infringement under the doctrine of equivalents.

Claim 1 of the patent originally recited HPMC as the sustained release agent for bupropion. Because the applicant did not narrow this claim, Glaxo contended that the *Festo* presumption does not divest claim 1 of its equivalents armor. Under Federal Circuit law, the *Festo* bar to the doctrine of equivalents applies to all of the patent claims containing the "critical" HPMC limitation. The Federal Circuit has noted that subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation. The concept initiated by *Builders Concrete,* and confirmed by *Allen Engineering,* is that different claims of a single patent should not be afforded different ranges of equivalents for the same claim term, absent an unmistakable indication to the contrary. Glaxo asserted that because the patentee did not argue that HPMC is critical to enablement of the patent claims, the principles of argument-based estoppel should not apply to any of its claims. Indeed, the examiner initiated the arguments giving rise to the estoppel. Prosecution history estoppel, however, is not limited to the applicant's own words, but may embrace the applicant's responses to the examiner's actions. If the patentee does not rebut an examiner's comment or acquiesces to an examiner's request, the patentee's unambiguous acts or omissions can create an estoppel. No record evidence indicates that the examiner viewed HPMC as less critical to the patentability of claim 1 than its amended counterparts. The Federal Circuit determined there is ample evidence to find that HPC, the asserted equivalent, was a foreseeable sustained release agent for bupropion. Even though claim 1 was not amended to recite HPMC during prosecution, claim 1 will receive the same treatment as its amended counterpart.

Rule 11

Q-Pharma Inc. v. Andrew Jergens Co., 70 U.S.P.Q.2d 1001 (Fed. Cir. 2004). Q-Pharma Inc. (Q-Pharma), the assignee of the patent, sued Andrew Jergens Co. (Jergens) alleging that Jergens' sale of a particular lotion infringed its patent. The only independent claim of the patent required a "therapeutically effective amount" of CoQ_{10}. During the lawsuit, Jergens revealed that the accused lotion contained no more than 0.00005% CoQ_{10} by weight. On obtaining this information from Jergens, Q-Pharma dropped the suit and Jergens instituted a motion for sanctions under Rule 11. The district court found that Q-Pharma's attorneys had performed a claim construction analysis based upon Jergens' literature, which suggested that the lotion contained a therapeutically effective amount of CoQ_{10}. According to the district court, this satisfied Q-Pharma's Rule 11 duties.

Jergens appealed and argued that Q-Pharma's claim construction was overly broad. The Federal Circuit stated that claim interpretation is not an exact science, and that parties often offer competing definitions for claim terms. Q-Pharma's interpretation was broad, but was reasonable. Jergens contended that the written description limited the term "therapeutically effective amount" to be between 0.1% and 10% CoQ_{10}. The Federal Circuit disagreed, stating that nothing in the specification mandated such a limitation. Jergens then argued that pre-filing analysis was not adequate because Q-Pharma only relied on Jergens' advertising literature and did not perform a chemical analysis of the lotion prior to filing suit. The Federal Circuit held that this was not required, and

that Q-Pharma did not solely rely on the advertising and labeling of the lotion, but also compared the advertising and labeling of the lotion with the patent claims. The Federal Circuit also agreed with the district court (1) that this case was not exceptional and did not warrant the awarding of attorney fees; and (2) in its decision to dismiss Jergens' antitrust claim because Q-Pharma's suit was not objectively baseless and it had probable cause to believe that its patent was valid and infringed.

Standing

Fieldturf, Inc. v. Southwest Recreational Industries Inc., 69 U.S.P.Q.2d 1705 (Fed. Cir. 2004. Fieldturf, Inc. (Fieldturf) and Southwest Recreational Industries, Inc. (Southwest) are competitors in the artificial turf market. Fieldturf accused Southwest of infringing its patent. Before addressing the merits, the Federal Circuit must decide whether Fieldturf has standing to sue on its patent.

To bring an action for patent infringement, a party must be either the patentee, a successor in title to the patentee, or an exclusive licensee of the patent. A purported exclusive licensee must show that he possesses all substantial rights in the patent. Lacking all substantial rights, a suit may be brought against third parties only as a co-plaintiff with the patentee or a successor in title to the patentee. Fieldturf asserted that it has standing to enforce the '283 patent against third parties not because it is the patentee or a successor in title to the patentee, but rather because it is an exclusive licensee.

There were two agreements of interest in determining whether Fieldturf was an exclusive licensee. First, the 1994 agreement stated that (1) the assignees had the exclusive right to manufacture and market commercial embodiments of the patent; and (2) the assignors retained the right of first refusal to enforce the patent against infringers, enabling the assignees to bring suit only after the assignors had declined to do so. Second, the 1998 agreement, which cancelled and replaced the 1994 agreement, did not discuss the exclusive right to manufacture and market or enforcement rights.

Because the 1998 agreement is silent with respect to these important considerations (whether the agreement conveys in full the right to exclude others and right to enforce the patent), it is nothing more than an exclusive licensing agreement that fails to convey all substantial interest in the '283 patent. Therefore, Fieldturf lacks standing, and the claim must be dismissed. The Federal Circuit remanded to the district court to determine whether the case should be dismissed with or without prejudice.

35 U.S.C. § 271(g)/Claim Construction

Kinik Co. v. International Trade Comm'n, 362 F.3d 1359 (Fed. Cir. 2004). The Federal Circuit addressed how defenses to infringement available under 35 U.S.C. § 271(g) apply to actions before the International Trade Commission (ITC). The Federal Circuit agreed with the ITC and held that these defenses do not apply when the issue is offshore practice of a patented process.

The patent involves manufacturing an abrasive article by first making a soft and flexible preform from a mixture containing a liquid binder, powdered matrix material, and abrasive particles, and then sintering the preform. The accused infringer argued that the claims are limited to preform mixtures that contain a larger volume of liquid binder composition than powdered matrix material.

The Federal Circuit agreed with the accused infringer and found that the claims require the preform process to employ a volume of liquid binder that exceeds the volume of powdered matrix. The Federal Circuit relied on several statements in the prosecution history and specification. The statements distinguished the excess volume of liquid binder over matrix powder in the preform mixture found in the prior art as well as described the prior art preforms as being hard, stiff, and brittle. Thus, in reversing the ITC decision, the Federal Circuit stated the patent terms have the meaning and scope with which they are used in the specification and the prosecution history.

35 U.S.C. § 272

National Steel Car Ltd. v. Canadian Pacific Railway Ltd., 69 U.S.P.Q.2d 1641 (Fed. Cir. 2004). United States Code title 35, section 272, provides that using certain foreign-owned means of transit or transport entering into the jurisdiction of the United States "temporarily or accidentally" is not an infringing use provided a host of conditions is satisfied. Although the Federal Circuit recognizes that in some instances, there may be ambiguity between containers that are merely the cargo of a vessel or vehicle and vessels or vehicles that are themselves aggregated and transported together. Here, Congress defined "vehicle" with sufficient breadth to include an individual rail car. The Federal Circuit therefore determined that a depressed center beam flat car owned by Canadian Pacific Railway Ltd. (CPR) may be a foreign vehicle and therefore is not disqualified from the noninfringing status created by Section 272 on this basis. On the issue of when is a vehicle only entering the United States temporarily under Section 272, the district court held that the accused rail car will not be temporarily present in the United States because it will spend the majority of its time delivering lumber to United States destinations and because CPR will derive significant benefit from using the accused railcar in the United States. Confronted with an ambiguous statute, the Federal Circuit turned to the legislative history to discern Congress' intent in defining "temporarily." The Federal Circuit defined a vehicle entering the United States "temporarily" as a vehicle entering the United States for a limited period of time for the sole purpose of engaging in international commerce. The Federal Circuit concluded that CPR's defenses demonstrate substantial challenges to National Steel Car's allegations and remanded the district court's preliminary injunction.

Written Description

University of Rochester v. G.D. Searle & Co., 69 U.S.P.Q.2d 1886 (Fed. Cir. 2004). An invention may be described without an enabling disclosure of how to make and use it. For example, a description of a chemical com-

pound without a description of how to make and use it, unless within the skill of one of ordinary skill in the art, is an example. Moreover, an invention may be enabled even though it has not been described. Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B if B were described. A specification can likewise describe an invention without enabling the practice of the full breadth of the claims. Still further disclosure might be necessary to satisfy the best mode requirement.

The Federal Circuit stated that the asserted patent is deficient in failing to adequately describe the claimed invention. First, although compliance with the written description is a question of fact, the University of Rochester's arguments that a patent may not be held invalid on its face is contrary to Federal Circuit case law. Second, it is undisputed that the patent does not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known. In sum, because the patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art at the relevant time, the University of Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention.

Trademarks

ACPA Was Not Violated Because Defendant Did Not Act in Bad Faith

Lucas Nursery & Landscaping, Inc. v. Grosse, 70 U.S.P.Q.2d 1149 (6th Cir. 2004). Michelle Grosse (Grosse) was dissatisfied with landscaping performed by her contractor, Lucas Nursery and Landscaping Inc. (Lucas Nursery). Consequently, Grosse registered the domain name "lucasnursery.com" and posted her negative complaints about Lucas Nursery on that site.

Lucas Nursery filed suit against Grosse, alleging violation of the Anticybersquatting Consumer Protection Act (ACPA), 15 U.S.C. § 1125(d)(1)(A). Under the ACPA, a "cybersquatter" who registers a domain name that is identical or confusingly similar to a protected mark is potentially liable to the mark owner, if the cybersquatter had a bad-faith intent to profit from the mark. The district court concluded that Grosse lacked bad faith and granted summary judgment in her favor.

On appeal, the Sixth Circuit stated that, when determining whether a person acted in bad faith under the ACPA, courts usually look to several ACPA factors regarding intent. The first four factors focus on whether the defendant may have had a reasonable basis for registering the domain name. The first three factors did not favor Grosse: (1) she did not hold intellectual property rights in the domain name; (2) the domain name did not consist of her name; and (3) she had not used the domain name to offer goods or services. However, the fourth factor did favor her because she used her website for bona fide noncommercial purposes.

None of the other four factors, which are indicative of the presence of bad faith, disfavored Grosse: (1) Grosse could not have sought to divert customers from Lucas Nursery's website because Lucas Nursery did not have a website; (2) Grosse did not offer to sell the site to Lucas Nursery; (3) Grosse did not provide misleading contact information; and (4) Grosse did not acquire any other domain names.

Even though the first three ACPA factors weighed against Grosse, the court attached great significance to the fact that Grosse had not acquired multiple domain names. The Sixth Circuit ultimately reasoned that Grosse seemed to have been motivated by a desire to inform the public about Lucas Nursery, rather than by a bad-faith intent to profit. The Sixth Circuit therefore affirmed the grant of summary judgment in favor of Grosse.

Determination of Laches First Requires Examination of Confusion

What-A-Burger of Virginia, Inc. v. Whataburger, Inc., 69 U.S.P.Q.2d 1829 (4th Cir. 2004). Whataburger, Inc., of Corpus Christi, Texas (Texas WAB) owns several U.S. registrations for WHATABURGER, the first of which issued on September 24, 1957. What-A-Burger of Virginia, Inc. (Virginia W-A-B) has purportedly used the name What-A-Burger in Virginia since at least August 1, 1957. Virginia W-A-B and Texas WAB first learned of one another in 1970. At that time, the parties discussed a license agreement. Texas WAB made clear that if the parties were unable to reach agreement, it would expect Virginia W-A-B to change its name. The next contact between the companies occurred in 2002 when Texas WAB sent Virginia W-A-B a letter indicating it understood that Virginia W-A-B may have been previously granted the right to use the mark WHATABURGER, but that Texas WAB needed documented proof. Virginia W-A-B then filed a declaratory judgment action in federal district court regarding ownership of the trademark WHAT-A-BURGER in Virginia. Texas WAB filed a counterclaim for declaratory judgment as to its ownership of the mark.

The district court ruled *sua sponte* that Texas WAB was barred by laches and acquiescence from enforcing its right in the mark WHATABURGER in Virginia. The district court found that Texas WAB had known of the activities of Virginia W-A-B since 1970 but had failed to follow-up on its original contacts for over thirty years.

On appeal, the Fourth Circuit found that there was never any infringing use of the mark WHATABURGER by Virginia W-A-B to which Texas WAB needed to respond. The Fourth Circuit examined laches under

three factors: (1) whether the mark owner knew of infringing use; (2) whether the owner's delay in challenge was inexcusable; and (3) whether the infringing user was unduly prejudiced by the delay.

The Fourth Circuit held that the period of delay should be measured from the point at which an owner knows of an infringing use that is sufficient to require litigation. It further noted that a trademark owner is not obligated to sue until "the likelihood of confusion looms large," and that requiring an owner to sue at the first sign of a potential infringing use would "foster meritless litigation." The Fourth Circuit affirmed the district court's holding that Texas WAB was the rightful owner of WHATABURGER and held that a likelihood of confusion did not exist. The Fourth Circuit found that the district court did not have a basis for invoking laches because it had not made any finding as to likelihood of confusion. The Fourth Circuit also held that a likelihood of confusion did not exist and remanded for entry of judgment for Texas WAB.

"Exceptional" Case Described As "Oppressive"

Eagles Ltd. v. American Eagles, 69 U.S.P.Q.2d (6th Cir. 2004). American Eagle Foundation (AEF) appealed a denial by the U.S. District Court for the Eastern District of Tennessee of a motion for attorney's fees and costs under 15 U.S.C. § 1117(a).

AEF is a nonprofit organization dedicated to the preservation and protection of the bald eagle. In addition to its other activities, AEF sells and promotes music-related products. Defendant Eagles, Ltd. (EL) is affiliated with the rock and roll band, the Eagles and owns the registered trademark and service mark EAGLES.

In 1995, AEF filed a trademark application for the mark AMERICAN EAGLES RECORDS, and EL filed an opposition. In 1998, before the PTO ruled on the application, EL filed suit against AEF in federal district court for violations of the Lanham Act.

Two weeks before trial, which was set to begin in April 2000, EL moved for substitution of counsel and requested a continuance. The district court granted the motion for substitution of counsel but denied EL's request for a continuance. EL then moved for voluntary dismissal of its action, and the district court dismissed EL's case with prejudice. Following dismissal, AEF moved for attorney's fees and costs under 15 U.S.C. § 1117(a). The district court denied AEF's motion, finding that the case was not "exceptional" under 15 U.S.C. § 1117(a).

On appeal, AEF claimed that the district court abused its discretion because it failed to adequately articulate reasons for its finding. The Sixth Circuit disagreed and determined that the district court had clearly stated the applicable law and had given reasons for its denial. However, the Sixth Circuit reviewed the district court's findings *de novo*. Acknowledging that circuits apply different tests, the Sixth Circuit held that an exceptional case is one "where a plaintiff brings a suit that could fairly be described as 'oppressive'"—both objectively and subjectively. The Sixth Circuit held that EL's conduct could not be described as oppressive and it affirmed the district court's decision.

Finding of Dilution in Absence of Survey Evidence

NASDAQ Stock Market, Inc. v. Antartica S.r.l., 69 U.S.P.Q.2d 1718 (T.T.A.B. 2003). Antartica S.r.l (Antartica) filed an application to register the mark NASDAQ & Design for various sporting goods in Classes 9, 25 and 28. The application was filed under Section 44 based on a prior Italian registration having a filing date of July 14, 1998. The term "NASDAQ" is identified by Antartica as an acronym for the Italian phrase "Nuovi Articoli Sportivi Di Alta Qualita," which translates as "new sports products of high quality."

NASDAQ Stock Market, Inc. (Nasdaq) filed an opposition to Antartica's application claiming prior use, asserting that its NASDAQ mark was inherently distinctive and famous throughout the world and that Antartica's NASDAQ & Design mark would dilute and diminish its famous mark. Nasdaq also claimed that its registration was incontestable and that its use of its mark on collateral promotional products gave it prior use in connection with the specific classes of goods covered by Antartica's application.

According to the Board, Nasdaq proved the fame of its mark through the evidence it submitted in the opposition proceeding. That evidence included: excerpts from printed publications dating back to the 1970s that referred to the NASDAQ mark; a tally of the number of hits to its website per day; an estimate of people who pass by its MarketSite facility in Times Square per year; and the dollar amount spent on television, radio, and print advertising. Nasdaq also provided testimony evidence concerning the sporting events the company had sponsored as part of its promotional activities and the length of time its branded clothing and sporting goods had been available to the public. Although the Board found this evidence insufficient to establish use of the NASDAQ mark in connection with clothing and sporting goods prior to the applicant's asserted date of priority, the Board did determine that Nasdaq's use of the NASDAQ mark on collateral merchandising activities was a natural outgrowth of its business and had expanded over time.

The Board found that Nasdaq had established fame in the NASDAQ mark and that its fame existed before the applicant's priority filing date. The Board determined that survey evidence of dilution was not necessary in this case because the marks were very unique and effectively identical, the NASDAQ mark was made famous by the opposer prior to the applicant's filing date and Nasdaq's activities over time had only served to increase the fame of the NASDAQ mark. The Board concluded that whether or not consumers were familiar with the NASDAQ mark for financial services, permitting Antartica to use the identical unique mark for sporting goods would result in consumer confusion and blurring of the famous NASDAQ mark.

Initial Interest Confusion

Playboy Enterprises, Inc. v. Netscape Communications Corp., 69 U.S.P.Q.2d 1417 (9th Cir. 2004). Playboy Enterprises International Inc. (PEI) appealed a grant of summary judgment awarded to Netscape Communications Corp. and Excite Inc. (collectively, NCC/EI) in PEI's suit alleging trademark infringement and dilution under the Lanham Act. In reversing and remanding the district court's decision, the Ninth Circuit applied the standard of initial interest confusion it adopted in *Brookfield Communications, Inc. v. West Coast Entertainment Corporation*, 174 F.3d 1036 (9th Cir. 1999).

When an Internet user searched for PEI's marks on NCC/EI's search engines, a number of banner advertisements for competitor's websites would automatically appear. NCC/EI also included PEI's marks on a list of key words that advertisers were *required* to incorporate into banner advertisements for adult entertainment. Many of the banner advertisements were unlabeled and had "click here" buttons linked to third-party websites. Additionally, NCC/EI did not require advertisers to include a source identifier on banner ads or to label their advertisements to distinguish them from PEI. NCC/EI also refused to require advertisers to cease using PEI's trademarks as key words. The Ninth Circuit found that NCC/EI's actions could reasonably be construed as an intent to cause confusion among consumers.

The Ninth Circuit found that consumers, under the mistaken belief that the banner advertisements were affiliated with PEI, could click on the labeled links and enter a competitor's website. Although a consumer might immediately realize, after clicking on a banner ad, that the website was not affiliated with PEI, the Ninth Circuit found that the damage would have already been done because the consumer would have reached a competitor's site solely because of the use of PEI's trademarks as key words.

In applying the eight-factor "likelihood of confusion" test, the Ninth Circuit found that PEI's expert study presented to the district court was sufficient to prove the extent of the initial interest confusion between PEI's marks and its competitor's. Although NCC/EI criticized PEI's expert survey, they had not offered evidence contradicting the expert report and thus a genuine issue of material fact as to actual confusion still existed. The Ninth Circuit remanded the case on both the trademark infringement and dilution issues.

"Lawoffices" in Internet Domain Name Descriptive

DeGidio v. West Group Corp., 69 U.S.P.Q.2d (6th Cir. 2004). Anthony DeGidio (DeGidio) appealed a summary judgment order granted to West Group Corporation (West Group) by the U.S. District Court for the Northern District of Ohio.

DeGidio registered the domain name "lawoffices.net," but he did not own or obtain a federal or state trademark registration for the designation. DeGidio owns and founded a corresponding web site that provides legal information, a directory of forty attorneys, a vanity e-mail service, listing of domain names for sale, and a hosting service for legal-related websites. West Group markets the West Legal Directory, an online source of legal information, using the designation and domain name "Lawoffice.com."

DeGidio filed suit against West Group on August 24, 1999, alleging violation of various federal and state trademark laws. Both parties moved for summary judgment. Relying on a six-factor test for distinctiveness articulated by Professor McCarthy, the district court found that DeGidio's mark LAWOFFICES was, at best, descriptive. The district court further found that the mark had not acquired a secondary meaning and therefore was not protectable.

On appeal, the Sixth Circuit found that, even viewing the evidence in the light most favorable to DeGidio, the mark LAWOFFICES was very close to the descriptive end of the suggestive/descriptive continuum of marks as applied to online legal information. The Sixth Circuit did not address whether the mark LAWOFFICES would be descriptive or suggestive with regard to domain name sales, website hosting, and vanity e-mail because West Group was not accused of providing those services on their website. The Sixth Circuit affirmed the district court's decision.

Personal Name Protected by Trademark

Peaceable Planet, Inc. v. Ty, Inc., 70 U.S.P.Q.2d 1386 (7th Cir. 2004). Peaceable Planet, Inc. (Peaceable Planet) began selling a plush toy camel named "NILES" in 1999. Approximately one year later, Ty, Inc. (Ty) also began selling a plush toy camel named "NILES." Peaceable Planet filed an action against Ty, asserting claims of trademark infringement and false advertising under the Lanham Act, as well as several state law claims. The district court ruled that NILES, as a personal name, was a descriptive mark and was not protectable without proof of secondary meaning. The district court granted summary judgment in favor of Ty, holding that Peaceable Planet had not established that NILES had acquired secondary meaning.

On appeal, the Seventh Circuit stated that the common law "personal name rule," which denies trademark protection to personal names until they acquire secondary meaning, should not be applied in all cases. The Seventh Circuit stated that the personal name rule should not be followed when the policies behind the rule are not implicated. The Seventh Circuit held that none of the policies was implicated in this action because: (1) protecting NILES, as applied to toy camels, did not prevent people from using their own names in business; (2) Niles was not a common name, so consumer confusion will not be likely; and (3) protecting NILES would not deprive consumers of useful information. Additionally, the Seventh Circuit held that NILES, as applied to toy camels, is suggestive rather than descriptive.

The Seventh Circuit concluded that NILES was a valid trademark as applied to Peaceable Planet's toy camel and reversed the grant of summary judgment. On remand, Peaceable Planet would have the opportunity to prove trademark infringement through "reverse confusion."

"REALTOR" Held Not Generic

Zimmerman v. Nat'l Ass'n of Realtors, 70 U.S.P.Q.2d 1425 (TTAB 2004). Jacob Zimmerman (Zimmerman) sought cancellation of the registered marks REALTOR and REALTORS. Zimmerman alleged that the marks are generic because the words "realtor" and "realtors" are synonymous with "real estate agent." Zimmerman claimed to have been injured in his domain name sales business because The National Association of Realtors (NAR), owner of the marks, has threatened to file suit against any person using the term "realtors" in a website name without authorization; thus inhibiting his ability to sell his domain names to real estate agents.

The Board examined the extensive record under the six-factor test for genericness delineated by the Federal Circuit, focusing its attention on the parties' survey evidence. Although both parties produced survey evidence, the surveys were focused on different subsets of the public. Zimmerman's survey focused on members of the general public who had approached a real estate agent in the past year or were planning to do so in the coming year. NAR's survey targeted real estate brokers and agents. Zimmerman's survey showed that only 10 percent of ninety-six participants thought "Realtor" was a brand name. NAR's survey showed that 84 percent of its 204 participants associated the term with members of NAR or its associations.

The Board found deficiencies in Zimmerman's survey and accorded it very little weight. In contrast, the Board agreed with NAR that real estate professionals make up a significant subgroup of relevant consumers. It also found that Zimmerman's survey expert noted that people in the real estate industry would likely identify "Realtor" as a mark. As such, the Board held that in the channels of trade where the services offered under the marks are directed to real estate agents and brokers, the terms function as source-identifiers. The Board recognized that it might have analyzed the case differently had Zimmerman's survey been less deficient. Nevertheless, it held that the record before it supported a finding that the marks REALTOR and REALTORS functioned as collective service marks and were not generic terms.

Technical Difficulties Using Trademark Electronic Application System

In re Henkel Loctite Corp., 69 U.S.P.Q.2d 1638 (Director P.T.O. 2003). Henkel Loctite Corporation (Henkel Loctite) filed a petition with the commissioner's office seeking review of the filing date awarded in its application after its original earlier attempts at filing the application through the Trademark Electronic Application System (TEAS) were unsuccessful because of technical difficulties.

On April 16, 2003, Henkel Loctite attempted to file a trademark application using TEAS. The entire application process proceeded normally until the applicant clicked the Pay/Submit button after completing the deposit account information page, at which point the applicant received the error message "Fatal Error—Access Denied." Several hours later, the applicant again attempted to file the application through TEAS and received the same error message at the same stage in the application process. The applicant then sent an e-mail to the TEAS Help Desk outlining the situation and requesting instructions on how to proceed. The TEAS Help Desk responded by e-mail later that evening and advised the applicant that TEAS had begun having technical problems earlier that day and that all TEAS forms would be unavailable until the problem was resolved, probably by the morning of April 17, 2003.

On April 17, 2003, the TEAS Help Desk contacted the applicant by e-mail to advise that the TEAS forms were available and that the system had been restored at 7:20 p.m. on April 16, 2003. Thereafter, applicant successfully submitted its application and received the filing date of April 17, 2003. Henkel Loctite filed its petition to the commissioner several days later.

In granting the applicant's request for the April 16, 2003 filing date, the Commissioner considered the following facts: (1) the applicant was unable to submit its application through TEAS because of technical difficulties beyond the applicant's control; (2) the applicant acted conscientiously in refiling the application twice in the same day; and (3) the applicant notified the TEAS Help Desk of the technical difficulties in a timely manner.

Copyrights

Comic Characters Copyrightable

Gaiman et al. v. McFarlane et al., 360 F.3d 644 (7th Cir. 2004). Comic-book scriptwriter Neil Gaiman sued comic-book artist and publisher Todd McFarlane under the cCopyright aAct to be declared a joint copyright owner in three comic-book characters from the *Spawn* series: Medieval Spawn, Angela, and Count Nicholas Cogliostro. Gaiman developed the characters in writing, and McFarlane illustrated the characters and incorporated them into a number of stories. The district court entered a judgment that Gaiman was a co-creator of the three characters, and McFarlane appealed.

The Seventh Circuit first resolved in Gaiman's favor a statute-of-limitations issue turning on the accrual of Gaiman's action for declaration as a joint copyright owner. The Seventh Circuit next turned to McFarlane's argument that Gaiman was not a co-owner of copyrights in the three characters. McFarlane submitted two arguments to thwart Gaiman's claim. First, McFarlane argued that Gaiman contributed only the ideas for the characters, and is thus not a co-owner of the copyrights, because ideas are not copyrightable. Second, McFarlane argued that Gaiman's contributions of the Medieval Spawn and Cogliostro characters were not copyrightable because Gaiman merely contributed stock characters under the "scenes a faire" doctrine. The Seventh Circuit pointed to distinctive qualities in Gaiman's contributions—including the differences between Medieval Spawn, which the Seventh Circuit determined was a co-creation of Gaiman and McFarlane, and Spawn, created

solely by McFarlane—to determine that Gaiman was indeed a co-creator of all three characters.

Film Faceoff: Independent Creation and Substantial Similarity

Murray Hill Pub., Inc. v. Twentieth Century Fox Film Corp., 361 F.3d 312 (6th Cir. 2004). Murray Hill owned all rights in a treatment and a screenplay for a movie entitled *Could This Be Christmas* (CTBC). After learning of Fox's development of a similarly themed film, *Jingle All The Way* (JATW), Murray Hill informed Fox of its rights in CTBC and sent a series of cease-and-desist letters to Fox. The two companies entered into unsuccessful settlement negotiations, Fox released JATW in 1996, and Murray Hill sued Fox for copyright infringement in 1997.

The district court found that a treatment for JATW, which was created prior to submission by Murray Hill of the CTBC screenplay to Fox, did not infringe on the CTBC screenplay. But the jury, uninformed of the court's decision, rendered a verdict in favor of Murray Hill. The district court entered judgment in favor of Murray Hill in the sum of $19 million. Fox moved for judgment as a matter of law and also moved for a new trial. The court granted Fox's motion for judgment as a matter of law on most damage items, reducing the award to $1.5 million. Fox and Murray Hill both appealed.

Before the court of appeals, the key issue was the supposed substantial similarity of the two works. In the Sixth Circuit, resolving substantial similarity first requires identification of the protectable firstly identifying which aspects of the artist's work, if any, are protectible by copyright, and secondly allowing aa jury to must determine whether the two works taken as a whole are substantially similar in look and feel. Murray Hill's expert prepared a list of twenty-four similarities between the JATW movie and the CTBC screenplay, but all but six of these similarities existed in a treatment prepared independently of access to the CTBC screenplay by the writer of JATW. Finding in favor of Fox, the Sixth Circuit determined that the independently created elements must be discounted from the substantial similarity analysis, and that the six other similarities "differ significantly" at the level of actual expression and are extremely common at a level of abstraction that covers both JATW and CTBC.

Not Much Fun for Poem Compiler: Creativity Questionable

Silverstein v. Penguin Putnam Inc., 368 F.3d 77 (2d Cir. 2004). Plaintiff compiled and published 122 poems in a book entitled *Not Much Fun: The Lost Poems of Dorothy Parker*. The poems were not included in the original author's existing collections. The poems were collected primarily from magazines and newspapers, and two had never been published. The plaintiff had given the defendant publisher the opportunity to publish the collection, which the defendant turned down. Subsequently, the defendant published *Dorothy Parker: Complete Poems*, which included her existing collections and added a section containing 121 of the 122 poems found in the plaintiff's book. The defendant admitted photocopying the poems directly from *Not Much Fun*, but rearranged the poems chronologically, rather than in the plaintiff's more subjective arrangement.

The lower court granted the plaintiff's motion for summary judgment and issued a permanent injunction, finding that the selection of poems evinced the level of creativity needed to support copyright protection in the compilation. On appeal, the Second Circuit reversed the lower court, holding that material questions of fact existed as to whether the plaintiff exercised sufficient creativity in selecting the works for *Not Much Fun*.

The plaintiff argued that several original contributions to the collection demonstrated sufficient creativity, including differences with Parker biographers in the classification of works as poems, additions and omissions made to the manuscript after it was presented to the defendant, and subjective copyediting changes. The Second Circuit called into question these activities, noting first that the biographers in question had no communications with plaintiff. The biographers had acknowledged in their writings that their lists of works may be incomplete. Likewise, the omission of a few poems from those found in the bibliographies doesn't conclusively show creativity, since no evidence was presented that the plaintiff even knew the poems existed. The addition of about twenty-five poems after the manuscript was submitted to the defendant was not supported by evidence showing when the plaintiff discovered these poems, or when or why he decided to exclude them. Finally, while it is questionable whether copyedits such as changes in punctuation, capitalization, indentation, and titling are protectable elements, plaintiff's introduction of the book jacket implied the works appear as originally published, and failure to provide notice of such changes estopped the plaintiff from asserting infringement on this basis.

Official Registration Certificate Required to Maintain Infringement Claim

Loree Rodkin Management Corp. v. Ross-Simons Inc., 2004 U.S. Dist. LEXIS 7534 (C.D. Cal. 2004). The plaintiff designer filed several copyright applications for five jewelry designs with the United States Copyright Office. Subsequently, the plaintiff filed suit against various defendants claiming copyright infringement of the jewelry designs. One defendant moved to dismiss the action for lack of federal subject matter jurisdiction.

The central district court of California noted a split of authority on the issue of whether a pending copyright application is sufficient to confer to subject matter jurisdiction, including a decisive split between various California district courts. Several courts have found a pending registration sufficient, corresponding with the conclusion in the leading treatise on copyright law. Nonetheless, the court followed a second line of cases holding that the plain language of the Copyright Act

unambiguously mandates the actual issuance of a registration certificate.

In particular, Section 411(a) of the Act prohibits a party from suing until registration of the copyright claim has been made. Section 410(a) of the Act states that the register of copyrights shall register a claim and issue a certificate after examination. However, Section 410(d) states that the effective date of a copyright registration is the day on which an application, deposit, and fee have all been received. The court agreed with the conclusion that, because only the register of copyrights can register a claim, the deposit of material and application does not constitute registration. The court noted that this conclusion is further supported by the second sentence of Section 411(a), which permits an applicant to institute an action for infringement when registration has been refused, so long as notice is served on the register of copyrights. Thus, examination is a prerequisite of "registration." The court found that Section 410(d) was merely a mechanism for "backdating" a registration, which can only be obtained from the Copyright Office after examination.

Protect Your Parts: Expression of Doll's Features Is Copyrightable

Mattel, Inc. v. Goldberger Doll Mfg. Co., 365 F.3d 133 (2d Cir 2004). Plaintiff Mattel is the creator of, and owns copyright in, the world famous Barbie doll. Defendant Radio City operates the Radio City Music Hall theater in New York City, which features the widely renowned Rockettes chorus line. To celebrate the millennium, Radio City created a doll, which it named the "Rockettes 2000" doll. Mattel brought suit alleging that in designing the Rockettes 2000 doll, Radio City infringed its copyrights by copying facial features from various Barbie dolls.

The district court granted summary judgment of noninfringement, believing there was nothing copyrightable about the doll's facial features: "[w]hen it comes to something as common as a youthful, female doll, the unprotectible elements are legion, including, e.g., full faces; pert, upturned noses; bow lips; large widely spaced eyes; and slim figures." The Second Circuit disagreed, finding that Mattel's particular depiction of the Barbie doll's facial features to be protectible—however limited that protection might be. The Second Circuit stressed that Mattel's copyright will not protect these features but, rather, its particular expression of the features. The district court's grant of summary judgment was vacated, and the case was remanded.

V.A.R.A. Protection Requires Recognition

Scott v. Dixon, 309 F. Supp. 2d 395 (E.D.N.Y. 2004). Plaintiff Scott is an artist who designed a gigantic swan sculpture for the defendants' estate at the defendants' request. The swan sculpture, which was approximately forty feet long and about ten feet tall, was placed in the private backyard of the defendants, but was not clearly visible to the public due to the configuration of the backyard. Later, the defendants sold their estate and, as a condition of the sale, removed the sculpture and placed the dismantled sculpture in storage. The sculpture was damaged during storage.

The plaintiff, seeking damages under the Visual Artists Rights Act (VARA) for destruction of her artwork, alleged that the plaintiff's storage conditions destroyed her swan sculpture. To prevail under VARA, the plaintiff must demonstrate, *inter alia,* that the sculpture is a work of "recognized stature." 17 U.S.C. § 106A(a)(3)(B). Works of recognized stature, within the meaning of VARA, are those works of artistic merit that have been recognized by members of the artistic community, the general public, or both. The district court concluded the swan sculpture was not recognized within the meaning of VARA because the sculpture was never reviewed by the artistic community or viewed by the public.

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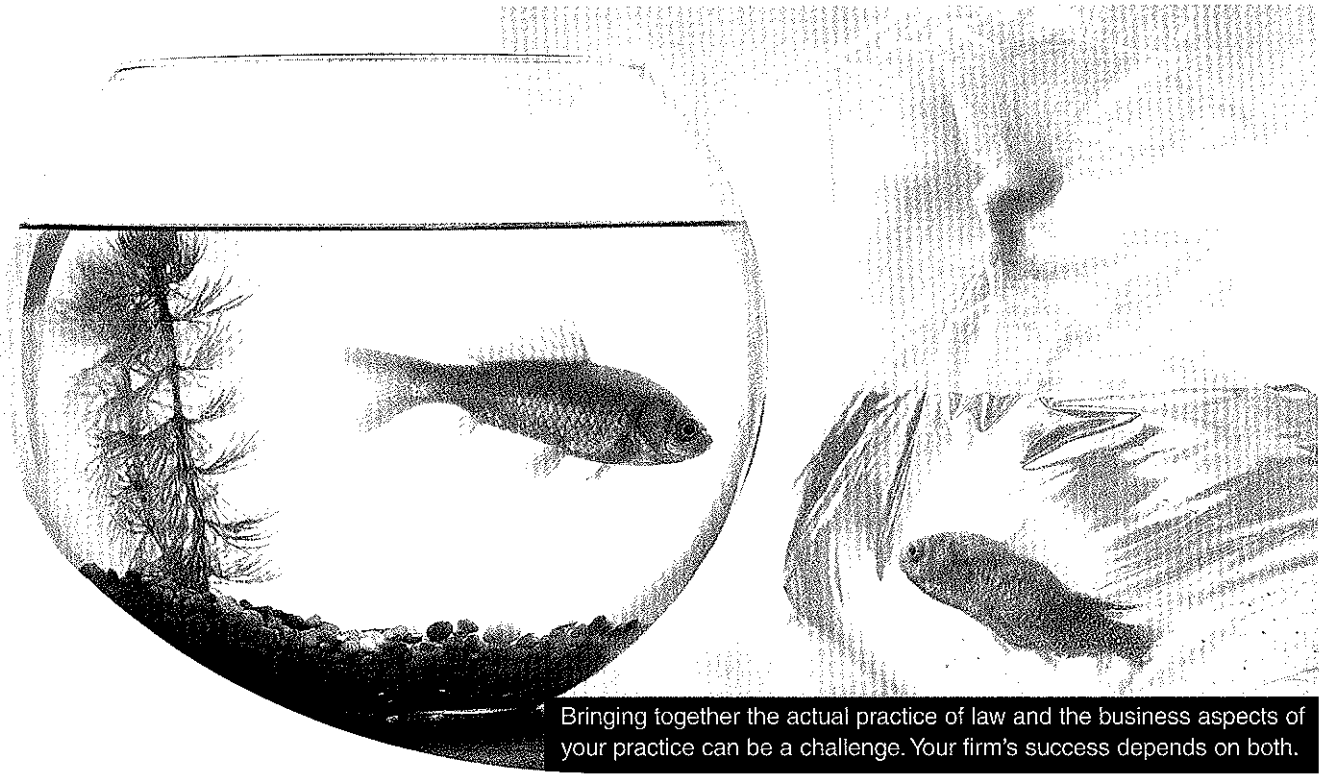

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