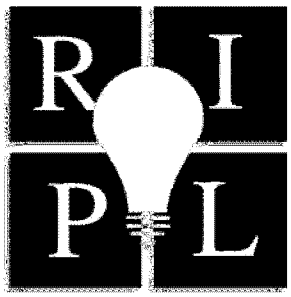
THE JOHN MARSHALL
REVIEW OF INTELLECTUAL PROPERTY LAW



DEVELOPMENTS IN PATENT LAW 2004

HAROLD C. WEGNER

ABSTRACT

There are a great number of patent law doctrines that are currently under reconsideration by the Federal Circuit. These doctrines include patent claim construction under the 2006 *Phillips* case, the problem of foreign activity being used as patent-defeating prior art as shown in the recent *Elsner* case, the growing challenge of extraterritorial acts as patent infringement as presented in the 2004 expected cases of *Blackberry* and *Eolas*, the "Rule 105" implications for patent office practice in *Star Fruits*, the change in willful infringement law set forth in the recent *Knorr-Bremse* case, the continuing problem of co-inventorship recurring in *Xechem*, the search for statutory utility dealt with in the 2005 *Fisher* case and the ever present possession requirement for utility. This article presents a brief summary of the cases involving these eight doctrines and discusses the potential implications of each on current patent law and practice.

Cite as Harold C. Wegner, *Developments in Patent Law 2004*, 4 J. MARSHALL REV. INTELL. PROP. L. 1 (2004).

DEVELOPMENTS IN PATENT LAW 2004*

HAROLD C. WEGNER**

OVERVIEW

A great number of patent law doctrines are under reconsideration by the Federal Circuit. This paper provides an overview of recent decisions and current cases that are likely to shape the patent laws for the years to come.

The most important area of controversy in patent law today is the area of patent claim construction. Currently, the United States has by far the most arcane and complex set of rules to interpret patent claims of any major country in the world. This truth is to the great detriment of business certainty and Wall Street confidence behind investments in technology-dependent industries. Yet, panel predictability and a "shuffling" of precedent may in the end be all that can be expected in the en banc decision expected perhaps fifteen months or so from now in the *Phillips* case, discussed in Part I.

A major trend in the patent law is the growth of the use of foreign activity as patent-defeating prior art, which was triggered by the recent *Elsner* case, discussed in Part II.

Another hot area of controversy is the challenge of adapting to the global reality that internet technology may be practiced in part outside the United States but still impact domestic commerce. Claims, therefore, need to be tailored to provide for infringement by a party within the United States. Even now, some of the claims before the courts have been drafted to recite at least one element that pertains to activity outside the United States. Expected before the end of 2004 is a key case in this area: the *Blackberry* case, discussed in Part III.A. A different issue in this area of controversy involves the *Eolas* case, in which an American patentee who failed to obtain foreign patent coverage but sought to bootstrap claims to foreign infringement through the special export infringement provision of § 271(f). The *Eolas* case is discussed in Part III.B.

Perhaps the most important procedural case to be decided in some time relating to practice before the U.S. Patent and Trademark Office ("USPTO") is the *Star Fruits* case that, if affirmed, will provide a Federal Circuit imprimatur of acceptance of the controversial "Rule 105"—whereby the USPTO can require "information" from an assignee unrelated to the persons involved in the procurement of the patent application and on issues far broader than the scope of "material" information under the now familiar "duty of disclosure." The *Star Fruits* case is discussed in Part IV.

In addition, in its opinion in *Knorr-Bremse*, the Federal Circuit recently returned the issue of willfulness awards in patent infringement to the discretion of

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* This paper was prepared for and presented to the Cleveland Intellectual Property Law Association, October 20, 2004.

** Harold Wegner is the former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School; Foley & Lardner, Washington, D.C. The views expressed herein are entirely pro bono and personal to the author and do not necessarily reflect the views of any colleague or client or any organization with which the author is affiliated.

the trial courts under a "totality of the circumstances" test. The *Knorr-Bremse* case is discussed in Part V.

Co-inventorship continues to be a problem for post-grant attempts by third parties to add an inventor who has not assigned his patent rights to the original assignee. By naming the additional co-inventor, the assignee from that co-inventor then has a free right to practice the invention independent of the rights of the original patentee(s) or any original "exclusive" licensee(s). This scenario is illustrated in the *Xechem* case, discussed in Part VI.

For emerging technologies, such as nanotechnology, as well as those in the more mature biotechnology and chemical areas, the potential blockbuster case for 2005 may be *Fisher*, which involves an attempt by a biotechnology applicant to have the court find statutory utility under 35 U.S.C. § 101 based upon a nebulous statement of usefulness that is contrary to the controlling precedent of the 1967 split opinion in the *Kirk* case. The *Fisher* case is discussed in Part VII.

Finally, continuing for now to exist—and fester—on the doctrinal "back burner," as well as a furthering a sense of aggravation and uncertainty in the chemical industry, is the special panel-dependent requirement for "possession" of an invention as a species of the "written description" requirement, discussed in Part VIII.

I. THE LIKELY 2006 *PHILLIPS* CLAIM CONSTRUCTION CASE

In *Phillips v. AWH Corp.*, the Federal Circuit determined to hear the case en banc to resolve seven issues related to the construction of patent claims:

> (1) Is the public notice function of patent claims better served by referencing primarily to 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 narrowly construed for the sole purpose of avoiding invalidity under, e.g., 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.*, 517 U.S. 370 (1996), and our en banc decision in *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998), 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?[1]

Patent managers cannot wait until 2006 for the en banc opinion in *Phillips* to retool their overall patent procurement procedures to deal with the results of that case. The legal standards that are likely to emerge from *Phillips* are dealt with elsewhere.[2] Much can *already* be seen that must be done and *should* be done "today."

A. A Focus upon Clear and Literally Infringed Claims

While *Phillips* may be up to eighteen months away from a decision, what *is* clear already is that the trend of the past several years toward a strict construction of claims against a careless patentee will continue.[3] Thus, even under the mainstream approach of the *Liebel-Flarsheim* case, the best that a patentee can hope for from an infringement claim construction determination is that his claims will be given their ordinary meaning *if* they are clearly drafted.[4] Even under *Liebel-Flarsheim,* a clearly worded claim may well be given a diminished scope if there is an unequivocal argument surrendering a given scope protection.[5] Cases have shown that even if the terminology is clear, the use of the wrong two-letter preposition—"to" instead of "at,"

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[1] Phillips v. AWH Corp., 376 F.3d 1382, 1383 (Fed Cir. 2004).

[2] *See* Harold C. Wegner, *Claim Construction: The En Banc Phillips Case: Substantive Law of Claim Construction, Procedural Deference to the Trial Court, Policy Concerns & Practice Under the Trend of Recent Case Law*, 160, *available at* http://www.foley.com/files/tbl_s31Publications/FileUpload137/2190/claimconstruction.pdf (last visited Nov. 8, 2004).

[3] *Phillips*, 376 F.3d at 1382.

[4] Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 913 (Fed. Cir. 2004).

[5] *Id.* at 906.

as shown in the *Chef America* case[6]—may lead to a nonsensical interpretation which makes the claim worthless. A simple spelling mistake of one word—"from" instead of "for"—led to the same result in *Teknowledge*.[7] With the notable exception of one of the twelve members of the court who has shown a continuing attitude of liberality as manifested in *Merck v. Teva*,[8] the majority of the court—including the mainstream followers of *Liebel-Flarsheim*—follows the strict and unforgiving approach of *Chef America*. If *Liebel-Flarsheim* and *Chef America* represent the center of the court, and *Merck v. Teva* represents a solitary vote at one end of the bell-shaped curve, the other end is represented by the panel opinion in *Phillips*—an *even stricter* view of claim interpretation. Whereas the center-viewed members of the court in *Liebel-Flarsheim generally* look to the specification and prosecution history only for the contextual setting of claim wording, the vacated majority opinion in *Phillips* looks to the specification as a major and *primary* source for claim construction, even at the expense of the ordinary meaning of the claim's wording.

The various briefs amici curiae in the *Phillips* case primarily embrace the *Liebel-Flarsheim* middle road, while a minority endorses the stricter view of the *Phillips* panel. However, *nobody* endorses the holistic and unstructured approach of *Merck v. Teva*.

The bottom line for industry is that these harsh limits of claim construction which have existed for the past few years will either continue in their current form or be made more severe. There is *no* trend toward the liberality of earlier days when the court was far more forgiving of patentee mistakes, omissions, or simply the tunnel vision or lack of 20-20 hindsight appreciation of the need for broader claims.

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[6] Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1375 (Fed. Cir. 2004). The *specification* disclosed a baking process that included a step of heating dough *at* a temperature of up to 850° F. for a period of at little as ten seconds to set the batter. *Id.* at 1372. However, the *claim* instead stated a limitation of "heating the . . . dough *TO* a temperature in the range of about 400° F. to 850° F. for a period of time ranging from about 10 seconds to 5 minutes" for the purpose of setting the batter. *Id.* at 1371 (emphasis added). Obviously, the examples did not disclose creating a dough product at 850°—a temperature so high that a self-cleaning oven is automatically locked to safeguard the kitchen user. *Id.* at 1373. Such at temperature would transform any bakery effort into a charcoal-like result. *Id.* Yet, the claim called for heating *TO* a temperature of 800° degrees, a totally nonsensical result. *Id.* (emphasis added).

[7] Teknowledge Corp. v. Akamai Techs., Inc., No. C02-05741 SI, 2004 WL 2042864, at *5 (N.D. Cal. Sept. 11, 2004). A typographical error created a nonsensical meaning for an internet business claim where a part of the process concerned objects "fetched *for* [the] clients." *Id.* at *4. However, the claim called for "objects fetched *from* [the] clients." *Id.* at *5. Finding this nonsensical claim construction not infringed—and the claim itself fatally indefinite and thus invalid—the court noted that "[t]he clear line of Federal Circuit authority dictates that this Court may not re-draft claims to change their ordinary meaning, even if the ordinary meaning produces a nonsensical result." *Id.* at *7. Thus,

> even assuming that this was a typographical error, the Court cannot redraft the claim to render it operable. The purpose of claim language is to "put[] competitors on notice of the scope of the claimed invention", and to "prevent[] unduly burdening competitors who must determine the scope of the claimed invention based on an erroneously drafted claim."

Id.

[8] Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1371 (Fed. Cir. 2003) (reading a claim limited to a specific "acid" to reach the chemically absurd result, *see id.* at 1374–75 (Mayer, J., dissenting), that the claimed acid was considered to be a "salt" to save the patentee who failed to claim the acid *and derivatives* of the acid).

Industry in the nineties clamored for greater certainty in claim construction as the notice function of patents became of paramount importance. The ultimate reach of the notice function as viewed by the mainstream members of the Federal Circuit necessarily comes at a price to patentees who do *not* provide fair notice for their invention in their patent. This is evident where the patentee discloses but does not claim the invention. The result is a hardball claim construction regime, which, at its most extreme, is perhaps best exemplified by *Chef America*. The patent community had in essence *asked* that the court provide the tough rubric of *Chef America,* and now the flip side of the question is how to adapt patent drafting and prosecution techniques to the realities of such an approach.

B. The Need to Claim all Disclosed Embodiments

It is extremely important when a patent is drafted that the claims be carefully checked against the essential *disclosed* embodiments to ensure the claim wording is broad enough to cover those embodiments. Failure to obtain *literal* coverage may translate into failure to obtain *any* coverage under the *Johnson & Johnston* "disclosure-dedication" rule.[9] In *Johnson & Johnston*, the court held that

> when a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would "conflict with the primacy of the claims in defining the scope of the patentee's exclusive right."[10]

While the patentee in *Johnson & Johnston* had *intentionally* refrained from literally claiming the disclosed equivalent, the court in *Toro* expressly held "that intent is not part of the *Johnson & Johnston* disclosure-dedication analysis."[11] In contrast, the patent drafters of *Merck v. Teva* made a simple mistake—one which had occurred not infrequently in previous years but without penalty.[12] Merck owned a patent to an acid that could be administered in the form of its salts. [13] The salts were specifically disclosed in the patent's specification.[14] The patentee *should* have claimed the specific "acid and pharmaceutically acceptable salts thereof."[15] Instead, the patentee merely claimed the acid, per se.[16] The salts were clearly *equivalent* to the acid; anyone with even a fundamental knowledge of chemistry would understand

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[9] Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc).

[10] *Id.*

[11] Toro Co. v. White Consolidated Indus., Inc., 383 F.3d 1326, 1333 (Fed. Cir. 2004). The court also found that "[t]he language of *Johnson & Johnston* [was] clear" and quoted it with approval: "'The patentee's subjective intent is irrelevant to determining whether unclaimed subject matter has been disclosed and therefore dedicated to the public.'" *Id.* (quoting *Johnson & Johnston*, 285 F.3d at 1053 n.1).

[12] *Merck*, 347 F.3d at 1370–71.

[13] *Id.* at 1371.

[14] *Id.*

[15] *Id.*

[16] *Id.*

that the salts were *disclosed equivalents* and—until recently—should have been found to be covered under the doctrine of equivalents.[17] However, under the en banc ruling in the *Johnson & Johnston* case, it is better to *fail* to disclose an unclaimed equivalent because a disclosed equivalent is now barred from being considered an infringing equivalent.[18]

C. A Frills-Free First Patent Application

1. Focus on the Claim Drafting Exercise

Patent attorneys must focus their patent drafting skills on both the claims and providing definitions and other support for the claims. Often, patent attorneys who are "stumped" by trying to figure out the scope of an invention disclosure will idle their mental gears by describing the prior art known to them and creating "objects" and other background information that has nothing to do with support for the claims under 35 U.S.C. § 112, ¶ 1.[19] This "filler" material is essentially worthless and has no place in an original provisional (or perhaps other) application. If anything, it can hurt the patentee if the true state of the art later develops to include closer prior art. This is especially the case where an "object" is not met by all aspects of the invention, or a faux statement of criticality is created which could be used by an opponent to narrow the scope of protection or create an issue of inequitable conduct. *The bottom line is none of this patent "garbage" needs to be in an application, even if accurate.*[20]

2. Simple Claim Language

Claim language should be extremely simple. The elements of the claim should be worded as simply as possible. In addition, the default should be for an open transition such as "comprising."

3. Arcane American Claim Formats

Jepson language should be eschewed wherever possible to avoid any admission as to the state of the art. Above all, the default should be to *never* use a "means" term in a claim.

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[17] *Id.*

[18] Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1053 (Fed. Cir. 2002) (en banc).

[19] 35 U.S.C. § 112, ¶ 1 (2000).

[20] To be sure, the applicant *must* comply with his duty of disclosure under 37 C.F.R. § 1.56. Yet, the duty does *not* require the applicant to provide a general (or other) *characterization* of the prior art; rather, it requires only that the applicant *identify* the prior art. *See* 37 C.F.R. § 1.56 (2004).

4. A Limited Number of Claims

It is far better to provide five to ten crisply worded and clearly defined claims than to have 100 claims that are difficult to piece together and understand.

5. A Simple Summary with Definitions

The "Summary" in the specification should start with a *verbatim* copy of "claim 1," including other generic descriptions from other claims, modified by adding a verb. This should be followed by definitions of terms. It is also important before the application is filed that, after it has had a chance to "sit" for a few days, the claims be reviewed from the perspective of a third party who may not understand the claim language. Therefore, when the claim is read from such a perspective, if it is discovered that there is any ambiguity or terms that require a definition, the definition section can be used to "fill in the gaps" early on.

6. Avoiding a Court-Imposed Dictionary Definition

It is too early to tell precisely what the Federal Circuit will decide in *Phillips* regarding the role of dictionaries in the claim construction analysis. Whether dictionaries may become a "primary" tool, on par with "intrinsic" evidence, or remain merely a secondary tool to help educate the court in the claim construction inquiry, is uncertain. Yet, the problem of a court relying on a dictionary is due in large part to the failure of the patent draftsman to have *anticipated* the need for a definition. Beyond the obvious suggestion that clear and unambiguous language should be used, there are some things that can easily be done today to avoid whatever problems may continue to be present in the wake of *Phillips*.

a. Definitions in the Patent Specification Itself

The writer of a patent application who has worked on the document through several revisions, without pause, is perhaps the least likely person to observe a defect in claim wording in terms of either ambiguity or lack of definition. If the draft of the application can be left to "sit" for several days, then the draftsman can review the case with a fresh set of eyes. Thus, when terms in a given claim are identified as ambiguous—if not simply replaced or eliminated with a redrafted claim—such terms can be *defined* in the specification. In so doing, the patentee acts as his own lexicographer and trumps any dictionary or ordinary meaning to the contrary.

b. Nomination of a Dictionary or Review Article

Often, a patent attorney is working with one particularly useful review article or a certain edition of a particular scientific dictionary. In this case, the original

specification may include a citation to that particular work as the arbiter of any definitional disputes.

7. Continual Review of the Claim Language During Procurement

a. Review Within Eighteen Months of the First Filing

One of the best safeguards against mistakes in draftsmanship is that an invention is maintained in secrecy for a full eighteen months starting from the time of the provisional (or other) application filing and ending with the automatic publication of the patent application.[21] If a mistake in draftsmanship is found which would prove fatal *if the patent were granted* and if there is no basis to redraft the claims based upon the original specification and if there is secrecy throughout this period, then it is possible to file a *new* application because the faulty one has not yet been publicly disclosed.[22]

It is extremely important within the first year after filing to have a complete and careful review of all aspects of the application because at the end of that time there needs to be a "perfect" patent application to file under the Patent Cooperation Treaty ("PCT") for foreign protection (or otherwise via the national route).[23] *Changed* definitions or scope in the PCT application should never be the general rule because a *changed* definition or scope that is not supported in the original application may stand naked as of the *actual* PCT filing date. Rather, the better approach is to *maintain* all original definitions and have claims keyed to these original definitions (which will then enjoy priority) and to then, if necessary, *add* additional definitions and claims (that will stand as of the later date). To the extent the original disclosure is not carried forward into the later case, to only have a *changed* definition and to *delete* definitions from the earlier case as part of the PCT filing *nullifies* the original disclosure for purposes of the PCT application.

b. Review as Part of an Integrated, Global Procurement

The same person who drafted the original application also should prosecute the domestic application as well as any foreign counterpart applications. Every office action—whether from Alexandria or Munich or Tokyo or elsewhere—may provide a clue as to an ambiguity or a formal problem in the language used. These serve as immediate triggers to study whether (1) there is a fundamental problem in the

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[21] *Id.* § 1.211.

[22] It is possible to defer the U.S. "new" filing until up to thirty months from the original date because the statutory bar under 35 U.S.C. § 102(b), which is based upon the inventor's publication, takes effect only one year after publication. 37 C.F.R. § 1.495. However, if one waits beyond the publication date, then any chance to use the new patent application for *foreign* purposes will be swept aside, as the publication of the application will create an immediate bar in Europe and Japan, where there is no grace period based upon the publication of the patent application by the government—in fact, Europe has no grace period whatsoever. *Id.*

[23] Patent Cooperation Treaty, June 19, 1970, art. 8, 28 U.S.T. 7645, 9 I.L.M. 978.

underlying document which would require a re-filing of the case (unless a statutory bar already exists) or (2) claim wording can be modified to overcome the problem. Only if the same person handles *all* aspects of the application process—from drafting to domestic and foreign procurement—will the opportunity to catch these kinds of mistakes be optimized. To the extent that foreign procurement is segregated to a different unit, a Pandora's Box of problems is created which, at the very least, can lead to inconsistent definitions and arguments. Even worse, the segregation of the drafting process to a unit or person who never sees the application after it has been returned to corporate headquarters for prosecution can cause these same problems to begin as early as the domestic application.[24]

c. Pre-Grant, Post-Allowance Review of the Patent Claims

At some point downstream in the procurement process—not later than the review of an application after a Notice of Allowance—at the very least, the independent patent claims should be carefully reviewed to ensure accurate literal coverage and clarity of claim draftsmanship. This should be part of an integrated review to make sure that where an embodiment is *disclosed* in the specification, it is also *literally claimed.* As part of this review, the attorney should play devil's advocate to find loopholes in the coverage for obvious embodiments that are outside the range of literal coverage.[25]

d. Post-Grant Review (Within Two Years)

Seemingly simple mistakes must be caught early. Minor mistakes in wording can often be corrected without causing the problem of new matter or "written description" basis in the specification. However, if such changes are proposed in a reissue application, more than two years after the grant date, they may be barred under 35 U.S.C. § 251, which proscribes filing a reissue for a claim broader than that found in the original patent.[26]

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[24] In the era before *Chef America* and *Johnson & Johnston,* a climate of cheap patent procurement developed in some arts. The entire patent drafting process would be shipped out to the Sun Belt to retired patent attorneys on a case by case basis or to firms with large pools of patent agents or draftsmen who never had face-to-face contact with the inventors. Once drafted, a different pool of generally in-house patent lawyers would pick up a case for the first time to consider the merits—after an Examiner's first action. This meant that an entirely different set of eyes which were out of tune with both the inventor and the drafter of the patent application evaluated and defended the merits of the application.

[25] This does not mean that the case must be refiled and the current case abandoned. To the contrary, the norm today is to file a "*Vogel* trailer." *See* Symposium, *The End of Equivalents? Examining the Fallout from Festo,* 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 727, 742 (2003) (discussing the "*Vogel* Trailer" and implications of *In re Vogel,* 422 F.2d 438 (C.C.P.A. 1970)). Before the grant of the patent, a continuation application is filed to cover miscellaneous embodiments that could not be fit within the claims as allowed by the examiner. *Id.* A terminal disclaimer is required for such a case with overlapping claim coverage. *Id.*

[26] 35 U.S.C. § 251 (2000).

II. *ELSNER*: FOREIGN ACTIVITY AS "PRIOR ART"

In *Elsner*, a Board of Patent Appeals and Interferences panel further eroded the definition of "prior art" insofar as previously there had been an exclusion of foreign uses or sales as patent-defeating prior art.[27] Once Japan switched camps to move in the direction of the French absolute novelty standard,[28] the historic proscription on foreign use or sale as "prior art" under American patent law became a unique peculiarity in the global patent scene.[29] In 1978, the absolute novelty standard became the common denominator for Europe with the implementation of the Munich Patent Convention, which serves as the cornerstone treaty for the European patent system.[30] There has been much discussion as to whether the United States should unilaterally adopt this system or whether it should hold out for a balanced treaty with other countries—using its now unique position on prior art as a "bargaining chip."[31]

Regardless, without any citation of authority whatsoever from any of the public policy debates in support of such a radical change—or citation of any scholarly or other writing—an en banc panel of the Federal Circuit in *Elsner* has judicially legislated a repeal of the territoriality limitation.[32] The court dismissed the retroactivity aspect of its judicial legislation, with the advice—too late for patentees and applicants who have already filed or who are outside the new time bar—that "avoidance of a bar [merely requires] a timely filing at the PTO."[33] Beyond the damage of retroactivity and the necessary destabilization and cries of panel uncertainty and unpredictability that are created by judicial legislation of this nature, one clear point that remains is when Congress does decide to make a statutory change to codify the ruling in *Elsner*, it will be clear whatever "bargaining chip" value there had been in the limitation of territoriality, the judiciary has unilaterally swept the rug out from under our negotiator's feet.[34]

A. One of the Last "Bargaining Chips"

Use or sale of an invention in Europe or Japan or, for that matter, anywhere outside the United States, is not—under most aspects of the patent statute—patent-

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[27] *In re* Elsner, 381 F.3d 1125, 1126 (Fed. Cir. 2004) (en banc) (finding claims anticipated in view of foreign sales).

[28] *See, e.g.*, James E. Ruland, *Identifying the Unglittering Gold: Recognizing Minor Improvements & Obtaining Valuable Patents*, 15 No. 4 J. PROPRIETARY RTS. 4, 8 n.32 (2003) (stating that France and Japan have "world-wide absolute novelty with a limited number of exceptions").

[29] *See* 35 U.S.C. § 102(b).

[30] European Patent Convention, Oct. 5, 1973, art. 54(2), 1065 U.N.T.S. 199 (also known as the Munich Patent Convention), *available at* http://www3.european-patentoffice.org/dwld/epc/epc_2002_v1.pdf (last visited Nov. 8, 2004). "The state of art shall be held to comprise *everything made available* to the public by means of a written or oral description, by use, *or in any other way*, before the date of filing of the European Patent application." *Id.* (emphasis added).

[31] *See infra* Part II.A.

[32] *See infra* Part II.B.

[33] *In re* Elsner, 381 F.3d 1125, 1129 (Fed. Cir. 2004) (en banc); *see infra* Part II.C.

[34] *See infra* Part II.D.

defeating against an original innovator.[35] This is due to the territorial limitations of United States patent law that bar the grant of a patent if the same invention has been "in public use or on sale in this country."[36] Should the United States internationalize its patent laws to conform to the goals of the scholar critics and international patent community which do not have such a geographic limitation? Should the United States do so unilaterally in the interest of the American innovative community? Should the United States hold out for a harmonization treaty using our disparity with international practice as a "bargaining chip" to gain concessions from European and Asian negotiating partners in international fora?

Scholars, including Professors Takenaka[37] and Bagley,[38] have been highly critical of the geographic limitations on prior art. Professor Takenaka presents a comparative trilateral view of the geographic restrictions within American law in the context of patent harmonization and the need for the United States to eliminate the existing geographic restrictions under 35 U.S.C. § 102(b).[39] She points out that "[a]n adoption of [the Substantive Patent Law Treaty] will require the United States to remove the geographical restrictions that presently limit the definition of prior art."[40] She also suggests the more sweeping mandate that even unwritten foreign activities be considered prior art.[41] Perhaps more importantly, however, Internet-keyed information is clearly "prior art" under the treaty,[42] a point which was domestically addressed in Japan five years ago with a revision of its domestic patent law.[43] Professor Moy states that "particularly modern [authorities] assert the major

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[35] There has been some erosion of this principle in the context of limited reliance upon foreign activity under 35 U.S.C. § 102(g) (2000).

[36] Title 35 U.S.C. § 102(b) bars a patent to an "invention . . . patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Additionally, under 35 U.S.C. § 102(a), an invention is unpatentable if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

[37] Toshiko Takenaka, *The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a "First-to-Invent" Exception for Domestic Applicants*, 11 TEX. INTELL. PROP. L.J. 259, 305–06 (2003).

[38] Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 680 (2003).

[39] Takenaka, *supra* note 37, at 305 (discussing the *Draft Substantive Patent Law Treaty*, art. (1), Sept. 24, 2001, World Intellectual Property Organization, Standing Committee on the Law of Patents, 7th Sess.).

[40] *Id.* Professor Takenaka notes that "Article 8(1) [defines the] prior art as 'all information, which has been made available to the public anywhere in the world in any form.'" *Id.* at 276–77 (quoting *Draft Substantive Patent Law Treaty*, art. 8(1), Sept. 24, 2001, World Intellectual Property Organization, Standing Committee on the Law of Patents, 7th Sess.). "SPLT Regulation Rule 8 explains any form that includes oral communication, display, and use of the invention." *Id.* at 305 n.372 (citation omitted).

[41] *Id.* at 305. "The current U.S. system discriminates between written and unwritten information and removes from the prior art unwritten information that is available only in foreign countries. This distinction introduces unnecessary complexity in examination at the USPTO." *Id.* (footnote omitted).

[42] *Id.*

[43] *Id.* at 305 n.374 ("Japanese patent law was revised to remove geographical restriction on non-documentary prior art in Article 29, § 1, and made foreign public use and knowledge as the prior art for rejecting an application regarding both novelty and inventive step.").

justification [for the geographic limitation on prior art] to be largely administrative."[44] Professor Moy counts as one of several writers who have criticized the American policy, including Professors Bagley,[45] Kadidal[46] and Bliss,[47] as well as Donald Chisum, who was an advocate for elimination of the geographical limitation more than a full generation ago.[48]

B. Judicial Legislation from Madison Place

In an act of judicial legislation, an en banc panel of the Federal Circuit in *Elsner* has swept the negotiating chips off the table and unilaterally and retroactively started the United States down the slippery slope toward elimination of the geographic limitation on public uses and sales.[49] The technical issue before the court in *Elsner* was whether an otherwise non-enabling prior art publication is an anticipation.[50] This, of course, is obviously not the case.[51] However, in addition to the publication itself, there was a foreign sale of the claimed subject matter.[52] There was, however, no nexus between the non-enabling prior art publication and the foreign activity.[53] Nevertheless, the court held that since there was a foreign use or sale, this meant one skilled in the art could practice the invention and, as such, the otherwise non-enabling prior art was enabled by that foreign sales activity.[54]

The court, at first, acknowledged that "[o]rdinarily, foreign sales of an invention in combination with a publication will not constitute a bar because such a result

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[44] R. CARL MOY, MOY'S WALKER ON PATENTS § 8:192 n.1 (4th ed. 2004) (citing William LaMarca, *Reevaluating the Geographical Limitation of 35 U.S.C. § 102(b): The Policies Considered,* 22 U. DAYTON L. REV. 25 (1996)) [hereinafter WALKER ON PATENTS]; *see also* PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, "TO PROMOTE THE PROGRESS OF THE . . . USEFUL ARTS" IN AN AGE OF EXPLODING TECHNOLOGY 5 (1966).

[45] WALKER ON PATENTS, *supra* note 44, § 8.192 n.1.

[46] *Id.*

[47] Daniel H. Bliss, *Bridge Over Troubled Water: Extending the Public Use Bar to Foreign Countries,* 1987 DETROIT C.L. REV. 65 (1987).

[48] Donald S. Chisum, *Foreign Activity: Its Effect on Patentability Under United States Law*, 11 I.I.C. 26, 26 (1980).

[49] *See generally In re* Elsner, 381 F.3d 1125, 1129 (Fed. Cir. 2004) (en banc).

[50] *Id.* at 1127–28.

[51] In *Elsner* and a companion *Zary* case, the facts involved publication of plant breeders' rights certificates that qualified as 35 U.S.C. § 102(b) prior art, but which clearly did not enable practice of the invention under *In re* LeGrice, 301 F.2d 929 (C.C.P.A. 1962). Thus,

> appellants . . . assert that, because foreign sales are not prior art under the patent statute, they may not be considered within the knowledge of one of skill in the art and cannot be used to enable an otherwise non-enabled publication. They claim that the published [prior art] applications are not enabled because it is impossible to recreate the claimed plants from the textual descriptions alone, and they assert that the published applications are therefore not effective as § 102(b) references.

Elsner, 381 F.3d at 1128. The court stated that "[t]he particular question thus before us is whether evidence of the foreign sale of a claimed reproducible plant variety may enable an otherwise non-enabled printed publication disclosing that plant, thereby creating a § 102(b) bar. On that issue of first impression, we hold in the affirmative." *Id.*

[52] *Id.* at 1127.

[53] *Id.* at 1131.

[54] *Id.*

would circumvent the established rules that neither non-enabling publications nor foreign sales can bar one's right to a patent."[55] Indeed, that has been the law. Notwithstanding, the court reasoned that "[w]hat sets this case apart is that it deals with plant patents[.]"[56] Distinguishing the body of law that otherwise clearly bars use of foreign activity as a statutory bar, the court affirmed the foreign activity to create a statutory bar under 35 U.S.C. § 102(b), noting that "[b]ecause we perceive a difference between plants and statutorily distinct inventions, we disagree with Appellants' contention that this holding will operate to create a printed publication bar whenever a non-enabling publication and a foreign sale are involved."[57]

The court cited no Federal Circuit precedent for its distinction of "plants" versus other patents in connection with the scope of prior art under 35 U.S.C. § 102(b).[58] As such, the court implicitly recognized that the distinction it had drawn was one without meaning.

At oral argument, Judge Clevenger posed the hypothetical question of whether an announcement in a "Finnish" paper about a new "Nokia" product which was not enabling could be converted into a statutory bar against a later filing to that product if the "Nokia" product were available in Finland.[59] Indeed, one can well imagine that there could be countless trade papers, e-mails to the industry, website postings and the like that could technically be considered a "printed publication" similar to the prior art in the *Elsner* case and yet be equally non-enabling. The author of *Elsner* would distinguish Judge Clevenger's hypothetical case on the basis that *Elsner* claimed a plant.[60] However, there is nothing in 35 U.S.C. § 102(b) on which to draw such a distinction.[61] *Elsner* is simply the latest in a series of cases where a Federal Circuit panel has judicially expanded the scope of prior art.[62]

C. "You Should Have Filed Earlier"

In terms of the retroactivity of the law, the *Elsner* court was not concerned that its decision would adversely impact pre-existing patent applicants, stating that: "in any event, the inventor is in control of the activities relating to his invention, and avoidance of a bar is accomplished by making a timely filing at the PTO."[63]

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[55] *Id.*

[56] *Id.* at 1128.

[57] *Id.* at 1129.

[58] *See id.* at 1128–31.

[59] Transcript of Oral Arguments Before the United States Court of Appeals for the Federal Circuit, *In re* Elsner, 381 F.3d 1125 (Fed. Cir. 2004) (en banc) (Nos. 03-1569, 03-1585).

[60] *See Elsner*, 381 F.3d at 1128.

[61] *See* 35 U.S.C. § 102(b) (2000).

[62] *See, e.g., In re* Kathawala, 9 F.3d 942 (Fed. Cir. 1993) (transforming the forfeiture provision for novelty only for what is claimed into a prior art basis for obviousness under 35 U.S.C. § 103(a) including the unclaimed teachings of the patent); OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396 (Fed. Cir. 1997) (transforming the bar based upon derivation into prior art for obviousness under 35 U.S.C. § 103(a)); *cf.* WALKER ON PATENTS, *supra* note 44, § 8:278 ("The issue under [35 U.S.C. §] 102(d) is whether patenting would result in domestic industry being unfairly constrained in relation to the industry of the foreign country. This requires reference, not to the foreign patent's ability to teach the art, but to its preclusive effect.").

[63] *Elsner*, 381 F.3d at 1129.

Certainly, this is good prospective advice. However, to the patent applicant with a case already on file who relied upon the law at the time he filed his case, there is little solace.

D. The March to End Prior Art "Territoriality"

The "bargaining chip" value *vel non*—in terms of gaining reforms of European and Asian laws as a price for the internationalization of American law—of the unique American viewpoint has now been largely spent. Surely, Congress will eventually codify the change in the patent laws which have taken place in *Elsner*. Whether it was wise for the Federal Circuit to have judicially jumped the legislative gun is now be a subject for the scholars to debate.

III. EXTRATERRITORIAL ACTS AS PATENT INFRINGEMENT

Two very high-profile Internet infringement cases are in the pipeline for ultimate resolution at the Federal Circuit.[64] Expected at any time is a decision by the court in the *NTP, Inc. v. Research in Motion, Ltd.* patent litigation—popularly known as the "*Blackberry*" case.[65] Not yet docketed at the Federal Circuit is an appeal in the case of *Eolas Technologies, Inc. v. Microsoft Corp.*,[66] where the trial court awarded $521 million in damages.[67] Each case involves the issue of patent extraterritoriality.[68]

A. Blackberry*: A Claimed Combination with an Offshore Element*

Internet patent claims often include a combination of elements. In addition, crucial acts often take place outside the United States. The *Blackberry* patent litigation involves a claim to an Internet-based combination (system).[69] One of the issues is whether such a claim is infringed if one of the elements of that combination

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[64] *See* NTP, Inc. v. Research in Motion, Ltd., 261 F. Supp. 2d 423 (E.D. Va. 2002); Eolas Techs., Inc. v. Microsoft Corp., 274 F. Supp. 2d 972 (N.D. Ill. 2003).

[65] *NTP*, 261 F. Supp. 2d 423. The appeal was argued on June 7, 2004. The defendant in *NTP*, Research in Motion, Ltd., or "RIM," is the manufacturer of the Blackberry Pager, one of the accused devices in the case. *Id.* at 426.

[66] *Eolas*, 274 F. Supp. 2d 972.

[67] Paul Festa, *The Eolas-Microsoft case—patent ending?,* CNET NEWS.COM, Mar. 16, 2004, *at* http://news.com.com/2100-1032_3-5173287.html.

[68] *See NTP*, 261 F. Supp. 2d at 429 (finding that to be liable for infringement "it is only necessary that [the defendant] provide some of the components of [the] patented invention in the United States, even if such component [sic] will be combined outside of the United States"); *Eolas*, 274 F. Supp. 2d at 973–74 (permitting plaintiffs to seek damages for infringing products made outside of the United States).

[69] *See NTP,* 261 F. Supp. 2d at 425–26.

is practiced offshore (in Canada).[70] A key ground for noninfringement in the case relates to the offshore practice of at least one element of the combination.[71]

In *Pellegrini v. Analog Devices, Inc.*, the Federal Circuit put another nail in the extraterritoriality coffin against patentees who either failed to properly claim their inventions to provide for a domestic act of infringement or simply failed to obtain foreign patent protection to cover foreign infringement.[72]

B. Eolas*: § 271(f) Offshore Assembly of a Patented Combination*

In *Eolas*, the question which resulted in a substantial portion of the $500 million plus damages awarded at the trial court level was whether the export from the United States of a "golden master" disk containing software to be recreated and assembled offshore which then was used to create a patented combination was an act of patent infringement.[73] In both *Eolas* and *Pellegrini,* a claimed combination was assembled offshore with the use of a component that was also made offshore.[74] The difference between the two cases is that whereas the component in *Pellegrini* was physically made offshore as a "thing,"[75] the component at issue in *Eolas* was software, which was made or recreated offshore by using a "golden master" that was shipped to the offshore site from the United States.[76]

C. The Pellegrini *Case*

1. Pellegrini *Extraterritoriality*

Pellegrini was decided by a panel that included Circuit Judges Rader and Bryson.[77] The court found that the question in this case was whether the components which were made outside of the United States and never actually physically shipped to or received from the United States can nevertheless still be considered infringing.[78] The question centered on whether it would still be within the meaning of 35 U.S.C. § 271(f)(1) if those components were originally designed in the United States and the instructions for using those components to assemble the actual invention were transmitted from the United States to the offshore assembly location.[79]

The court noted that the statute finds infringement where someone "supplies or causes to be supplied" from within the United States all or even a substantial portion

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[70] *Id.* at 435.
[71] *See id.*
[72] Pellegrini v. Analog Devices, Inc., 375 F.3d 1113, 1119 (Fed. Cir. 2004).
[73] Eolas Techs., Inc. v. Microsoft Corp., 274 F. Supp. 2d 972 (N.D. Ill. 2003).
[74] *Eolas*, 274 F. Supp. 2d at 973–74; *Pellegrini*, 375 F.3d at 1115–17.
[75] *Pellegrini*, 375 F.3d at 1115 (integrated circuit chips).
[76] *Eolas*, 274 F. Supp. 2d at 973–74.
[77] *Pellegrini*, 375 F.3d at 1113.
[78] *Id.* at 1115.
[79] *Id.*

of the components necessary to create the patented invention.[80] In addition, the supplier must actively encourage the combination the components in a way that would cause infringement of the patent if the same combination were to be made within the United States.[81]

Thus, the court found that it is necessary that the actual "components" be physically present and exported from the United States to meet the requirements of the statute.[82] The court acknowledged that the history of § 271(f) showed that it was created only after the Supreme Court's decision in *Deepsouth Packing Co. v. Laitram Corp.*[83] The *Deepsouth* opinion had found a loophole in the patent laws wherein the unauthorized manufacture of patented devices would not be infringement where the creation of the unassembled components occurred within the United States and the components were subsequently shipped out of the United States for assembly.[84]

Citing *Rotec Industries, Inc. v. Mitsubishi Corp.*,[85] the court noted that "Congress enacted § 271(f) in order to close that loophole."[86] The legislative history indicated that the bill was designed "'to avoid encouraging manufacturers outside the United States'" and to "'prevent copiers from avoiding U.S. patents by supplying components of a patented product in this country so that the assembly of the components may be completed abroad.'"[87]

However, no component in *Pellegrini* was actually made in the United States.[88] Although the direction to make the components abroad (in Ireland and Taiwan) originated from the United States, the accused infringer defended simply on the basis that the actual components themselves were not made in the United States and therefore did not satisfy the "supplies" requirement of § 271(f)(1).[89]

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[80] *Id.* at 1116.

[81] 35 U.S.C. § 271(f)(1) (2000).

[82] *Pellegrini*, 375 F.3d at 1117.

[83] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972).

[84] *Pellegrini*, 375 F.3d at 1116.

[85] Rotec Indus., Inc. v. Mitsubishi Corp., 215 F.3d 1246, 1250 n.2 (Fed. Cir. 2000).

[86] *Pellegrini*, 375 F.3d at 1116.

[87] *Id.* (quoting 130 CONG. REC. 10,525 (1984)).

[88] *Id.* at 1115.

[89] *Id.* at 1118. The patentee alleged that the accused infringer

> is incorporated in the United States and has executive, marketing, and product line responsibilities for ADMC products; that [it] conceived and designed the ADMC products; that [it] is the exclusive manufacturer of ADMC products; that [it] makes all development and production decisions for ADMC products; that [it] is responsible for the fabrication, assembly, and testing of ADMC products; that ADMC uses, subcontracts with, and pays others for the express purpose of the proprietary fabrication, assembly, and testing of ADMC products; that [it]'s ADMC products are capable of motor control; that [it] sets budgetary pricing and receives payment for ADMC products sold worldwide; and that [it] receives purchase orders from and invoices customers worldwide for ADMC products and increases production levels for ADMC products in response to those purchase orders.

Id. at 1116.

2. The Pellegrini *Affirmance of Non-Infringement*

Affirming summary judgment of noninfringement, the court noted that this issue was explained by the Supreme Court in *Brown v. Duchesne*,[90] where the Court found that the patent laws "'do not, and were not intended to, operate beyond the limits of the United States.'"[91] The court criticized the patentee for having failed to seek foreign patent protection.[92] Indeed, the accused infringer set forth that the patentee had made a conscious decision to not obtain any foreign patent protection on the invention and, as such, should be bound by that choice.[93]

The court denied the patentee's appeal on the basis that § 271 is clear on its face, stating:

> [§ 271] applies only where components of a patent invention are physically present in the United States and then either sold or exported "in such a manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States."[94]

The court then noted that the actual patent infringement is committed not where the injury is felt, but instead where the offending act actually occurs.[95] The court emphasized that the actual language of § 271(f)(1) is primarily focused upon the location of the components, not the location of the infringer.[96] The patentee argued that all the business activities and directions for assembly came from the United States.[97] Denying the merits of this argument, the court stated that

> the language of [35 U.S.C.] § 271(f) clearly contemplates that there must be an intervening sale or exportation; there can be no liability under § 271(f)(1) unless components are shipped from the United States for assembly. . . .
>
> . . . [A]lthough [the accused infringer] may be giving instructions from the United States that cause the components of the patented invention to be supplied, it is undisputed that those components are not being supplied in or from the United States.[98]

In addition, the court noted that it was probable that the sales and offers for sales may well have been made in the United States, but nonethless

> there is no evidence of record that any of that manufacturing occurs in the United States or that Analog offers to sell those products in the United

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[90] Brown v. Duchesne, 60 U.S. (19 How.) 183 (1857).
[91] *Pellegrini*, 375 F.3d at 1117 (quoting *Brown*, 60 U.S. at 195).
[92] *See id.*
[93] *Id.*
[94] *Id.* (citations omitted).
[95] *Id.*
[96] *Id.*
[97] *Id.* at 1118.
[98] *Id.* at 1117–18.

States. As the Supreme Court explained in *Dowagiac Mfg. Co. v. Minn. Moline Plow Co.*, "the right conferred by a patent under our law is confined to the United States and its territories, and infringement of this right cannot be predicated on acts wholly done in a foreign country."[99]

D. An Increased Focus on Patents that Pinpoint American Activity

Perhaps the most comprehensive consideration of extraterritorial issues in the context of computer software and internet infringement took place three years ago in Tokyo, at the 2001 SOFTIC conference.[100] As considered at that conference, great care was cautioned to ensure that claims which could be infringed under American law were provided in the patent—or to provide claims that could be locally enforced in foreign territories.[101] In addition, in the case of offshore assembly, claims that are infringed under foreign law are important. In terms of invention residing in a combination of elements where one element, such as a server, could be offshore, one is cautioned against failing to claim an element that is practiced in the United States.[102] This represents a potentially fatal problem for the combination claims in the *Blackberry* case.

E. Focus on Specific, Domestically Infringed Claims

As pointed out by Judge Linn in *International Rectifier Corp. v. Samsung Electronics Co.*, "it is well known that United States patent laws 'do not, and were not intended to, operate beyond the limits of the United States.'"[103] Whatever arguments patentees may have had before, their cases have grown weaker in the wake of both the *Pellegrini* case,[104] as well as one of the recent cases the court cites in *Pellegrini*, the case of *International Rectifier*.[105] As such, the opinions of the Federal Circuit in both *Blackberry* and *Eolas* are highly anticipated.

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[99] *Id.* at 1118 (citation omitted) (quoting Dowagiac Mfg. Co. v. Minn. Moline Plow Co., 235 U.S. 641, 650 (1915)).

[100] *See* Harold C. Wegner, *E-Business Patent Infringement: Quest for a Single Station Direct Infringement Claim Model*, SOFTIC SYMPOSIUM 2001 (Software Information Center, Tokyo, Japan), Nov. 20–21, 2001, *at* http://www.softic.or.jp/symposium/open_materials/10th/en/wegner-en.pdf. The conference was attended by judges, practitioners and scholars from several countries, including the United States.

[101] Wegner, *supra* note 100.

[102] *Id.*

[103] Int'l Rectifier Corp. v. Samsung Elecs. Co., 361 F.3d 1355, 1360 (Fed. Cir. 2004) (quoting Brown v. Duchesne, 60 U.S. (19 How.) 183, 195 (1857)).

[104] Pellegrini v. Analog Devices, Inc., 375 F.3d 1113 (Fed. Cir. 2004).

[105] *Int'l Rectifier*, 361 F.3d at 1361 (holding that the defendant did not violate the terms of an injunction by selling allegedly infringing products outside of the United States).

IV. *STAR FRUITS*: THE RULE 105 "INFORMATION"

Under regulations that are just now being tested in the courts, patent examiners have been given the powerful tool of "Rule 105," a mechanism that permits the examiner to ask an extremely wide range of questions to obtain "information" for the patent examination process.[106] The scope of Rule 105 goes far beyond the "duty of disclosure" under Rule 56,[107] extending to "any assignee" and covering information beyond materiality.[108]

A. The Star Fruits *Test Case*

The case of *Star Fruits S.N.C. v. United States* that is now awaiting a decision from the Federal Circuit[109] is the first test case that may very well confirm the authority of the USPTO to issue "information" requirements under Rule 105.

In *Star Fruits*, just as in the *Elsner* case,[110] the patent applicant sought plant patent protection for an invention that had been the subject of a printed publication—a foreign plant certificate—published more than one year before the application was filed in the United States.[111] Because the plant certificate was clearly not enabling—as in *Elsner*[112]—the examiner made an "information" inquiry under Rule 105.[113] Unlike *Elsner*, where the patent applicant complied with the request and challenged the rejection on the merits (albeit unsuccessfully),[114] in *Star Fruits*, the applicant refused to comply with the "information" requirement.[115] From a holding of abandonment that was sustained by the Alexandria Division of the Eastern District of Virginia,[116] the *Star Fruits* case was recently argued before the Federal Circuit and is now awaiting decision.[117]

B. Foreign Use and Sale "Information" Requirements

The implications of *Star Fruits* in the first instance will focus upon requirements for information concerning foreign uses or sales by the inventor (or others) in

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[106] 37 C.F.R. § 1.105(a)(1) (2004) ("[T]he examiner . . . may require the submission [from the inventor or attorney], or any assignee[] of such information as may be reasonably necessary to properly examine [the application].").

[107] *Id.* § 1.56.

[108] *See id.* § 1.105.

[109] On September 9, 2004, the Federal Circuit (Newman, Clevenger & Dyk, JJ.), heard the oral argument in Star Fruits S.N.C. v. United States, 280 F. Supp. 2d 512 (E.D. Va. 2003), *appeal docketed*, No. 04-1160 (Fed. Cir. Jan. 14, 2004).

[110] *Star Fruits*, *see* 280 F. Supp. 2d at 513–14, started out on a factually similar basis as *In re* Elsner, *see* 381 F.3d 1125, 1126–27 (Fed. Cir. 2004).

[111] *Star Fruits*, 280 F. Supp. 2d at 514–15 & n.8.

[112] *Elsner*, 381 F.3d at 1129.

[113] *Star Fruits*, 280 F. Supp. 2d at 513–14.

[114] *See Elsner*, 381 F.3d at 1126.

[115] *Star Fruits*, 280 F. Supp. 2d at 514.

[116] *Id.* at 517.

[117] *See supra* note 109 and accompanying text.

connection with non-enabling publications—the factual setting of both *Star Fruits*, as well as the substantively far more important *Elsner* case.[118]

It may now be expected that skimpy "printed publications" relating to foreign use or sale of an invention will now be reasons for major concern. At the oral arguments in *Elsner* and the companion *Zary* case,[119] Judge Clevenger posed the question whether an affirmance in these cases would result in early foreign newspaper advertisements of new products ("printed publications") creating a statutory bar problem for applicants if there were an enabling foreign use or sale.[120] One can also imagine a brief, cursory explanation of a product on a website where that website posting is not enabling yet still a "printed publication." Is the existence of a foreign use or sale, contemporaneous with such a website posting, a patent-defeating event under 35 U.S.C. § 102(b)?

C. A Far Broader Sweep than the Duty of Disclosure

1. Information from "the Assignee"

The Rule 105 sweep includes "the assignee," which is far broader than the duty of disclosure under Rule 56.[121] Thus, under Rule 105,

> [i]n the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. § 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other Office employee may require the submission, from individuals, or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter . . . .[122]

The broader sweep of Rule 105 versus the narrower scope of Rule 56 is justified on the basis that the information required may be known to the assignee even if not known by the inventor.[123] One can imagine a multinational conglomerate with several hundred patent professionals scattered over venues in several continents who collectively prepare and file several thousand patent applications per year. Also, imagine further unrelated research units in this multinational conglomerate who have absolutely nothing to do with the patenting process or any knowledge of patent law. Yet, the effect of "the assignee" sweep would be to literally cover both the aforementioned groups of people and require an inquiry of perhaps thousands of

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[118] *See supra* note 110 and accompanying text.

[119] *Zary* and *Elsner* were argued sequentially, before the same panel, and consolidated into the single opinion now known as *In re* Elsner. *See Elsner*, 381 F.3d at 1126.

[120] Transcript of Oral Arguments Before the United States Court of Appeals for the Federal Circuit, *In re* Elsner, 381 F.3d 1125 (Fed. Cir. 2004) (en banc) (Nos. 03-1569, 03-1585).

[121] 37 C.F.R. § 1.105(a)(1) (2004); *see id.* § 1.56.

[122] *Id.* § 1.105(a)(1).

[123] MANUAL OF PATENT EXAMINING PROCEDURE § 704.10 (8th ed., rev. 2, 2004) [hereinafter MPEP].

persons who have no knowledge of the application and are outside the sweep of the Rule 56 duty of disclosure.

In contrast, there is no duty of disclosure under Rule 56 that runs to "the assignee" apart from those with knowledge of the application.[124] Thus, the Rule 56 duty of disclosure is limited to those persons with actual involvement or knowledge of the procurement process including the inventor,[125] the legal representatives who "prepare[] or prosecute[] the application",[126] and all others "substantively involved" with the procurement.[127] Further, the examiner is also given the authority to demand that the patent attorney identify the field of search, or, according to the rule itself, "what was searched."[128]

2. Information Beyond Rule 56(a) "Material[ity]"

The scope of Rule 105 is far broader than the Rule 56 requirement for information about foreign uses and sales, or information "material" to patentability.[129] The "information" obtainable under Rule 105 represents a true Pandora's Box for the average patent practitioner, as the "information" is extremely wide-ranging and far afield from the traditional duty of disclosure imposed by Rule 56 to provide the most relevant prior art or related information. In fact, Rule 105 delves into the thought process of the patent attorney in his drafting of the patent application. For example, if the applicant has been faced with a patent infringement question and the problem of designing around a third party's patent, the examiner has the right under Rule 105 to inquire about this thought process and the identity of the third party's patent[130]—despite the fact that it may be clearly irrelevant to the patent examination process.[131] Where it is known that a prior art patent is material to patentability, the patent attorney should cite that patent.[132] However, to have a rule that permits a sweep into the thought process of a patent attorney to retrieve information that is not material is a step beyond what is relevant to the examination process.

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[124] *See* 37 C.F.R. § 1.56.

[125] *Id.* § 1.56(c)(1).

[126] *Id.* § 1.56(c)(2).

[127] *Id.* § 1.56(c)(3). "Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." *Id.*

[128] *Id.* § 1.105(a)(1)(ii).

[129] Section 1.56(a) provides "a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." *Id.* § 1.56(a).

[130] *Id.* § 1.105(a)(1)(v). "Information used in invention process: A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used in the invention process, such as by designing around or providing a solution to accomplish an invention result." *Id.*

[131] It is often the case that there will be a broad generic formula in a chemical case that may raise an infringement question but is so broad that it raises neither a question of anticipation nor obviousness of a species thereunder. *See In re* Baird, 16 F.3d 380, 382 (Fed. Cir. 1994). "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." *Id.*

[132] *See* 37 C.F.R. § 1.56.

If the Examiner is new to the field and does not know how to search the prior art on electronic databases, instead of making fan inquiry of a senior examiner or other library resources within the USPTO, he may instead under Rule 105 choose to question the patent attorney as to how he had the application searched. The examiner is even allowed to ask what literature or other documents of the inventor exist and also what documents were used in the drafting of the application.[133] All such documents may be required to be produced.

V. *KNORR-BREMSE:* WILLFUL INFRINGEMENT

Willful infringement under 35 U.S.C. § 284 has survived the en banc clarification in *Knorr-Bremse v. Dana Corp.*, which returned the inquiry to a heavily factually based totality of the circumstances test entrusted to the sound discretion of the trial judge.[134] While many in the patent community thought that the *Underwater Devices* affirmative duty to avoid infringement of a patent would be thrown out, the court voted 10-1 to maintain the standard that "'where, as here, a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing.'"[135] All other aspects of the case were without dissent of any kind.[136]

It may now be expected that there will be relatively few holdings of willful infringement at the trial level, and that the court will generally honor the determination of a trial judge who refrains from reaching a holding of willfulness in this highly fact-dependent inquiry.

A. A "Totality of the Circumstances" Test for Willfulness

In essence, the *Knorr-Bremse* court turned the clock back a generation to the pre-Markey era of the regional circuits where willfulness was judged by a "totality of the circumstances" test. Sitting en banc, the court has now cited to *Read v. Portec*[137] and stated that "[d]etermination of willfulness is made on consideration of the totality of the circumstances and may include contributions of several factors."[138] This portion of the opinion was made by a unanimous court.[139]

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[133] *Id.* § 1.105(a)(1)(iii) ("Related information: A copy of any non-patent literature, published application, or patent (U.S. or foreign), by any of the inventors, that relates to the claimed invention."); *id.* § 1.105(a)(1)(iv) ("Information used to draft application: A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used to draft the application.").

[134] Knorr-Bremse v. Dana Corp., 383 F.3d 1337, 1343–44 (Fed. Cir. 2004).

[135] *Id.* at 1343 (quoting Underwater Devices, Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1389 (Fed.Cir.1983)). Circuit Judge Dyk dissented on this issue. *Id.* at 1348 (Dyk, J., dissenting).

[136] *See id.* at 1348–52 (Dyk, J., dissenting). Circuit Judge Dyk's dissent on the affirmative duty issue was the only dissenting opinion in the case. *See id.*

[137] Read Corp. v. Portec, Inc., 970 F.2d 816, 826–27 (Fed. Cir. 1992).

[138] *Knorr-Bremse*, 383 F.3d at 1342 (citation omitted).

[139] The twelfth member of the court, who did not sit for this case, was Circuit Judge Michel. *Id.* at 1340.

There are nine *Read v. Portec* factors which will now be at the center of attention for any willfulness inquiry:

> (1) [W]hether the infringer deliberately copied the ideas or design of another;
> (2) [W]hether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; and
> (3) [T]he infringer's behavior as a party to the litigation . . . . In addition, other circumstances which courts appropriately have considered, particularly in deciding on the extent of enhancement, are:
> (4) [The d]efendant's size and financial condition.
> (5) [The c]loseness of the case.
> (6) [The d]uration of defendant's misconduct.
> (7) [Whether any r]emedial action [was taken] by the defendant.
> (8) [The d]efendant's motivation for harm.
> (9) [W]hether [the] defendant attempted to conceal its misconduct.[140]

B. No Adverse Inference

The *Knorr-Bremse* court unanimously overruled earlier precedent to the extent that it held there to be an adverse inference where an opinion of counsel concerning infringement is not produced at trial.[141] Instead, the court "h[e]ld that no adverse inference that an opinion of counsel was or would have been unfavorable flows from the alleged infringer's failure to obtain or produce an exculpatory opinion of counsel."[142]

The court thus unanimously said "no" to the first question it had set forth in its briefing order: "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?"[143] In striking down the adverse inference, the court also unanimously answered "no" to the second question: "When the defendant had not obtained legal advice, is it appropriate to draw an adverse inference with respect to willful infringement?"[144]

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[140] *Read*, 970 F.2d at 827 (citations omitted). The "closeness of the case" issue in factor five is related to Question (4) of the en banc briefing order concerning whether there is a substantial defense presented to the infringement charge. *Knorr-Bremse*, 383 F.3d at 1347. This is considered in more detail in Part IV.C.2., *infra*.

[141] *Knorr-Bremse*, 383 F.3d at 1347.

[142] *Id.* at 1341.

[143] *Id.* at 1344.

[144] *Id.* at 1345.

C. Substantial Defense as a Basis to Avoid Willfulness

1. Substantial Defense is not a per se Basis to Avoid Willfulness

The court found that a substantial defense to an infringement charge should be considered by the court only as one factor in analyzing willfulness.[145] Thus, the court answered "no" to the per se rule which was raised as the fourth question in the briefing order: "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?"[146]

2. Consideration as Part of the Read v. Portec *Factors*

The court also stated that the case law includes the existence of a substantial defense as one of the factors to be considered by the fact finders under the totality of the circumstances test.[147] Paramount to this consideration is whether a reasonable person would agree that if litigated, the patent would be found invalid, unenforceable, or not infringed.[148] Because the fact-finder is to "accord each factor the weight warranted by its strength in the particular case," the court found this approach better suited to apply to all of the circumstances in any given case than a per se rule.[149] Therefore, the court expressly declined to adopt a per se rule.[150] This may be considered as one aspect of the "[c]loseness of the case" factor under the totality of the circumstances test announced in *Read v. Portec*.[151]

D. "An Affirmative Duty of Due Care"

Finally, the court noted that "there continues to be 'an affirmative duty of due care to avoid infringement of the known patent rights of others.'"[152] Yet, while there is a continued affirmative duty of due care, the failure to produce an exculpatory opinion of counsel at trial no longer allows the court to apply an adverse inference which presumes that such an opinion, if obtained, was unfavorable.[153]

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[145] *Id.* at 1347.
[146] *Id.*
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] Read v. Portec, 970 F.2d 816, 827 (Fed. Cir. 1992).
[152] *Knorr-Bremse*, 383 F.3d at 1345–46 (quoting L.A. Gear Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1127 (Fed. Cir. 1993)).
[153] *Id.* at 1346.

VI. *XECHEM*: COINVENTORSHIP TO EXPLOIT INVENTION

The case of *Xechem International, Inc. v. University of Texas M.D. Anderson Cancer Center* is a controversial panel opinion; *Xechem* is the latest chapter in the saga of unnamed co-inventors being added or sought to be added to a patent in order to gain the right to exploit the patent, notwithstanding the exclusive rights of the patentee or an exclusive licensee.[154]

Historically, every claim in a patent required an inventive contribution of every inventor named on the patent.[155] Yet, under the current and more liberal statute that was introduced twenty years ago, today a single person who has made an inventive contribution to any claim may be added to the patent as a co-inventor.[156] Thus, "[i]nventors may apply for a patent jointly even though . . . each did not make a contribution to the subject matter of every claim of the patent."[157]

A. The Seemingly Late Filing of a Coinventorship Suit

To the extent that "claim 102" recites a trivial modification of a generic concept, where "claim 102" was the co-invention of a minor research employee or collaborator who was not named as an inventor and did not have an assignment obligation to the patentee, adding the co-inventor of "claim 102" thus permits him to transfer the right to make, use and sell all subject matter of all claims to a competitor of the patentee.[158] It is a default rule unique to the United States that gives this right to each co-inventor.[159]

The American rule has led to litigation seeking to add an unnamed co-inventor even many years after the patent has been granted.[160] If such a move were to be successful, then that co-inventor may grant a license or transfer his right to anyone.[161] This is true even though the patentee may have been relying upon its exclusive rights under the patent or there may be an exclusive license to a third

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[154] *See* Xechem Int'l, Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr., 382 F.3d 1324, 1327 (Fed. Cir. 2004).

[155] Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1470 (Fed. Cir. 1998) (Newman, J., dissenting).

[156] Patent Law Amendments Act of 1984, Pub. L. 98-622, sec. 1, tit. I., § 104(a), 98 Stat. 3384 (codified as amended at 35 U.S.C. § 116 (2000)).

[157] 35 U.S.C. § 116 (2000).

[158] *See id.*; *id.* § 262.

[159] *Id.* § 262.

> In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, *without the consent of and without accounting to the other owners.*

Id. (emphasis added).

[160] *See, e.g.*, Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1552 (Fed. Cir. 1997) (involving an appeal of a co-inventorship suit originally filed four years after the first of the several patents at issue was granted).

[161] *See* 35 U.S.C. § 262.

party under the patent.[162] Unless an exclusive license agreement is construed as an "agreement to the contrary," the co-inventor's right trumps the exclusivity of the "exclusive" licensee.[163]

B. The Right to Seek Correction Years Later

In one case, the court permitted a suit to correct inventorship several years after the omitted inventor knew or should have known of the possible error in the inventorship nomination.[164] As a result, a lenient rule was announced for the correction of inventorship in issued patents.[165]

C. State University Immunity from Federal Court Correction

Absent consent of all parties, the sole avenue for the correction of inventorship of a patent is through a Federal Court action.[166] Yet, as held in *Xechem*, where a state university is the patentee, the patentee can defend a federal court action for the correction of inventorship simply by pleading sovereign immunity.[167]

D. State Court Resolution of Inventorship Changes in Patents

In a bizarre instance, while the panel in *Xechem* denied the right to correct inventorship of a state-owned patent, it also provided obiter dictum which suggests that a state court may provide a remedy.[168] It has heretofore been crystal clear that

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[162] Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1465–66 (Fed. Cir. 1998).

[163] *See* 35 U.S.C. § 262.

[164] Stark v. Advanced Magnetics, Inc., 29 F.3d 1570, 1575 (Fed. Cir. 1994). The Federal Circuit reversed a claim of late filing where

> [t]he district court granted summary judgment to [the defendant] with respect to correction of inventorship. The [district] court held that [the plaintiff] knew or should have known of the existence of the . . . patent when he received the Annual Report in early 1989, and that he had not acted diligently in seeking the correction. The summary judgment was applied to all six patents. The state law tort claims were dismissed as barred by the three-year statute of limitations. The contract and unfair trade practice claims were also dismissed, the court ruling that [the plaintiff] had one year from the date of dismissal to bring these claims in state court.

Id. at 1572.

[165] *Id.* "[Title 35 U.S.C. §] 256 does not limit the time during which inventorship can be corrected. Section 256 thus serves the public policy of preserving property rights from avoidable forfeiture." *Id.* at 1573 (citation omitted).

[166] Pannu v. Iolab Corp., 155 F.3d 1344, 1350 (Fed. Cir. 1998).

[167] Xechem Int'l, Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr., 382 F.3d 1324, 1327–32 (Fed. Cir. 2004) (relying on Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627 (1999); Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 527 U.S. 666 (1999)).

[168] *See id.* at 1332.

only a federal court can order correction of inventorship under 35 U.S.C. § 256.[169] However, the court suggests that a state court may have jurisdiction to resolve the inventorship dispute.[170] Yet, by statute, only a federal court may order correction of an inventorship error.[171]

VII. *FISHER*: PATENT-ELIGIBILITY "USEFUL[NESS]"

The *Ex parte Fisher* appeal that is expected to be argued and decided in 2005[172] reopens a controversy dating back to the controversial 1967 split opinion of a predecessor court in *Kirk*.[173] The question presented in *Kirk* was: does patent-eligibility reside in a chemical or biotechnology invention to a new entity where that new entity has no established or purported specific utility?[174] The *Fisher* case has the potential of being either the single most important pharmaceutical patent case in recent years—or a yawn—as the court is presented with the challenge of the review of debates over patent-eligibility of pharmaceutically uncharacterized, new biological and chemical entities.[175]

A. The 1991 NIH Attempt to Patent Thousands of Express Sequence Tags (ESTs)

Thousands of mostly uncharacterized ESTs[176] were the subject of a single controversial 1991 patent application filed by the National Institutes of Health

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[169] *See* 35 U.S.C. § 256, ¶ 1 (2000). The USPTO, alone, is without authority to correct inventorship where the State hides behind its sovereign immunity and refuses to join in a USPTO correction action: "[T]he Director may, on application of *all* the parties and assignees, . . . issue a certificate correcting [the inventorship] error." *Id.* (emphasis added).

[170] *Xechem*, 382 F.3d at 1332.

[171] 35 U.S.C. § 256, ¶ 2.

> The error . . . shall not invalidate the patent . . . if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

Id.

[172] *Ex parte* Fisher, No. 2002-2046 (U.S.P.T.O. Bd. Pat. App. & Interferences Mar. 31, 2004), *appeal docketed*, No. 04-1465 (Fed. Cir. July 14, 2004), *available at* http://lorac.typepad.com/patent_blog /files/fisher_est_sequences.pdf (last visited Nov. 8, 2004).

[173] *In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

[174] *Id.*

[175] *See Fisher*, No. 2002-2046.

[176] *See generally,* Leora Ben-Ami et al., *Biotech Patent Law Developments, in* BIOTECH PATENT LAW DEVELOPMENTS 557–58 (PLI Pats., Copyrights, Trademarks, & Literary Prop. Course, Handbook Series No. 573, 1999), *available at* WL, 573 PLI/Pat 555.

> The [Human Genome Project or] HGP exploits the fact that in a given genome, only a small percentage of the DNA present actually codes for proteins. Under this approach random sequences of the coding DNA are "fished out" often without any knowledge of what the DNA encodes. The DNA sequences produced by this technique are referred to as expressed sequence tags or "ESTs."

Id. at 558.

("NIH").[177] It was pointed out by a biotechnology patent examiner that the NIH itself had admitted that "[a]bout 83% [of the claimed ESTs] are unrelated to any previously known sequences, as determined by homology comparisons to nucleotide databases."[178] Patent eligibility of a naked EST, without more, was widely questioned because it was widely thought that an EST, alone, did not have statutory utility under 35 U.S.C. § 101.[179]

Three years later, Professors Eisenberg and Merges—two of the leading patent academics of the day—published a famous opinion letter criticizing the patenting of ESTs.[180] They also challenged the patent-eligibility of such ESTs.[181] Contemporaneous with the NIH attempt to patent ESTs, Lorance Greenlee, a Ph.D. scientist-lawyer, expressed doubt about any degree of predictability for EST utility based upon the state of the art at that time.[182] Greenlee's thoughts on the matter supported the view of critics of the NIH patent application that it should be denied on the basis that the subject matter did not meet the patent-eligibility test of 35 U.S.C. § 101.[183]

B. The Emerging Face of Predictable Functionality

Stripping away the policy arguments of Professors Eisenberg and Merges to focus solely on the issue of patent-eligibility under 35 U.S.C. § 101, the USPTO's then-leading legal expert in biotechnology, Associate Solicitor Scott Chambers,

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[177] Stephen B. Maebius, *Novel DNA Sequences and the Utility Requirement: The Human Genome Initiative*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 651, 651 n.2 (1992) (citing *Geneticists and Religious Leaders Ponder Implications of the Human Genome Project*, GENETIC ENG'G NEWS, Apr. 15, 1992, at 29); *see also* Ben-Ami, *supra* note 176, at 557–58.

> The leading case concerning utility, *Brenner v. Manson*, [383 U.S. 519 (1966),] suggested that ESTs would not be patentable. In that case, the Supreme Court held that a process useful solely as a step in further research failed to meet the statutory requirement of being "useful" and a process or product with no known use, or that is useful only in the sense that it may be the subject of scientific research, is not patentable. Opponents of EST patents argued that ESTs, with no known function or associated protein, had no use beyond being the subject of scientific research.

Id. at 558 (footnotes omitted).

[178] Maebius, *supra* note 177, at 653. Mr. Maebius resigned from the USPTO in 1991, before he authored the *Journal of the Patent and Trademark Office Society* article cited in note 177, *supra*.

[179] *See* Ben-Ami, *supra* note 176, at 558 ("Although ESTs may be useful as probes in locating particular genes, *they may not identify the function of the gene or any associated protein* (emphasis added)).

[180] Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 A.I.P.L.A. Q.J. 1 (1995).

[181] *Id.* at 51–52.

[182] Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 136 n.48 (1991) ("At present, models of protein structure are not sufficiently developed to predict accurately three-dimensional configurations of a given sequence. The functional properties of a given amino acid sequence are almost never predictable from sequence alone.").

[183] *See id.*

foresaw a different picture.[184] Mr. Chambers saw the day when ESTs would be able to pass patent muster with sufficient utility, arguing nearly ten years ago that

> [i]f the patent applicant provide[s] precise chromosomal map locations for each of the EST fragments, sufficient utility for 35 U.S.C. § 101 might be present. Numerous scientific articles have stated that precise marker locations are very important to the Human Genome Project ('HGP'). This project represents a 3-5 billion dollar market. Any element that is fundamental to a $3 billion market has utility.[185]

Indeed, at the relatively primitive time in the evolution of the science in 1995, Chambers noted that the use of EST markers as genetic probes does satisfy the requirement of utility in 35 U.S.C. §101.[186] Because the cytological locations of many diseases are known, making a large number of probes available to researchers allows them to quickly identify probes that "correlate closely with the disease locus, speeding the development of diagnostic probes."[187] The result of this use of ESTs creates a more efficient and easier method to create these diagnostic probes.[188]

Chambers also points out that currently, researchers identify a disease by looking at what parts of which chromosomes are similar in all individuals with that disease.[189] However, this practice does not provide sufficient information regarding the location of a gene on a chromosome and is less precise than using ESTs because the use of an EST can supply the exact location of corresponding DNA.[190]

C. Sequence Motifs and Computer Biochemistry

It is now more than ten years since the NIH filings with naked utility disclosures for the functionally of unidentified ESTs. Much has changed. Patentees are now routinely defining their ESTs in terms of their "sequence motifs," the unique amino acid patterns within genes that are seen to provide a specific biological function. Where there are multiple sequence motifs present that can be linked to a specific utility, an otherwise uncharacterized EST may very well have a highly predictable utility. One expert, Lee Bendekgey, opined that traditional laboratory research in the future will only be used to confirm the results of research performed using computers and databases.[191] Bendekgey also noted that researchers can

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[184] *See* Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 A.I.P.L.A. Q.J. 53, 55–56 (1995) (footnote omitted).

[185] *Id.*

[186] *Id.* at 55–56.

[187] *Id.* at 56.

[188] *Id.*

[189] *Id.*

[190] *Id.*

[191] Lee Bendekgey, *The Transition to E-Research in Pharmaceutical Research and Development: Public Policy Implications*, *in* WORKSHOP REPORT ON MANAGING IPR IN A KNOWLEDGE-BASED ECONOMY - BIOINFORMATICS AND THE INFLUENCE OF PUBLIC POLICY, app. A1 at viii (European Comm'n Nov. 2001), *available at* http://europa.eu.int/comm/research/era/pdf/ipr-bioinformatics-workshopreport.pdf (last visited Nov. 8, 2004).

currently identify genes using EST datasets and gene prediction software, and further assign the proposed function of such genes through homology analysis, which confirms the existence of "motifs" associated with classes of genes.[192] This expression data can assist researchers in identifying what genes to "target" in the formulation of a therapeutic drug or diagnostic tests.[193] Bendekgey proceeded to imagine a time when "wet lab" experimentation is only needed to verify the results predicted via electronic research.[194]

Teresa Attwood discussed an electronic database, "PRINTS," that consists of "protein fingerprints" that identify family relationships among recently discovered gene sequences.[195] This was achieved by

> exploit[ing] groups of conserved [sequence] motifs within sequence alignments to build characteristic family signatures; an uncharacterised sequence that matches all motifs can thus be readily assigned to a particular family. The diagnostic power of fingerprints, and the extent of documentation manually attached to each database entry, has lent PRINTS a significant role in protein sequence analysis and, ultimately, genome annotation.[196]

The use of sequence motifs in patents has now become a widespread practice, with at least 1,500 references to a "sequence motif" having been used in United States patents and patent applications published within the past year.[197] Also, there are a vast amount of electronic databases that contain already determined gene sequences and their purported functions.

D. Three Levels of EST Utility

1. No Specific Utility (NIH)

As in both the cases of the NIH patent application and *Fisher*, there remain some patent applicants who are seeking protection on naked ESTs with no particularized utility statement. This is a classic *Larson* case[198] in biotechnology

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[192] *Id.*

[193] *See id.*

[194] *Id.*

[195] Teresa K. Attwood, *Mobile, Metamorphosing Academic Databases – Capturing IP on the Move*, *in* WORKSHOP REPORT ON MANAGING IPR IN A KNOWLEDGE-BASED ECONOMY - BIOINFORMATICS AND THE INFLUENCE OF PUBLIC POLICY, app. A1 at iv (European Comm'n Nov. 2001), *available at* http://europa.eu.int/comm/research/era/pdf/ipr-bioinformatics-workshopreport.pdf (last visited Nov. 8, 2004).

[196] *Id.*

[197] A search of the LEXIS database conducted on September 17, 2004 for all domestic patents (and patent applications) for the past year having the term "sequence motif" yielded 1,513 hits, of which twenty-nine used the terminology in at least one claim.

[198] *See* Larson v. Crowther, 26 F.2d 780, 787 (8th Cir. 1928), *cert. denied*, 278 U.S. 648 (1928) ("An inventor is entitled to all the uses to which his invention may be put, even if he is not aware of such uses when he secures his patent.").

clothing and is hardly distinguishable from the bulk of the ESTs which were the subject of the 1991 NIH application.

2. Prophetic Specific Utility (Sequence Motifs)

Yet, thanks to the collection of vast amounts of information and the creation of databases with sequence motifs that fingerprint the functional identity of the new ESTs, the state of the art has progressed geometrically to provide a much higher degree of predictability as to specific utility. Thus, there have been more than 1,500 American patents and patent applications published in the past year that refer to a "sequence motif."[199] To the extent that the state of the art has progressed to the particular point that a specific utility can be fairly and reasonably predicted—as is now the case with ESTs—then prophetic statements of utility are equally applicable to ESTs as they are to classic organic molecules.

Thus, if there are several common sequence motifs in a particular DNA vis-à-vis several known DNA sequences having a particular utility, there are varying degrees of predictability that the new fragment will share the same utility. Computer banks of information already have the existing knowledge in an electronic storeroom that makes the determination of common utility a matter of simple calculation.

3. "Wet Lab" Confirmation of Utility

The third level of confirmation is through "wet lab" tests that will commence only after there has been a clear conception of the invention.[200] One expert "imagine[s] a time . . . when the first actual 'wet lab' experimentation with a gene, protein, antibody, or small molecule drug will occur when it is time to confirm the predicted results using an assay or drug screen."[201]

E. Case Law Evolution Since the 1967 Kirk *Opinion*

1. The 3-2 C.C.P.A. Holding in Kirk

Since the controversial split opinion in *Kirk*,[202] there has been a disputed United States policy that a new entity must have a disclosure of a specific utility to meet the patent-eligibility requirements of 35 U.S.C. § 101, which require the invention to be "useful."[203] In addition, *a fortiori*, absent such a disclosure, there is no explanation of

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[199] *See supra* note 197 and accompanying text.

[200] *See* Bendekgey, *supra* note 191.

[201] *Id.*

[202] *In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

[203] Brenner v. Manson, 383 U.S. 519, 529 (1966); *see also* MPEP, *supra* note 123, § 2107.01.

"how to . . . use" the invention under 35 U.S.C. § 112, ¶ 1, and therefore, the new entity is not patentable.[204]

2. Modern Pronouncements from the Court

The *Kirk* case was distinguished in *Brana*, in which the court noted the lack of specificity of the teaching of utility as a basis for denial in *Kirk*.[205] Under classic principles of patent law, any statutory utility meets the requirement for patent-eligibility.[206] "The threshold of [statutory] utility [under 35 U.S.C. § 101] is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit."[207] As pointed out by Judge Clevenger:

> [f]or over 200 years, the concept of utility has occupied a central role in our patent system. Indeed, '[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.' Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.[208]

In the context of a reduction to practice, the court has emphasized that any activity may establish patent-eligibility: "In the pharmaceutical arts, our court has long held that practical utility may be shown by adequate evidence of *any* pharmacological activity."[209] The court quoted with approval from the *Campbell v. Wettstein* case in the context of establishing a reduction to practice: "'[U]nder well-established precedent, evidence establishing substantial utility for any purpose is sufficient to show reduction to practice.'"[210] Thus,

> [s]uch activity constitutes a practical utility because "[i]t is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as

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[204] *See* 35 U.S.C. § 112, ¶ 1 (2000).

[205] *In re* Brana, 51 F.3d 1560, 1565 (Fed. Cir. 1995). In *Kirk*, the court found that

> [t]he specification . . . failed to disclose which biological properties made the compounds useful. Moreover, the court found that known specific uses of similar compounds did not cure this defect since there was no disclosure in the specification that the properties of the claimed compounds were the same as those of the known similar compounds.

Id.

[206] *See, e.g.*, Fuller v. Berger, 120 F. 274, 275 (7th Cir. 1903) (stating that an invention meets the utility requirement for patentability unless it "is incapable of serving any beneficial end").

[207] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999).

[208] Fujikawa v. Wattanasin, 93 F.3d 1559, 1563 (Fed. Cir. 1995) (citations omitted).

[209] *Id.* at 1564 (emphasis added).

[210] *Id.* (quoting Campbell v. Wettstein, 476 F.2d 642, 646–47 (C.C.P.A. 1973)).

possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility."[211]

F. "Bet the Company": The Fisher *Test Case*

The utility statement for modern EST patent applications is today often quite complete insofar as the sequence motifs that are disclosed are the basis for a reasonable prediction of a statutory utility that meets the *Kirk* standard. Yet, the *Fisher* case is a throwback to the earliest EST applications.

If *Fisher* is to be a frontal assault on the *Kirk* standard, it represents a difficult test case vis-à-vis one with a better utility disclosure. To the extent that the *Fisher* case is affirmed, this could well translate into a much more difficult time for patent applicants seeking any kind of EST patent.

VIII. THE POSSESSION REQUIREMENT FOR PRIORITY

A. The Necessity of a Common Standard of Disclosure for Priority

Priority for an invention based upon an earlier application requires that the same invention be disclosed in the earlier application in a manner sufficient to permit the invention to be reproduced by an individual of ordinary skill in the art.[212] It is extremely important that there be a harmonious standard for what constitutes the "same" invention for purposes of priority. This is because the bulk of patent filings around the world claim priority based upon an earlier "home country" or other first filing.[213] If that home country has a *different* standard, then this upsets the international patent regime regardless of whether that standard is higher or lower.

If the standard for disclosure is *higher* in the home country, then, as a general rule, the original filing will be delayed somewhat as the application will more likely be filed when the disclosure requirements of the home country are met. While this does not hurt the applicant in the later country from a standpoint of meeting the disclosure requirements, if the priority date is deferred it may mean that an intervening third party could obtain superior rights.[214]

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[211] *Id.* (quoting Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980)).

[212] 35 U.S.C. § 120 (2000).

[213] *See* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution,* 53 VAND. L. REV. 2099, 2119–20 (2000) (noting that approximately forty percent of patents filed in the United States during the period the study was conducted claimed priority to applications filed outside the United States).

[214] Under the patent laws of most countries, if a third party files an application in any country that *discloses* the same invention with a priority date under the Paris Convention before a first-to-invent but second-to-file competitor, then (absent derivation), the publication of the third party's application constitutes a novelty-defeating absolute bar against the first-to-invent but second-to-file competitor. *See* Paris Convention for the Protection of Industrial Property, Sept. 5, 1970, art. 4., 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]. The United States does not follow the international rule on this point of law; instead, under the notorious *Hilmer* rule, it denies a patent-

If the standard for disclosure is *lower* in the home country than in the United States, then a perfectly proper United States application that is filed based upon a perfectly proper foreign application disclosing the same invention may be denied priority. This is precisely the problem that was dealt with thirty years ago in the notorious case of *Kawai v. Metlesics*, where a Japanese applicant filed a United States application fully meeting the statutory requirements of 35 U.S.C. § 112, ¶ 1, based upon a Japanese application fully meeting the statutory requirements of Japanese law at the time.[215] However, priority was denied because the foreign application did not meet the disclosure requirement of 35 U.S.C. § 112.[216] *Kawai* sparked retribution in the Japanese courts, which denied priority in Japan for a Japanese application fully meeting Japanese disclosure requirements where the home country priority application met the home country's legal requirements but not a unique Japanese requirement.[217]

B. The Unique, American Parent "Possession" Rule

As with all other countries,[218] the United States historically has had a requirement that in order to enjoy filing priority, the same invention must be disclosed in the original, priority application (and in a manner to permit a worker skilled in the art to carry out the invention).[219] But, exceptionally, renegade panels of the Federal Circuit have imposed an *additional* requirement for priority: There also must be "possession" of the full scope of the generic invention in the priority application *even if there is an identical disclosure of a generic invention in the priority application.*[220]

The en banc Federal Circuit has refused to consider this issue; most recently, the court failed by a 7-5 vote to take the matter en banc in the notorious case of *University of Rochester v. G.D. Searle & Co.*[221] This domestic law and the merits of the issues are considered exhaustively elsewhere.[222]

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defeating date as of the Paris Convention priority date. *See In re* Hilmer, 359 F.2d 859 (C.C.P.A. 1966).

[215] Kawai v. Metlesics, 480 F.2d 880 (C.C.P.A. 1973).

[216] *Id.* at 891.

[217] T. Aoyama, *The Hoechst Case - A New Kawai,* 59 J. PAT. OFF. SOC'Y 263 (1977); Lutz Walter, *Comment to the Hoechst Case*, 8 INT'L REV. INDUS. PROP. & COPYRIGHT L. 566, 570 (1977).

[218] Paris Convention, *supra* note 214, art. 4.H.

[219] 35 U.S.C. § 120 (2000).

[220] *See* Enzo Biochem., Inc. v. Gen-Probe, Inc., 296 F.3d 1316 (Fed. Cir. 2002).

[221] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004), *reh'g en banc denied,* 375 F.3d 1303 (Fed. Cir. 2004).

[222] *See* Stephen B. Maebius et al., *"Possession" Beyond Statutory Enablement: The Remains of the Day after Rochester*, 2004 FOLEY & LARDNER IP ROUNDTABLE (Foley & Lardner, Osaka, Japan), July 21, 2004, *available at* http://www.foley.com/files/tbl_s88EventMaterials/FileUpload587/106/Rochester.pdf (last visited Nov. 8, 2004).

C. American Violation of the Paris Convention

The American priority requirement keyed to *Rochester* "possession" goes beyond the maximum requirement for priority that is stated in the Paris Convention: "Priority [for] elements of the invention [requires] that the [priority] application documents as a whole specifically disclose such elements."[223] Thus, provided an invention is "specifically disclose[d]" in the parent priority application, this is the end of the inquiry. The *Rochester* possession requirement goes beyond this treaty requirement and creates the very disharmony amongst the patent laws that the Paris Convention proscribes.

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[223] Paris Convention, *supra* note 214, art. 4.H. ("Priority may not be refused on the ground that certain elements of the invention for which priority is claimed do not appear among the claims formulated in the application in the country of origin, provided that the application documents as a whole specifically disclose such elements.").