1991 AREA SUMMARIES

PATENT LAW DEVELOPMENTS IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DURING 1991*

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INTRODUCTION

Federal Circuit patent law watching was never more important or more challenging than it was in 1991 and promises to be in 1992. The soaring economic significance of patents forces more interest groups to monitor the court's work product. Recent changes in court membership complicate the task. New judges do not always cause major doctrinal changes in mature legal environments such as the patent system. Their fresh styles of opinion writing and legal analysis and diverse backgrounds may, however, give settled rules new twists. They may also subtly shift the court's focus to less trodden areas where "a new kid on the block" can have more influence.[1] The following review summarizes selected published opinions on substantive patent law by the Federal Circuit in 1991.[2]

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1. An example is the treatment of personal property interests in patents and the implications on standing to sue and recover infringement damages. In 1991, a number of plaintiffs sought to modify the rule that one must have legal title to a patent during the time of infringement to sue for damages, but the court was reluctant to loosen the standard. *See* FilmTec Corp. v. Allied-Signal Inc., 939 F.2d 1568, 1573-74, 19 U.S.P.Q.2d 1508, 1511 (Fed. Cir. 1991) (holding that plaintiff with questionable legal title to patent cannot obtain preliminary injunction); Arachnid, Inc. v. Merit Indus., Inc., 939 F.2d 1574, 1580-82, 19 U.S.P.Q.2d 1513, 1518-19 (Fed. Cir. 1991) (holding that agreement to assign does not vest legal title in plaintiff); *cf.* Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.p.A., 944 F.2d 870, 873-76, 20 U.S.P.Q.2d 1045, 1049-52 (Fed. Cir. 1991) (holding that patentee's grant of all substantial rights to plaintiff allows plaintiff alone to sue for infringement).

2. Space limitations dictate that some important areas be omitted, including:

(1) the laches and estoppel defenses, e.g., Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.p.A., 944 F.2d 870, 20 U.S.P.Q.2d 1045 (Fed. Cir. 1991);

(2) assignor estoppel, e.g., Intel Corp. v. International Trade Comm'n, 946 F.2d 821 (Fed. Cir. 1991); Acoustical Design, Inc. v. Control Elec. Co., 932 F.2d 939, 18 U.S.P.Q.2d 1707 (Fed. Cir. 1991);

(3) consent decrees' res judicata effect, e.g., Foster v. Hallco Mfg. Co., 947 F.2d 469, 20 U.S.P.Q.2d 1241 (Fed. Cir. 1991);

(4) preliminary injunction standards, e.g., Conair Group, Inc. v. Automatik Apparate-Maschinenbau GmbH, 944 F.2d 862, 20 U.S.P.Q.2d 1067 (Fed. Cir. 1991); Lund Indus., Inc. v. GO Indus., Inc., 938 F.2d 1273, 19 U.S.P.Q.2d 1383 (Fed. Cir. 1991); We Care, Inc. v. Ultra Mark, Int'l Corp., 930 F.2d 1567, 18 U.S.P.Q.2d 1562 (Fed. Cir. 1991); Nutrition 21 v. United States, 930 F.2d 867, 18 U.S.P.Q.2d 1347 (Fed. Cir. 1991); Oakley, Inc. v. International Tropic-Cal, Inc., 923 F.2d 167, 17 U.S.P.Q.2d 1401 (Fed. Cir. 1991);

(5) damages, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 939 F.2d 1540, 19 U.S.P.Q.2d 1432 (Fed. Cir. 1991); Slimfold Mfg. Co. v. Kinkead Indus., Inc., 932 F.2d 1453, 18 U.S.P.Q.2d 1842 (Fed. Cir. 1991); SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 926

I. PATENTABILITY ISSUES

A. The "On Sale" and "Public Use" Bars

The Patent Act bars a patent if an invention was "on sale" or "in public use" in the United States for more than one year before the inventor filed an application.[3] The hallmarks of "on sale" and "public use" law are fact specificity and policy domination. The court's decisions emphasize that application of the bars depends on the "totality of the circumstances"[4] and that their policies "in effect, define [them]."[5] The policies behind the bars include discouraging removal of inventions from the public domain that the public reasonably believes are freely available; encouraging speedy and widespread disclosure of inventions; allowing an inventor time to determine the patent's economic value; and preventing an inventor from the commercial exploitation of his invention beyond the time set by the statute.[6]

Two 1991 "on sale" bar decisions focused on burdens of proof and inference drawing in cases in which the evidence indicating exactly what was offered when was thin. These cases reach results inconsistent in tone, if not in holding. *Sonoscan, Inc. v. Sonotek, Inc.*[7] approved a district court's reliance on post-critical date evidence to infer, first, that pre-critical date price quotations were in fact for the patented invention and, second, that the inventors had sufficiently developed the invention before the critical date.[8] *Intel Corp. v. International Trade Commission*,[9] on the other hand, disparaged "extensive" inference drawing in applying the "on sale" bar.[10] The patent in *Intel* related to EPROM memory chips. Intel, the inventors' assignee, distributed fifty sample chips embodying the invention to

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F.2d 1161, 17 U.S.P.Q.2d 1922 (Fed. Cir. 1991); Kaufman Co. v. Lantech, Inc., 926 F.2d 1136, 17 U.S.P.Q.2d 1828 (Fed. Cir. 1991); and

(6) willful infringement, advice of counsel, and multiple damages, e.g., Quantum Corp. v. Tandon Corp., 940 F.2d 642 (Fed. Cir. 1991); Uniroyal, Inc. v. Rudkin-Wiley Corp., 939 F.2d 1540, 19 U.S.P.Q.2d 1432 (Fed. Cir. 1991); Acoustical Design, Inc. v. Control Elec. Co., 932 F.2d 939, 18 U.S.P.Q.2d 1707 (Fed. Cir. 1991); Jurgens v. McKasy, 927 F.2d 1552, 18 U.S.P.Q.2d 1031 (Fed. Cir. 1991); Beatrice Foods Co. v. New England Printing & Lithographing Co., 923 F.2d 1576, 17 U.S.P.Q.2d 1553 (Fed. Cir. 1991).

3. 35 U.S.C. § 102(b) (1988).

4. U.S. Envtl. Prods., Inc. v. Westall, 911 F.2d 713, 716, 15 U.S.P.Q.2d 1898, 1901 (Fed. Cir. 1990).

5. RCA Corp. v. Data Gen. Corp., 887 F.2d 1056, 1062, 12 U.S.P.Q.2d 1449, 1454 (Fed. Cir. 1989).

6. Envirotech Corp. v. Westech Eng'g, Inc., 904 F.2d 1571, 1574, 15 U.S.P.Q.2d 1230, 1233 (Fed. Cir. 1990).

7. 936 F.2d 1261, 19 U.S.P.Q.2d 1156 (Fed. Cir. 1991).

8. Sonoscan, Inc. v. Sonotek, Inc., 936 F.2d 1261, 1263, 19 U.S.P.Q.2d 1156, 1159 (Fed. Cir. 1991).

9. 946 F.2d 821 (Fed. Cir. 1991).

10. Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 830 (Fed. Cir. 1991).

fifty Intel salesmen at a May 1984 sales conference.[11] It placed no restrictions on the chips' disposal, and salesmen "were expected to pass the samples on to their customers."[12] Intel filed a patent application claiming the invention on June 7, 1985, making June 7, 1984 the critical date. In upholding the patent against an "on sale" bar challenge, the trier of fact found that (1) the samples were pre-production engineering samples that were not available for sale; (2) Intel's intent was "clearly commercial" and, if the salesmen distributed the samples before the critical date, there would be an "on sale" bar; but (3) the respondents failed to prove by clear and convincing evidence that any customer received the chip prior to June 7.[13] The Federal Circuit affirmed, holding that a finding of actual sale or offer before the critical date would require the fact-finder to draw "extensive inferences," which would be inconsistent with the standard of clear and convincing evidence.[14]

B. Novelty and Anticipation

An invention defined in one or more patent claims must be new. The test for novelty—or its absence, called "anticipation"—is the same as that for literal infringement. A claim flunks the novelty requirement if it covers a single prior art reference disclosure. Anticipation occurs only when a person of ordinary skill in the field of the invention would find no difference between the claimed invention and the reference disclosure.[15]

What a prior art reference teaches may present a complex fact question. In *Scripps Clinic & Research Foundation v. Genentech, Inc.*,[16] an issue centered on whether Robert Harris' earlier thesis anticipated the later patented invention—high purity and activity human Factor VIII:C preparations.[17] The parties filed three successive declarations by Dr. Harris, each explaining his dissertation. The Federal Circuit reversed the district court's summary judgment invalidating the claims for anticipation, holding that the district court improperly resolved the summary judgment motion because apparent inconsistencies existed among the three Harris declara-

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11. *Id.* at 829.
12. *Id.*
13. *Id.*
14. *Id.* at 830.
15. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010, *petition for reh'g denied and petition for reh'g in banc under consideration*, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).
16. 927 F.2d 1565, 18 U.S.P.Q.2d 1001, *petition for reh'g denied and petition for reh'g in banc under consideration*, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).
17. *Scripps*, 927 F.2d at 1570, 18 U.S.P.Q.2d at 1004-05.

tions that raised questions as to the credibility of witnesses and the weight of the evidence interpreting scientific data.[18] The court agreed that extrinsic evidence may be considered to explain the disclosure of a reference, but cautioned that such evidence is of limited probative value because a finding of anticipation is impossible unless all aspects of the claimed invention were already described in a single reference.[19] Such a finding cannot be made if it is necessary to prove facts beyond those disclosed in the reference. The court thus concluded that extrinsic evidence should be used only to show the decisionmaker the meaning of the reference to persons of ordinary skill in the field, and not to close gaps in the reference.[20] Going outside a single reference to provide missing disclosure of the claimed invention should therefore occur, not in cases involving section 102 anticipation, but rather in those involving section 103 obviousness.[21]

C. Obviousness

In past years, the Federal Circuit has labored to rationalize the section 103 nonobviousness requirement.[22] Although section 103 was not a central focus in 1991, a number of cases illustrated the continuing difficulties in applying it to high (and not so high) technology inventions.

Amgen, Inc. v. Chugai Pharmaceutical Co.,[23] involved an isolated DNA sequence encoding human erythropoietin (EPO) and host cells transformed with the sequence. The court held that the plaintiff's patent claims to this sequence were not obvious because no reasonable expectation of success existed on the invention date in cloning

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18. *Id.* at 1578, 18 U.S.P.Q.2d at 1011.
19. *Id.* at 1576, 18 U.S.P.Q.2d at 1010.
20. *Id.*
21. *Id.* at 1577, 18 U.S.P.Q.2d at 1010. *But see In re* Baxter Travenol Lab., 21 U.S.P.Q.2d 1281, 1284 (Fed. Cir. 1991) (holding that patent claims regarding system for processing and storing whole blood were barred by anticipation because document describing new system existed).
22. *See In re* Dillon, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1900-02 (Fed. Cir. 1990) (holding that proved structural similarity between subject matter of claimed and prior art, where prior art gives reason to make the claimed composition, creates prima facie case of obviousness), *cert. denied*, 111 S. Ct. 1682 (1991); Grain Processing Corp. v. American Maize Prods. Co., 840 F.2d 902, 907-08, 5 U.S.P.Q.2d 1788, 1792-93 (Fed. Cir. 1988) (finding that showing that every element of patent was demonstrated in prior art does not invalidate patent when combination of elements does not suggest the invention to person of ordinary skill in field); DMI, Inc. v. Deere & Co., 802 F.2d 421, 423, 231 U.S.P.Q. 276, 278-79 (Fed. Cir. 1986) (holding that finding of obviousness depends on scope of prior art, differences between invention and prior art, and unexpected results); Peterson Mfg. Co. v. Central Purchasing, Inc., 740 F.2d 1541, 1548, 222 U.S.P.Q. 562, 567 (Fed. Cir. 1984) (stating that obviousness claim requires consideration of distinguishing features of disputed design).
23. 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

the EPO gene using either the inventor's unique strategy or the infringer's alternative suggested strategy.[24]

In *In re Gorman*,[25] the Federal Circuit upheld the PTO's rejection of an applicant's claim to a "composite candy sucker on a stick, molded in an elastomeric mold in the shape of a human thumb."[26] The court upheld this finding of obviousness even though the claim was extremely specific and detailed and the PTO relied on thirteen prior art references.[27]

Similarly, in *In re Young*[28] the court upheld the PTO's rejection of an applicant's claim to an underwater acoustic pulse generating method for offshore seismic exploration as obvious in view of one prior art reference, even though a later reference purported to discredit the first.[29] The court stated that when prior art contains apparently conflicting references, the PTO "must weigh each reference for its power to suggest solutions to an artisan of ordinary skill."[30]

In *Jurgens v. McKasy*,[31] the court upheld a jury verdict that a patent claiming a windsock goose hunting decoy was not invalid for obviousness. The jury made presumed findings in the patentee's favor on the prior art's teachings and on the status of a disputed reference, a dragon's head windsock, as analogous art.[32] Because the infringer failed to make a timely directed verdict motion, he could not challenge the sufficiency of evidence underlying the jury's presumed findings.[33]

How amenable to summary judgment is the obviousness unpatentability defense? On the one hand, the defense often requires resolution of many fact issues, including "primary" technical facts

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24. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1207-09, 18 U.S.P.Q.2d 1016, 1020-23 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991); *see In re* Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991) (reversing PTO rejection of claims to a "chimeric" gene, uniting *Bacillus* genus bacterium gene, whose product is insecticidal protein, and DNA promoter in host cyanobacterium and stating that obviousness under section 103 requires consideration of (1) whether prior art would suggest to one ordinarily skilled in the art to make claimed composition or device, or carry out claimed process; and (2) whether prior art would also have revealed reasonable expectation of success in so doing); Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 835 (Fed. Cir. 1991) (finding claimed invention, extending EPROM chip's side walls to shield it from ultraviolet radiation, not to be obvious because it increased life of cell and gave it previously unknown practical uses).

25. 933 F.2d 982, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

26. *In re* Gorman, 933 F.2d 982, 983, 18 U.S.P.Q.2d 1885, 1886 (Fed. Cir. 1991).

27. *Id.* at 986-87, 18 U.S.P.Q.2d at 1886-88.

28. 927 F.2d 588, 18 U.S.P.Q.2d 1089 (Fed. Cir. 1991).

29. *In re* Young, 927 F.2d 588, 591-92, 18 U.S.P.Q.2d 1089, 1091-92 (Fed. Cir. 1991).

30. *Id.* at 591, 18 U.S.P.Q.2d at 1091.

31. 927 F.2d 1552, 18 U.S.P.Q.2d 1031 (Fed. Cir. 1991).

32. Jurgens v. McKasy, 927 F.2d 1552, 1557-60, 18 U.S.P.Q.2d 1031, 1036-38 (Fed. Cir.), *cert. denied*, 112 U.S. 281 (1991).

33. *Id.* at 1560, 18 U.S.P.Q.2d at 1038.

such as the prior art's teachings and "secondary" inferential facts such as commercial success.[34] Yet, invalidity in view of teachings of specific prior art is sometimes so clear that there can be no genuine fact issues preventing summary disposition.[35]

D. Prior Art

"Prior art" is central to determinations of patentability. Both the novelty and nonobviousness requirements involve comparing the patent claim with individual and collective teachings of the prior art. Unlike some other major patent systems which sweep all publicly available information released before the patent application filing date into the prior art,[36] United States patent law defines "prior art" in a complex manner, making distinctions based on place, person, and format as well as time.[37] For example, a pre-invention date, third-party public use is prior art if the use is in the United States but not if the use is in another country.[38]

In re Bartfeld[39] illustrates prior art's complexity. In *Bartfeld*, the court confirmed that a common owner of two patents or patent applications cannot use a terminal disclaimer to overcome a "[s]ection 102(e)/103 rejection."[40] One inventor's patent disclosures are prior art in assessing the patentability of a different inventor's subsequent claims even though both inventors assigned their rights to the same organization.[41] The section 103 common ownership prior art disqualifier, added by a 1984 amendment, applies to information derived under section 102(f) and to another's prior invention under section 102(g), but not to disclosure in a senior filed, different in-

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34. *See* Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1265-66, 20 U.S.P.Q.2d 1746, 1747 (Fed. Cir. 1991) (stating that erroneous granting of summary judgment prolongs litigation and increases its burdens, which is "of particular concern in patent disputes, where the patent property is a wasting asset, and justice is ill served by delay in final resolution.").

35. *See* Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 715, 21 U.S.P.Q.2d 1053, 1055 (Fed. Cir. 1991) (finding that all elements of combination invention were so well known that obviousness could not be questioned).

36. *See* Convention for the European Patent for the Common Market, Resolution Concerning Prior Use or Possession, *reprinted in* 15 INT'L LEGAL MATERIALS 39 (1976) (stating that prior art includes all information publicly available at time patent application is filed).

37. *See* 35 U.S.C. § 102 (1988). Section 102 governs the issuance of patents for an invention which is not novel. *Id.* A finding of lack of novelty depends on a number of factors. For example, a patent cannot be issued for an invention "known" in the United States, but it can for an invention "known" in a foreign country, unless it was patented or described in a patented publication. *Id.* § 102(a).

38. *See* 35 U.S.C. § 102(b) (1988) (stating that person is entitled to patent unless invention was in public use or on sale "in this country" for more than one year prior to date of application for U.S. patent).

39. 925 F.2d 1450, 17 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

40. *In re* Bartfeld, 925 F.2d 1450, 1451, 17 U.S.P.Q.2d 1885, 1886 (Fed. Cir. 1991).

41. *Id.* at 1452 & n.7, 17 U.S.P.Q.2d at 1887 & n.7.

ventor patent under section 102(e).[42] The court therefore found that the statute's clear exclusion of section 102(e) prior art from its coverage left it no room to respond to the appellant's argument that "corporate assignees are routinely forced to use burdensome and costly procedures such as abandoning both applications and refiling a combined application."[43] Terminal disclaimers are effective to overcome double patenting problems, but not section 102(e)/103 rejections.[44] The two differ in that "[d]ouble patenting depends entirely on what is *claimed* in an issued *patent* . . . [while] [o]bviousness relates to what is disclosed (whether or not claimed) in a prior art reference (whether or not a *patent*)."[45] Because terminal disclaimers seek to limit the term of a patent rather than to remove a reference as prior art, they are not appropriate to overcome section 102(e)/103 rejections.[46]

E. First Inventor

The United States patent system applies a first-to-invent rule to determine priority among conflicting claimants to the same invention. The Patent and Trademark Office (PTO) resolves invention priority questions in interference proceedings.[47] Priority questions

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42. 35 U.S.C. § 103 (1988). This section provides:

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Id.

43. *Bartfeld*, 925 F.2d at 1452-53, 17 U.S.P.Q.2d at 1887-88.

44. *Id.* at 1453, 17 U.S.P.Q.2d at 1888.

45. *Id.* (emphasis added).

46. *Id.*

47. *See* Minnesota Mining & Mfg. Co. v. Norton Co., 929 F.2d 670, 674, 18 U.S.P.Q.2d 1302, 1306 (Fed. Cir. 1991) (stating that interference proceedings are declared to determine priority among multiple patent applicants or applicant and patentee, and that such proceedings may consider issues of patentability but not infringement).

Minnesota Mining illustrates the complex relationships that may arise between PTO interference proceedings and judicial proceedings involving questions of patent infringement and validity. In the case, Norton filed a patent application covering a seeded gel process for making abrasive grain using aluminum seeds. *Id.* at 671, 18 U.S.P.Q.2d at 1303. Later, Minnesota Mining & Manufacturing (3M) filed an application claiming a similar process using both aluminum and iron seeds. *Id.*, 18 U.S.P.Q.2d at 1303-04. Norton obtained a patent claiming the aluminum seed process. *Id.* 3M filed a declaration of interference between its application and Norton's patent over priority of invention of the aluminum seed process. *Id.* Norton asserted that 3M's iron seed product infringed its patent under the doctrine of equivalents. *Id.* at 672, 18 U.S.P.Q.2d at 1304.

When Norton sent 3M's customers cease-and-desist letters, 3M filed suit for a declaratory judgment of noninfringement. *Id.* The district court exercised its discretion to dismiss the suit because the interference could have left the infringement issue moot by awarding 3M invention priority. *Id.* The Federal Circuit held that this was an abuse of discretion because the interference would not necessarily resolve the infringement question and because the delay would cause 3M irreparable injury. *Id.* at 676, 18 U.S.P.Q.2d at 1306.

may also arise in other contexts because prior invention may establish prior art for novelty and nonobviousness purposes.[48]

The first inventor is the person who first reduces the invention to practice, either actually or constructively, unless a rival shows prior conception and, from a time just before the other conception or reduction to practice, worked diligently to reduce it to practice.[49] Conception and reduction to practice are central to the determination of invention priority, and each was the subject of a 1991 Federal Circuit decision.

Focusing on conception in unpredictable technologies such as biotechnology, *Amgen, Inc. v. Chugai Pharmaceutical Co.*[50] applied the doctrine of simultaneous conception and reduction to practice. Amgen's patent claimed an isolated DNA sequence encoding human erythropoietin (EPO) and host cells transformed with the sequence.[51] Amgen's scientist, Dr. Fu-Kuen Lin, first reduced the invention to practice by cloning the EPO gene. Defendant Genetic Institute contended that its scientist, Dr. Fritsch, was the first to conceive the strategy eventually successful in cloning the EPO gene—screening a human genomic DNA library with two sets of fully degenerate cDNA probes from different EPO gene regions. The court found that whether there was an adequate conception of the invention depended entirely on reduction to practice because of the uncertainties of the method and lack of information about the sequence.[52]

The Federal Circuit explained that conception has two elements: (1) the idea of the invention's structure; and (2) the possession of a workable method for making it.[53] Sometimes, an inventor cannot establish a conception until the invention is reduced to practice through a successful experiment, which results in simultaneous conception and reduction to practice.[54] The court stressed that the EPO DNA sequence was unknown until plaintiff cloned it, and that because the inventor was unable to envision its detailed constitution or the method of obtaining it, conception was not achieved until the sequence was reduced to practice, the moment at which the gene

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48. *See* New Idea Farm Equip. Corp. v. Sperry Corp., 916 F.2d 1561, 16 U.S.P.Q.2d 1424 (Fed. Cir. 1990) (invalidating patents as anticipated because another individual conceived and implemented invention).

49. *Id.* at 1566-67, 16 U.S.P.Q.2d at 1429-30.

50. 927 F.2d 1200, 1205-07, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

51. Amgen, Inc. v. Chugi Pharmaceutical Co., 927 F.2d 1200, 1203-04, 18 U.S.P.Q.2d 1016, 1019-21 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

52. *Id.* at 1207, 18 U.S.P.Q.2d at 1022.

53. *Id.* at 1206, 18 U.S.P.Q.2d at 1020-21.

54. *Id.*

was isolated.[55] The court therefore concluded that neither Fritsch nor Lin invented EPO or the EPO gene because the claimed invention was the new, pure, isolated sequence and neither inventor knew its structure or physical characteristics or had a viable method to obtain it until it was actually obtained and characterized.[56]

Further, the court found lacking the defendant's argument that it had priority because the trial court found that Fritsch's two-probe strategy distinguished the invention over the prior art.[57] The court stated that Fritsch's alleged conception was "mere speculation" because it was not specific enough to allow an individual skilled in the relevant field to clone the EPO gene successfully.[58] Moreover, experts who testified for both sides indicated that success in cloning the gene was not ensured until the gene was in fact isolated and until its sequence was known.[59]

DSL Dynamic Sciences Ltd. v. Union Switch & Signal, Inc.[60] applied the testing requirement of actual reduction to practice. The case involved invention of a mount assembly for a railway car coupler.[61] The senior applicant-patentee, DSL, filed its application on September 9, 1983, which was the effective invention date because the invention's conception and reduction to practice occurred in Canada and section 104 precludes proof of invention dates by activity outside of the United States.[62] The junior applicant, Union Switch, filed its application on March 27, 1984.[63] To show a reduction to practice prior to the patentee's filing date, Union Switch relied on a prototype built around April 1, 1983 and tested on moving trains during May 1983.[64]

The senior party attacked the adequacy of the test on two grounds. First, Union Switch tested the prototype on a caboose rather than on its intended environment, a freight car. The senior party argued that freight cars have an inferior suspension system

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55. *Id.* The court stated that "Fritsch had a goal of obtaining the isolated EPO gene, whatever its identity, and even had a possible method of obtaining it, [but] . . . he did not conceive a purified and isolated DNA sequence encoding EPO and a viable method for obtaining it until after Lin." *Id.*

56. *Id.*

57. *Id.*

58. *Id.* at 1206-07, 18 U.S.P.Q.2d at 1021.

59. *Id.* at 1207, 18 U.S.P.Q.2d at 1021.

60. 928 F.2d 1122, 18 U.S.P.Q.2d 1152 (Fed. Cir. 1991).

61. DSL Dynamic Sciences Ltd. v. Union Switch & Signal, Inc., 928 F.2d 1122, 1123, 18 U.S.P.Q.2d 1152, 1153 (Fed. Cir. 1991).

62. *Id.*; *see* 35 U.S.C. § 104 (1988) ("[a]n applicant for a patent . . . may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country . . . .").

63. *DSL*, 928 F.2d at 1123, 18 U.S.P.Q.2d at 1153.

64. *Id.* at 1123-24, 18 U.S.P.Q.2d at 1153.

that might have caused the prototype to fail. The court, however, found the tests sufficient because Union Switch performed them under conditions sufficiently similar to those of the intended environment.[65] Second, the senior party pointed out that commercial assemblies built according to the prototype design later failed and required major modifications before they were suitable for use. The court found that this did not prove that the prototype test was inadequate because "there is . . . no requirement that an invention, when tested, be in a commercially satisfactory stage of development in order to reduce the invention to practice."[66]

F. Double Patenting

Double patenting is a judicially developed doctrine that prohibits an inventor or a common assignee of several inventors from obtaining more than one patent claiming substantially the same invention.[67] It prevents improper patent term extension and protects potential accused infringers from multiple suits. A terminal disclaimer in a second or subsequent patent eliminates a double patenting objection unless the two patents claim exactly the same invention.[68]

1. The "first-in," "second-out" problem

The usual double patenting test—whether the claimed subject matter in the second patent or application would have been unpatentably obvious in view of the claimed subject matter of the first—does not apply comfortably to situations in which the first patent is an improvement to or variation on the invention disclosed and claimed in an application filed first but examined or issued second.

In *In re Braat*,[69] the court held that the PTO erred in rejecting an applicant's claims on obviousness-type double patenting grounds.[70] A "two-way" rather than "one-way" patentability test applies when an inventor or assignee files a patent application claiming an improvement or combination invention after a patent application

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65. *Id.* at 1125, 18 U.S.P.Q.2d at 1154.

66. *Id.* at 1126, 18 U.S.P.Q.2d at 1155.

67. *See In re* Braat, 937 F.2d 589, 592, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991) (defining double patenting as judicially created doctrine that prevents improper timewise extension of patent right by prohibiting issuance of claims in second patent indistinguishable from claims in first).

68. *See* 35 U.S.C. § 253 (1988) (allowing patentee to disclaim "any terminal part of the term . . . of the patent," thus guaranteeing that both patents expire at same time); *see also In re* Lang, 759 F.2d 887, 892-95, 225 U.S.P.Q. 645, 648-50 (Fed. Cir. 1985) (discussing terminal disclaimers).

69. 937 F.2d 589, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991).

70. *In re* Braat, 937 F.2d 589, 589, 19 U.S.P.Q.2d 1289, 1289 (Fed. Cir. 1991).

claiming the basic or subcombination invention has been filed but the second-filed application issues first through no fault of the inventor or assignee.[71] In *Braat,* Dil's patent and Braat's application, both assigned to Philips, related to optical record carriers, such as compact discs (CDs), that store information to be retrieved by a radiation beam, such as a laser. Braat's U.S. application claimed an April 3, 1978 Netherlands application priority date. Dil's patent issued June 24, 1980 on an application filed January 31, 1979.[72]

Circular optical record carriers store information in tracks consisting of information areas, or "pits," separated by intermediate regions, or "lands." Information is encoded by varying the length or spacing between the pits, and the information is retrieved by projecting a read beam onto the information tracks, which detects variations in the light transmitted through or reflected from the tracks.[73] Because the ability of the read apparatus to focus the beam on a single track limits track density, one way to increase carrier information density is to place tracks closer together. If the tracks are too close, however, the beam may inadvertently illuminate an adjacent track, resulting in interference or "crosstalk."[74]

Braat's application disclosed a way to reduce "crosstalk" by alternating adjacent track phase depth and using two detection systems, one sensitive to first phase depth tracks and the other sensitive to second phase depth tracks. Dil's patent disclosed a way of controlling information record carrier phase depth by precisely angling phase depth.[75] Dil recognized that his invention was particularly useful in combination with Braat's. Dil's patent *independent* claim 1 was to the angle side wall improvement; its *dependent* claims 5/1 and 6/1 recited Braat's alternating phase depth structure as an additional feature.[76]

The PTO Board of Patent Appeals and Interferences (Board) affirmed the examiner's rejection of Bratt's claims for obviousness-type double patenting. The Board reasoned that (1) because Braat's claims were broader than Dil's claims 5/1 and 6/1, the double patenting rejection properly prevented an unjustified extension in time of the right to exclude; and (2) that the issue was not whether the claims in Dil were patentably distinct from the claims in

71. *Id.* at 593, 19 U.S.P.Q.2d at 1292.
72. *Id.* at 590, 19 U.S.P.Q.2d at 1290.
73. *Id.*
74. *Id.*
75. *Id.* at 591, 19 U.S.P.Q.2d at 1291.
76. *Id.* at 592, 19 U.S.P.Q.2d at 1291.

Braat's application but whether the claims on appeal were patentably distinct over claims 5/1 and 6/1 of Dil.[77]

On appeal, the assignee characterized Dil's invention as an improvement over Braat's invention and advanced the proposition that when a patent issues on a later-filed improvement before the issuance of a patent on an earlier-filed basic invention, rejection of the claims to the basic invention for double patenting is only proper if the improvement is not patentably distinct from the basic invention.[78] The court viewed the two inventions as combination and subcombination, rather than improvement invention and basic invention,[79] but agreed with the assignee's proposition. The court pointed out that an applicant who files applications for basic and improvement patents has no control over the rate at which applications are processed in the PTO and should not be penalized for it. Therefore, the order of issuance, out of fairness, should be ignored, making the relevant determination whether the improvement is "patentably distinct from the generic invention."[80] Thus, in this case, the court concluded that it would not have been possible for the assignee to include either the claims of Dil in the Braat application (for Braat did not invent the subject matter of the Dil claims) or the claims of Braat in the Dil application (for Dil did not invent the subject matter of the Braat application).[81] The assignee filed the Braat and Dil applications in order to maintain proper inventorship, with the first application containing claims directed to Braat's "subcombination" invention and the second containing claims directed to both Dil's "subcombination" invention and to the "combination" invention. The assignee could not control the fact that the PTO issued the Dil patent first.[82]

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77. *Id.*

78. *Id.* at 593, 19 U.S.P.Q.2d at 1292 (citing 3 DONALD S. CHISUM, PATENTS § 9.03[2][c], at 9-33 (1991) and *In re* Borah, 354 F.2d 1009, 1017, 148 U.S.P.Q. 213, 219-20 (C.C.P.A. 1966)).

79. *Braat*, 937 F.2d at 593, 19 U.S.P.Q.2d at 1292. The court stated that:

> The word "improvement" implies that it was developed specifically for use with the "basic" invention, and thus must have come later in time. . . . The Dil patent invention . . . is totally separate from that of Braat, and could conceivably have been developed earlier rather than later. The inventions of Dil and Braat are independent but when jointly used may complement each other, and it is for that reason that Dil disclosed the Braat invention in his own patent application and, in claims 5/1 and 6/1, claimed the use of the two inventions in combination. . . . Braat and Dil each developed separate subcombination inventions, which are described by their respective independent claims. Dil then *combined* these two subcombinations to form a third invention. This *combination* is described by [Dil's] dependent claims . . . .

Id. (emphasis in original).

80. *Id.*

81. *Id.*

82. *Id.* at 593-94, 19 U.S.P.Q.2d at 1293-94.

Applying the "two-way" test, the court reversed the double patenting rejection because Dil's patent claims 5/1 and 6/1 were patentably distinct from Braat's application claims, even though Braat's claims were not patentably distinct from Dil's claims.[83] The court admitted that allowing Braat's application would result in an extension of the time of the assignee's patent protection of the Dil structure because Braat's claims dominated the invention of Dil's claims.[84] It noted, however, that double patenting rejection is only appropriate when such an extension of a patent right is unjustified, and found the extension in this case to be justified.[85]

2. Section 121's protective shield

After an inventor files a patent application, the PTO may, and often does, impose a "restriction" identifying two or more separate and independent inventions and requiring the applicant to elect which invention to pursue. Patent Act section 121, together with section 120, allows the applicant to pursue the non-elected inventions in a divisional application, retaining the benefit of the original application's filing date. The third sentence of section 121 prohibits a patent that issues either (1) "on an application with respect to which a requirement for restriction under this section has been made"; or (2) "on an application filed as a result of such a requirement" from being used "as a reference" against either "a divisional application" (or any patent issuing thereon) or "the original application" (or any patent issuing thereon).[86]

Case law interpreting this portion of section 121 is amazingly sparse. In the 1990 decision, *Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*,[87] the Federal Circuit held that section 121 does not absolutely protect a patent issuing on a divisional or continuing application filed as a result of an examiner restriction requirement from double patenting invalidity.[88] The court concluded that this section applies only when a second patent's claims are consonant with the

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83. *Id.* Braat's rejected claims did not refer to any side wall angling, much less to Dil's specific angles. In Braat's preferred embodiment, the information areas are all rectangular and have side walls that are not inclined "relative to the normal to the record carrier." *Id.* at 594, 19 U.S.P.Q.2d at 1293-94.

84. *Id.* at 593, 19 U.S.P.Q.2d at 1293. The court's finding of "some" time extension, however, is an understatement. Because the Dil patent issued in 1980, the Braat patent would provide an 11-year extension (assuming a 1991 issue date).

85. *Id.* at 594, 19 U.S.P.Q.2d at 1293.

86. *See* 35 U.S.C. § 121 (1988) (discussing divisional applications in reference to section 120).

87. 916 F.2d 683, 16 U.S.P.Q.2d 1436 (Fed. Cir. 1990).

88. Gerber Garment Technology, Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688, 16 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1990).

claims not elected by the inventor in response to the restriction requirement.[89] The *Gerber Garment* consonance standard needs refinement, particularly with respect to the specification of the kinds of claim amendments and additions in the second application that will bring the claims outside the prohibition of section 121. *Symbol Technologies, Inc. v. Opticon, Inc.*,[90] which held that divisional application *apparatus* claims may be consonant with a PTO examiner's restriction requirement referring to the non-elected invention as a *method*, provides some guidance—but not much.[91]

In *Symbol Technologies*, the patents at issue related to hand-held laser bar code symbol readers.[92] The patentee filed an application in 1980. The examiner required restriction to one of seven inventions. The patentee elected "Group I" claims, directed to "aim and shoot" light-weight laser scanning heads with an optic sighting means and a "manually actuatable" trigger. Patent '297 issued, claiming the elected invention.[93]

The patentee filed a divisional application with claims directed to the "Group VI" invention which the examiner's restriction requirement referred to as a "method" of scanning, sensing, and decoding bar code symbols.[94] The Group VI invention allowed a reader to automatically stop scanning when the target for code was successfully decoded. In addition to the original automatic stopping *method* claims, the patentee added *apparatus* claims. Both the original method and new apparatus claims required a trigger and a step (in the method claims) or "means" (in the apparatus claims) for "determining a successful decoding of each symbol, and for nonmanually terminating the reading of each symbol upon the determination of the successful decoding thereof."[95]

The court found no breach of the restriction requirement when the patentee added apparatus claims in the divisional application because the method and apparatus claims are directed to the same system.[96] The patentee's expert testified that, with respect to

89. *Id.*

90. 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991).

91. *See* Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1579, 19 U.S.P.Q.2d 1241, 1249 (Fed. Cir. 1991) ("[N]ew or amended claims in a divisional application are entitled to the benefit of § 121 if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement. If that line is crossed, the issue is whether the invention claimed in the [second] patent would have been obvious in light of the invention claimed in the [first] patent.").

92. *Id.* at 1572, 19 U.S.P.Q.2d at 1243.

93. *Id.*

94. *Id.* at 1573, 19 U.S.P.Q.2d at 1244.

95. *Id.*

96. *Id.* at 1580, 19 U.S.P.Q.2d at 1249.

electronics, the PTO does not distinguish between claims to an apparatus and claims to a method of using it. Therefore, "the word 'method' in the description of Group VI during restriction did not mean that the claims were limited to a method, but was merely a short-hand description of the invented system. . . . [T]he examiner collectively characterized the method and apparatus claims of another non-elected group, Group IV, as a 'method.' "[97]

Symbol Technologies involved an easy consonance question; the new apparatus claims simply reworded the method claims in "means-plus-function" language. Cases in which the inventor substantially changes the scope of the non-elected invention claims in the second application or patent but does not introduce the limitation that is essential to the elected invention's patentability are much tougher.

3. Terminal disclaimer as an admission of obviousness

In *Quad Environmental Technologies Corp. v. Union Sanitary District*,[98] the Federal Circuit held that an inventor who submits a terminal disclaimer to overcome a PTO examiner's rejection of one patent's claims for obviousness-type double patenting in view of the inventor's prior patent is not thereby estopped from arguing that the claims are nonobvious in view of the first patent's subject matter.[99] In *Quad*, after the inventor submitted the disclaimer and obtained confirmation of the claims in a reexamination, it came to light that the subject matter of the prior patent was prior art for section 103 obviousness purposes because it had been in public use for more than one year before the second application's filing date.[100]

The court noted that a rejection for obviousness-type double patenting is appropriate when "the claims of a later patent application are deemed obvious from the claims of an earlier patent."[101] This occurs when the inventor or someone associated with the inventor makes developments and improvements as they continue to work in the field. When an applicant meets the statutory requirement of common ownership, a convenient response is a voluntary limitation of the term of the later-issued patent.[102] A voluntary limitation eliminates any enlargement of the term of exclusivity, but still provides limited protection to a patentee's later developments.[103]

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97. *Id.*
98. 946 F.2d 870, 20 U.S.P.Q.2d 1392 (Fed. Cir. 1991).
99. Quad Envtl. Technologies Corp. v. Union Sanitary Dist., 946 F.2d 870, 874-75, 20 U.S.P.Q.2d 1392, 1394-95 (Fed. Cir. 1991).
100. *Id.* at 873, 20 U.S.P.Q.2d at 1393.
101. *Id.*, 20 U.S.P.Q.2d at 1394.
102. *Id.*
103. *Id.* at 872-74, 20 U.S.P.Q.2d at 1393-95.

Thus, the court concluded that a rejection for double patenting "does not mean that the first-filed patent is a prior art reference under § 102 against the later-filed application" because only the claims are compared.[104]

Therefore, filing a terminal disclaimer only removes the double patenting rejection; it does not create a presumption or estoppel on the merits.[105]

II. DISCLOSURE AND CLAIMING ISSUES

Section 112's first paragraph sets forth three distinct specification disclosure requirements: the description-of-the-invention requirement, the enablement requirement, and the best mode requirement.[106] The second paragraph sets forth the requirement of clear claiming.[107] These four requirements are, in theory, distinct. Determining the distinctions between them, however, continues to vex courts, practitioners, and PTO examiners. An interplay exists between the requirement of clear claiming and the three disclosure requirements. A patent's claims define the "invention" that must be described, enabled, and "best moded." During PTO prosecution, the original ("as filed") patent specification disclosure restrains the ability of the applicant and the applicant's attorney to broaden, narrow, and re-orient claims. The temptation is great to amend claims after the original filing to avoid newly discovered prior art and yet encompass post-filing date evolving technology, as well as provide broad coverage of embodiments that turn out to be commercially important.

A. Enablement

Amgen, Inc. v. Chugai Pharmaceutical Co.,[108] a highly significant Federal Circuit enablement precedent, invalidated claims in two patents relating to human EPO, one held by Amgen, the other by Genetics Institute. As noted above, Amgen based its patent on the EPO gene cloning invention of its scientist.[109] The patent contained claims

104. *Id.* at 874, 20 U.S.P.Q.2d at 1395.

105. *Id.* at 873-74, 20 U.S.P.Q.2d at 1394-95.

106. 35 U.S.C. § 112 (1988) ("The specification shall contain a written description of the invention, and of the manner of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").

107. *Id.* ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention . . . .").

108. 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

109. *See supra* notes 50-52 and accompanying text (discussing facts of *Amgen*).

specific to *human* EPO, including DNA isolate claims (e.g., "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin") and transformed host cell claims (e.g., "procaryotic or eucaryotic host cell transformed or transfected with" the EPO DNA sequence).[110] The court upheld these claims.[111] The patent also contained a more general claim, number 7, "covering all possible DNA sequences that will encode any polypeptide having an amino acid sequence 'sufficiently duplicative' of EPO to possess the property of increasing production of red blood cells."[112]

The court affirmed the district court's invalidation of claim 7 as too broad in relation to the enabling disclosure because the number of sequences that could produce an EPO-like product is "potentially enormous."[113] The head of the patentee's EPO analog program testified that he did not know whether the patentee's EPO analogs "had the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake."[114] In finding insufficient disclosure to support claim 7, the district court relied on the unpredictability of the art—the fact that "[a]fter five years of experimentation . . . '[the patentee] is still unable to specify which analogs have the biological properties set forth in claim 7.' "[115] The court determined that the primary question centered on whether the scope of enablement of the claim was co-extensive with the scope of the claim itself.[116] The fact that some degree of experi-

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110. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1204, 18 U.S.P.Q.2d 1016, 1019 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

111. *Id.* at 1219, 18 U.S.P.Q.2d at 1031.

112. *Id.* at 1212, 18 U.S.P.Q.2d at 1026. Claim 7 was for

> [a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

Id. at 1204, 18 U.S.P.Q.2d at 1019. The patent specification stated that "one may readily design and manufacture genes" differing from that for mature EPO "in terms of the identity or location of one or more residues . . . ." It continued:

> [T]he present invention . . . comprehend[s] all DNA sequences suitable for use in securing expression in a . . . host cell of a polypeptide product having at least a part of the primary structural conformation and one or more of the biological properties of erythropoietin . . . .

Id. at 1212-13, 18 U.S.P.Q.2d at 1026.

113. *Id.* at 1213, 18 U.S.P.Q.2d at 1026.

114. *Id.*, 18 U.S.P.Q.2d at 1027.

115. *Id.*

116. *Id.* at 1212, 18 U.S.P.Q.2d at 1026 (citation omitted).

mentation is required would not result in a lack of enablement unless the required experimentation was "unduly extensive."[117]

The Federal Circuit found that, although the trial court's result was correct, its focus should have been on the "enablement of the DNA sequence analysis" rather than on the "biological properties of the EPO analogs" which were the subject of claim 7.[118] Additionally, the court held that the patent applicant need not test every embodiment of the invention, as long as enough is disclosed "to enable one skilled in the art to carry out the invention commensurate with the scope of his claims."[119] In the instant case, the patentee failed to disclose information sufficient to allow another to develop enough DNA sequences, resulting in a refusal to grant the requested claims.[120]

Genetic Institute's patent claimed a homogeneous protein of a minimally specific activity level.[121] The court held the claim invalid for want of enablement, overturning the district court's contrary decision.[122] The evidence indicated that the patentee's disclosed purification process did not produce a protein with the claimed activity level.[123] The court cautioned, however, that a patentee need not

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117. *Id.*

118. *Id.* at 1213, 18 U.S.P.Q.2d at 1027.

119. *Id.*

120. *Id.* at 1213-14, 18 U.S.P.Q.2d at 1026. The court found that:

> [A] patent applicant is entitled to claim his invention generically, when he describes it sufficiently to meet the requirements of Section 112. Here, however, despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This 'disclosure' might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for [the patentee's] desire to claim all EPO gene analogs.
>
> . . .
>
> Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, . . . more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity. It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity.

Id. (citations and quotations omitted); *see In re* Vaeck, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445-46 (Fed. Cir. 1991) (requiring higher level of disclosure for claim in area where there is less predictability, such as one concerning poorly understood microorganisms, than in predictable areas such as those involving mechanical or electrical elements).

121. *Amgen*, 927 F.2d at 1216, 18 U.S.P.Q.2d at 1029.

122. *Id.* at 1216-17, 18 U.S.P.Q.2d at 1030; *see In re* Buchner, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991) (affirming examiner's rejection of claim where examiner could reasonably conclude that application was inadequate to enable one skilled in art to carry out invention).

123. *Amgen*, 927 F.2d at 1217, 18 U.S.P.Q.2d at 1030. Genetic Institute's patent disclosed a human EPO purification method using reverse phase high performance liquid chromatography (RP-HPLC) and claimed both the method and purified EPO of defined characteristics,

always prove that a disclosed process operates effectively in order to produce a claimed product.[124]

B. Best Mode

The best mode requirement is troublesome. Its policy underpinning is understandable: an inventor should not be able to obtain effective patent protection covering a technology while concealing the best known implementation method. But in its current form and as judicially interpreted, best mode is a trap for the unwary and a temptation to the unscrupulous.

The disclosure requirement is absolute and pinpointed at a specific date: the patent application filing.[125] A better mode developed one day after filing is innocuous; a better mode developed one day before filing is fatal—even though the patent application is fully prepared and on its way to the PTO and the inventor and assignee act in good faith. Best mode also spawns uncertainty. How can one competitor fully assess the validity of another's patent, without risking litigation to obtain discovery, when the best mode patentability requirement depends on what the inventor contemplated on a precise date years ago?

Perhaps sensitive to these concerns, the Federal Circuit's 1991 cases took a "rule of reason" approach to best mode compliance. In

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including "a specific activity of at least 160,000 IU per absorbance unit at 280 nanometers." *Id.* at 1215, 18 U.S.P.Q.2d at 1029. The claims' specific activity measurement was "expressed as a ratio of International Units (which measure the ability of EPO to cause formation of red blood cells) per absorbance unit (the amount of light absorbed by a sample of EPO measured by a spectrophotometer at a given wavelength, 280 nanometers), *i.e.*, IU/AU." *Id.* at 1215 n.10, 18 U.S.P.Q.2d at 1029 n.10. The district court found that "in the absence of an express statement in the patent, the claims would be construed to refer to *in vivo* rather than *in vitro* specific activity." *Id.* at 1217, 18 U.S.P.Q.2d at 1030.

The patentee did not produce evidence that its methods had been used to prepare EPO with the claimed specific activity. Rather, the inventor obtained the 160,000 figure by calculation. He subjected EPO to RP-HPLC, obtained a value of 83,000, and determined by chromatography that at least 50% of matter was something other than EPO. *Id.* at 1216, 18 U.S.P.Q.2d at 1029. In a report to the Food and Drug Administration (FDA), the patentee stated it used RP-HPLC to purify EPO from natural urine sources (uEPO) and achieved a specific activity of 109,000, based on *in vivo* bioassays. *Id.* Other scientists used the inventor's purification method and obtained about 101,000 IU/AU. *Id.*

The Federal Circuit found that the district court erred in relying on certain *in vitro* data as support for claims containing what was found to be an *in vivo* limitation. *Id.* at 1216-17, 18 U.S.P.Q.2d at 1030. Also, the *in vitro* test on uEPO showed 173,640. The accused infringer argued that the *in vivo* equivalent would be only 65%, less than 160,000. *Id.*

The patent gave an example of purification of EPO from recombinant sources (rEPO), that is, by isolating the gene encoding the protein, inserting it into a host cell, replicating the cell, causing the cell to excrete the protein into a culture medium, and harvesting the protein. The rEPO example indicated that the inventor did not obtain purified rEPO. The patent, therefore, did not enable purification of either rEPO or uEPO. *Id.* at 1217, 18 U.S.P.Q.2d at 1030.

124. *Id.* at 1217, 18 U.S.P.Q.2d at 1030.

125. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535, 3 U.S.P.Q.2d 1737, 1745 (Fed. Cir. 1987).

Wahl Instruments, Inc. v. Acvious,[126] the court held that an inventor need not necessarily disclose routine manufacturing procedures and supplies preferred for a particular commercial embodiment.[127] In two biotechnology patent cases, *Amgen, Inc. v. Chugai Pharmaceutical Co.*[128] and *Scripps Clinic & Research Foundation v. Genentech, Inc.*,[129] the court found no best mode violation even though the inventors did not make a public deposit of preferred cell lines and monoclonal antibodies.

In *Amgen*, the Federal Circuit held that the district court did not commit clear error in finding that plaintiff's patent claiming transformed cells did not violate the best mode requirement.[130] Plaintiff was not required to deposit its preferred cell culture because its specification adequately demonstrated to those skilled in the art the procedures used to prepare such a culture. A disclosure may be adequate even though it does not allow skilled workers to duplicate exactly the inventor's best mode.[131]

In *Scripps Clinic*, the Federal Circuit held that the district court erred in holding that the patentee violated the best mode requirement by failing to make publicly accessible its antibody 2.2.9, used in carrying out the patent's claimed protein purification process.[132] The inventors' specification described the inventors' preferred method of obtaining the antibodies. The accused infringer did not charge "concealment of special manipulations, or undisclosed techniques."[133] Rather, it argued that, because screening monoclonal antibodies is a laborious process, the inventors should have voluntarily made its antibody, which was the first effective one obtained by the patentee's screening, available to the public.[134] The court concluded, however, that antibodies produced by the procedure described in the specification met the specifications of those used by the inventors.[135]

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126. 950 F.2d 1575, 21 U.S.P.Q.2d 1123 (Fed. Cir. 1991).

127. Wahl Instruments, Inc. v. Acvious, 950 F.2d 1575, 1580, 21 U.S.P.Q.2d 1123, 1127 (Fed. Cir. 1991); *see also* Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533-34, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991) (finding enabling requirement of patent for corner connections satisfied even though patent described different method of making invention than was actually used by inventors).

128. 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

129. 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991).

130. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1209-11, 18 U.S.P.Q.2d 1016, 1023-25 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

131. *Id.* at 1212, 18 U.S.P.Q.2d at 1025.

132. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1578-80, 18 U.S.P.Q.2d 1001, 1011-13 (Fed. Cir. 1991).

133. *Id.* at 1579, 18 U.S.P.Q.2d at 1012.

134. *Id.*

135. *Id.*

C. *Invention Description*

In *Vas-Cath, Inc. v. Mahurkar*,[136] the Federal Circuit noted that the purpose of the written description requirement is not only to explain how to make and use the invention. The description must also indicate to those skilled in the art, with reasonable clarity, that, as of the filing date sought, the applicant possessed the invention. Thus, "[t]he invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."[137]

In *Vas-Cath*, the court held that the district court erred in granting summary judgment after concluding that a design patent application with drawings depicting a catheter did not provide a sufficient "description of the invention" to support a later utility patent application's catheter claims.[138] Disputed fact issues existed as to whether the drawings conveyed with reasonable clarity to those of ordinary skill in the art that applicant had in fact invented the device recited in the later-asserted claims, including their "range of variation" limitations.[139]

Inventor Mahurkar's catheter was made up of a pair of tubes, or lumens, which allowed blood to be removed from an artery, processed to remove impurities, and returned at a location close to where it was removed. Prior art catheters used concentric circular lumens. The inventor's catheter used joined semi-circular tubes that come to a single tapered tip and had the advantage of a 42% smaller puncture area, yielding low rates of blood injury. The catheter captured "more than half of the world's sales."[140]

On March 8, 1982, Mahurkar filed a design application with six drawings of figures depicting a double lumen catheter's exterior and cross-section.[141] As is standard practice with design applications, Mahurkar's application contained minimal textual description. The drawings depicted a tapered catheter with a return lumen, indicated by a down arrow, ending with an opening at the catheter's tip and a lumen ending with an opening at the catheter's midpoint. Mahurkar filed a Canadian Industrial Design application, which issued on August 9, 1982.[142] On October 1, 1984, Mahurkar filed a utility patent application in the United States PTO, including the same drawings

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136. 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).
137. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991) (emphasis in original).
138. *Id.* at 1566-67, 19 U.S.P.Q.2d at 1119.
139. *Id.*
140. *Id.* at 1558, 19 U.S.P.Q.2d at 1112.
141. *Id.* at 1557-58, 19 U.S.P.Q.2d at 1112.
142. *Id.* at 1558, 19 U.S.P.Q.2d at 1112-13.

as the 1982 design application and claiming the benefit of the design application's filing date.[143] The PTO issued patent '329 on the 1984 application and a second one, patent '141, on a further continuation application filed in 1986. In a 1987 office action, the examiner stated that the utility application was "considered to be fully supported by applicant's parent [design] application."[144]

The utility patents' claims contained several limitations, including one specifying a range for the ratio between the upper two-lumen portion and the lower single-lumen portion diameters.[145] The district court granted summary judgment, finding the patents not entitled to the benefit of the design application's filing date under 35 U.S.C. § 120 and, therefore, anticipated by the inventor's 1984 Canadian design registration.[146]

The accused infringer conceded that the parent design application's drawings met the section 112 enablement requirement (i.e., they enabled one skilled in the art to practice the claimed invention) but contended that the drawings failed to fulfill section 112's written description requirement.[147] The district court found a want of written description on two grounds. First, the design application did not suggest what feature or "subset or superset of the features shown" constituted the invention.[148] Second, the application did not suggest the range of variation that was allowed within the scope of the claims.[149]

The Federal Circuit held that the district court did not impose the correct legal standard for "written description" compliance and erred in its conclusion that no genuine issues of material fact were in dispute.[150] The court stated that "[t]here is 'no legally recognizable or protected "essential" element, "gist" or "heart" of the invention in a combination patent.' . . . [Rather,] '[t]he invention' is defined by the claims on appeal."[151] In this case, the court noted that the claims did not recite the separate features of the invention, but instead, described a catheter having a combination of those fea-

143. *Id.* at 1558-59, 19 U.S.P.Q.2d at 1113.
144. *Id.* at 1559, 19 U.S.P.Q.2d at 1113.
145. *Id.* at 1567-69, 19 U.S.P.Q.2d at 1120-21. An example is '329 independent claim 1, which specifies that the "second cylindrical portion has a diameter substantially greater than one-half but substantially less than a full diameter of said first [distal] cylindrical portion." *Id.* at 1568, 19 U.S.P.Q.2d at 1120.
146. *Id.* at 1557, 19 U.S.P.Q.2d at 1112.
147. *Id.* at 1559, 19 U.S.P.Q.2d at 1113.
148. *Id.* at 1565, 19 U.S.P.Q.2d at 1118.
149. *Id.*
150. *Id.*
151. *Id.* (citing Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 345 (1961)).

tures. The combination was shown by the design application drawings.[152]

The court, however, had greater difficulty with the question of "range of variation." The patentee submitted an expert declaration explaining "why one of skill in the art of catheter design and manufacture, studying the drawings of the '081 application in early 1982, would have understood from them that the return lumen must have a diameter within the range recited by independent claims 1 and 7 of the '329 patent."[153]

The district court found the expert's reasoning logical, but noted that the inventor's later patents disclosed diameter ratios which would not be logically calculated under this explanation, and which were therefore not necessarily excluded by the design application.[154] The Federal Circuit ruled that the inventors' later patents using different range limitations were irrelevant to the issue at hand because the sufficiency of an application under section 112's first paragraph is determined as of the date the application is filed.[155]

D. Claims

Section 112's second paragraph imposes a requirement of claim definiteness. In *Amgen*, the court affirmed a district court's finding that a patent claim to a purified protein of "at least *about*" a numeri-

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152. *Id.*

153. *Id.* at 1566, 19 U.S.P.Q.2d at 1119. The expert stated that:

> [A] return (longer) lumen of diameter less than half that of the two lumens combined would produce too great a pressure increase, while a return lumen of diameter equal or larger than that of the two lumens combined would result in too great a pressure drop.
>
> . . .
>
> Higher pressure drops are associated with smaller cross-sectional areas for fluid flow. [The patentee's] opening brief to this court states that by applying well-known principles of fluid mechanics (i.e., the work of Poiseulle and Hagen), it can be calculated that the diameter of the circular (return) lumen would have to be in the range of 0.66 times the diameter of the two lumens combined in order to achieve proper blood flow at equal pressure drop. The 0.66 ratio falls within the noted claim limitation.

Id. at 1566 & n.7, 19 U.S.P.Q.2d at 1119 & n.7.

154. *Id.* at 1566, 19 U.S.P.Q.2d at 1119.

155. *Id.* The court stated that a drawing or other specification invention disclosure need not necessarily include

> all diameters other than those within the claimed range. . . . [T]he proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that [the applicant] had in fact invented the catheter recited in those claims, having (among other limitations) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens. Consideration of what the drawings conveyed to persons of ordinary skill is essential.

Id.

cally specific activity level was invalid for indefiniteness.[156] Genetic Institute's patent disclosed a method of purifying human EPO using reverse phase high performance liquid chromatography (RP-HPLC). It claimed both the method and the purified EPO of defined characteristics. Several claims recited "a specific activity of *at least* 160,000 IU per absorbance unit at 280 nanometers," while claims 4 and 6 recited specific activity of "*at least about* 160,000."[157] The claims' specific activity was measured by a ratio of International Units per absorbance unit, or IU/AU.[158] During the patent's prosecution, the inventor amended the claims' activity level from 120,000 to "at least about 160,000" after the examiner rejected the claims on a reference showing a 128,620 activity.[159]

The district court found that because bioassays provided imprecise measurement (use of the term "about" 160,000 IU/AU together with the inherent range of error in the activity), the invention was not distinguishable from the closest prior art and that it was unclear what activity values below 160,000 might constitute infringement.[160] With regard to the definition of "about 160,000," the inventor testified that "somewhere between 155[,000], might fit within that number."[161] The patent owner's joint venture partner questioned whether the specific activity value of 138,000 IU/AU for its own rEPO was within the claim coverage.[162]

The Federal Circuit noted that invalidity for indefiniteness entails determining whether a person skilled in the relevant art would understand what is claimed.[163] Because no evidence was presented indicating the range of activity referred to by the term "about," the meaning of the claims was sufficiently in doubt to justify invalidating them, especially in light of the existence of close prior art.[164] The court, however, cautioned that its holding did not rule out all use of the term "about" in patent claims. It stated that its use "may be acceptable in appropriate fact situations."[165]

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156. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1217-18, 18 U.S.P.Q.2d 1016, 1030-31 (Fed. Cir.) (emphasis added), *cert. denied*, 112 S. Ct. 169 (1991).

157. *Id.* at 1203, 18 U.S.P.Q.2d at 1018-19.

158. *Id.* at 1215 n.10, 18 U.S.P.Q.2d at 1029 n.10. International units measure EPO's ability to cause the formation of red blood cells, while absorbance units measure the amount of light absorbed by a sample of EPO at a wavelength of 280 nanometers. *Id.*

159. *Id.* at 1217-18, 18 U.S.P.Q.2d at 1030.

160. *Id.* at 1217, 18 U.S.P.Q.2d at 1030.

161. *Id.* at 1218, 18 U.S.P.Q.2d at 1031.

162. *Id.* at 1217, 18 U.S.P.Q.2d at 1030.

163. *Id.*

164. *Id.*, 18 U.S.P.Q.2d at 1031.

165. *Id.*

III. PATENT PROSECUTION ISSUES

A. Inequitable Conduct

The "duty of disclosure" applies to an inventor and the inventor's representatives, particularly the attorney or agent handling a patent application. Such persons must not misrepresent material facts or fail to disclose material information of which they are aware to the PTO during prosecution of the inventor's patent application.[166] "Inequitable conduct" means that noncompliance with this duty of disclosure during the prosecution of an application for a patent constitutes grounds for rendering the patent unenforceable—even if the patent is otherwise valid and infringed.[167]

In past years, Federal Circuit decisions focused primarily on the culpability component of the inequitable conduct defense, emphasizing that a conclusion of unenforceability due to inequitable conduct could be reached only if there was a finding of an "intent to mislead."[168] An intent to mislead could not be inferred solely from evidence establishing an actor's gross negligence.[169] This high culpability threshold has made inequitable conduct difficult, but not impossible, to sustain.[170]

The major 1991 decision involving the issue of inequitable conduct focused on the materiality standard. The court, in *Halliburton Co. v. Schlumberger Technology Corp.*,[171] emphasized that undisclosed information that is "cumulative" to the information considered by the PTO examiner during a patent's prosecution is not material, even under the low threshold of materiality under Rule 56.[172] In *Halliburton*, the court found that failure to disclose cumulative infor-

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166. *See generally* 5 DONALD S. CHISUM, PATENTS § 19.03 (1991) (examining concept of fraudulent procurement in patent).

167. *Id.*; *see* Mechanical Plastic Corp. v. Rawlplug Co., 14 U.S.P.Q.2d 1058, 1060-61 (S.D.N.Y. 1989) (discussing development of concept of inequitable conduct as means of invalidating patent of applicant who has breached duty to disclose).

168. Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872-73, 9 U.S.P.Q.2d 1384, 1389-90 (Fed. Cir. 1988) (reversing holding of inequitable conduct based on gross negligence rather than affirmative finding of intent), *cert. denied*, 490 U.S. 1067 (1989); FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 525, 5 U.S.P.Q.2d 1272, 1275 (Fed. Cir. 1987) (remanding to trial court for finding of intent); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d 1112, 1117 (Fed. Cir. 1987) (finding no inequitable conduct without evidence that applicant intended to withhold information).

169. *Kingsdown*, 863 F.2d at 876, 9 U.S.P.Q.2d at 1394.

170. *See* Fox Indus., Inc. v. Structural Preservation Sys., Inc., 922 F.2d 801, 803-04, 17 U.S.P.Q.2d 1579, 1580-81 (Fed. Cir. 1990) (finding intent where applicant failed to show good faith rationale for withholding material information).

171. 925 F.2d 1435, 17 U.S.P.Q.2d 1834 (Fed. Cir. 1991).

172. Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435, 1440, 17 U.S.P.Q.2d 1834, 1839 (Fed. Cir. 1991) (citing 37 C.F.R. § 1.56 (1991) (defining material information as that which would be "important in deciding whether to allow the application to issue as a patent")).

mation could not form the basis of a finding of inequitable conduct in patent procurement and held that the district court's findings of materiality and intent to deceive the PTO were clearly erroneous.[173]

The patents in suit related to oil well high energy neutron logging. An instrument descending a well borehole emits neutrons that collide with surrounding earth formations, generating "capture gamma rays" which the instrument detects. To screen out gamma rays from the well casing, prior art instruments used a technique called "timing out" based on an assumption that the neutron decay causing gamma rays occurs sooner in the borehole.[174]

"Timing out," however, was "fraught with uncertainty" because of borehole condition variation.[175] In lieu of "timing out," the applicant's inventions detected radiation over a minimum of four time intervals and generated at least four count signals, which were combined "according to a predetermined relationship to simultaneously separate the borehole and formation decay components and to derive at least two measurement signals representative of the . . . decay time of the borehole . . . and the earth formation . . . ."[176] The patent specifications teach taking four measurements to obtain data points and using a computer program based on a two-exponential equation with four unknowns to establish two values for borehole feedback and two values for formation feedback. The specifications further teach mathematical processing of the measurements to determine the borehole and formation neutron characteristics.[177]

The applicant did not disclose any prior art references to the PTO during the application process.[178] The examiner cited six patent references relating to pulse-moderation systems. The district court determined that the applicant committed inequitable conduct by failing to disclose seven other patents of which it was aware.[179] The examiner cited two Smith patents that assumed the mathematical relationship expressed in the two-exponential equation, but measured the neutron population at only two time gates. One relied on the "timing-out technique"; it assumed that borehole decay eventually reaches zero, obtained two data points, and reduced the equa-

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173. *Halliburton*, 925 F.2d at 1440, 17 U.S.P.Q.2d at 1839. The PTO recently proposed rule changes that would abandon the "important to a reasonable examiner" standard of materiality. *See* Notice of Proposed Rule Making, 56 Fed. Reg. 37,321 (1991) (to be codified at 37 C.F.R. § 1.56) (proposed Aug. 6, 1991).

174. *Halliburton*, 925 F.2d at 1436-48, 17 U.S.P.Q.2d at 1836-37.

175. *Id.* at 1438, 17 U.S.P.Q.2d at 1836-37.

176. *Id.* at 1438-39, 17 U.S.P.Q.2d at 1838 (quoting claim 1 of patent as representative of relevant technology of applicant's patents).

177. *Id.* at 1439, 17 U.S.P.Q.2d at 1838.

178. *Id.*

179. *Id.*

tion from one to two exponents. The other estimated the two borehole unknowns from borehole water salinity, again reducing the equation to one exponent and two data points.[180]

The Federal Circuit reaffirmed the materiality standard of Rule 56 but emphasized that information that is cumulative or "less material" than information already before the PTO is not material.[181] The court then held that the district court erred in dismissing the Smith patents as "less material" because they were based on timing-out. It concluded that "[i]n the art of neutron well logging, the Smith patents were highly material to [the] applications. The most pertinent prior art in the field was thus before the examiner."[182]

Another uncited reference, the Neufeld patent, recognized the two-exponential equation but reached its result differently than the applicant's inventions or the cited references.[183] It derived neutron decay results mathematically, discharging random neutron bursts, detecting the entire gamma ray feedback, and comparing the detector output with the neutron burst. The patents in suit, by contrast, directly measured neutron decay results at regular intervals.[184] The district court found the Neufeld patent to be material, stressing its similarities with the applicants' claims in that both recognized decay-rate derivation as exponential relationships.[185] The district court, however, did not appreciate the differences that made the Neufeld patent "less material" than the references cited in the application.[186]

The Federal Circuit noted that because the two-exponential equation common to Neufeld and the claimed invention was simply a "scientific truism acknowledged by both," a reasonable patent examiner would not consider Neufeld important to the appellant's patent.[187] The court, moreover, found the district court's conclusion that applicant's "principal invention" was "measuring and simultaneously decomposing the entire neutron decay curve . . . by a two-exponential relationship" to be clearly erroneous.[188] Thus, in so mischaracterizing the applicant's claims, which really involved "a method of measuring directly the formation and borehole compo-

180. *Id.* at 1440, 17 U.S.P.Q.2d at 1839.
181. *Id.* Stressing that Rule 56 is the proper starting point, the court excepted from disclosure "an otherwise material reference if the reference is cumulative or less material than those already before the examiner." *Id.*
182. *Id.*
183. *Id.* at 1440-41, 17 U.S.P.Q.2d at 1839.
184. *Id.*
185. *Id.*
186. *Id.* at 1441, 17 U.S.P.Q.2d at 1839-40.
187. *Id.*, 17 U.S.P.Q.2d at 1840.
188. *Id.*

nents of the decay curve between regular neutron pulses in four time gates," the district court missed the significance of the differences between it and the Neufeld reference.[189]

Additional uncited references, the Texaco patents, recognized the two-exponential equation but determined borehole and formation neutron decay times differently, using continuous neutron emission, varied harmonically as a function of time and modulated at three frequencies. Because these patents disclosed a different method, the court found them to be less material than the cited references.[190] Furthermore, although the patent attorney drafting the applicant's patents used one Texaco patent "as a template" in drafting the background portion of one of the applications, this did not increase its level of materiality.[191] Similarly, the court found uncited "skip-a-beat" patents that disclosed a background correction method included by the applicants as one step of their claimed method to be less material than the cited references.[192]

The Federal Circuit also held the district court's finding of intent to mislead to be clearly erroneous. There was no direct evidence of the applicant's intent to mislead in the record. The court refused to equate even gross negligence with intent unless " 'viewed in light of all the evidence, including evidence indicative of good faith,' the conduct is culpable enough 'to require a finding of intent to deceive.' "[193] The PTO examiner had found and relied upon "the most pertinent prior art in the field."[194] The withheld references solved the problem in question in an "entirely different way" than the patents in suit. Those references, unlike the most pertinent reference, disclosed an equation relied upon in the patents in suit, but that equation was known in the art and was "not part of the claims in any of the patents."[195] The Federal Court thus found the claim of the applicant's patent attorney that he had no intent to mislead to be objectively reasonable.[196]

In finding intent to mislead, the district court relied on various factors. For example, the applicant's assignee attempted to license one uncited patent, and its attorney used another uncited patent "as

189. *Id.*
190. *Id.* at 1442, 17 U.S.P.Q.2d at 1840.
191. *Id.*
192. *Id.* at 1441, 17 U.S.P.Q.2d at 1840.
193. *Id.* at 1442-43, 17 U.S.P.Q.2d at 1841 (quoting Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876, 9 U.S.P.Q.2d 1384, 1392 (Fed. Cir. 1988)).
194. *Id.* at 1440, 17 U.S.P.Q.2d at 1839.
195. *Id.* at 1443, 17 U.S.P.Q.2d at 1841.
196. *Id.*

a template in drafting" one of the applications.[197] While these factors might indicate carelessness or gross negligence on the part of the applicant, they may merely illustrate that the applicant understood the narrow technical basis for its claimed inventions.[198] The court found both scenarios insufficient to show inequitable conduct, concluding that "[a]n applicant's conduct in its entirety must 'manifest a sufficiently culpable state of mind to warrant a determination that it was inequitable.' "[199]

Finally, the Federal Circuit reaffirmed the "balancing" approach to inequitable conduct which requires that the trial court perform a two-step analysis.[200] First, the trial court must determine whether the withheld references meet a threshold level of materiality and whether the applicant's conduct meets a threshold showing of intent to mislead.[201] Second, assuming that the first inquiry is satisfied, the trial court must balance materiality and intent. At this level, "[t]he more material the omission, the less culpable the intent required, and vice versa."[202]

In *Scripps Clinic*, the Federal Circuit held that the district court erroneously granted summary judgment, finding a reissue patent unenforceable because of statements to the PTO concerning enablement.[203] The district court considered the materiality of undisclosed prior information but failed to mention intent.[204] The Federal Circuit stressed that intent is essential to a finding of inequitable conduct, and that intent must be proven by clear and convincing evidence.[205] The court also noted that a reference, which is only material to withdrawn claims, cannot form the basis of an inequitable conduct finding.[206] It is irrelevant how a reference reaches the examiner's attention; the reference is not considered to be withheld

197. *Id.* at 1442-43, 17 U.S.P.Q.2d at 1840-41.

198. *Id.* at 1443, 17 U.S.P.Q.2d at 1841.

199. *Id.*, 17 U.S.P.Q.2d at 1841-42 (quoting Consolidated Aluminum Corp. v. Fosco Int'l Ltd., 910 F.2d 804, 809, 15 U.S.P.Q.2d 1481, 1484 (Fed. Cir. 1990)).

200. *Id.* at 1439, 17 U.S.P.Q.2d at 1838.

201. *Id.* (citing J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 1560, 223 U.S.P.Q. 1089, 1092 (Fed. Cir. 1984)).

202. *Id.* at 1439, 17 U.S.P.Q.2d at 1832; *see* Under Sea Indus., Inc. v. Dacor Corp., 833 F.2d 1551, 1559, 4 U.S.P.Q.2d 1772, 1777 (Fed. Cir. 1987) (balancing intent with materiality such that "if one is particularly strong, a lesser degree of the other" is sufficient to find inequitable conduct).

203. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1571-74, 18 U.S.P.Q.2d 1001, 1006-08 (Fed. Cir. 1991).

204. *Id.* at 1573, 18 U.S.P.Q.2d at 1008.

205. *Id.* at 1573-74, 18 U.S.P.Q.2d at 1008.

206. *Id.* at 1583, 18 U.S.P.Q.2d at 1014-15 (citing Kimberly-Clark Corp. v. Manitowac Co., 835 F.2d 1437, 1457, 223 U.S.P.Q. 603, 616-17 (Fed. Cir. 1984).

if it is disclosed by the applicant or discovered by the examiner's search.[207]

B. Reissue

Federal Circuit decisions oscillate on what constitutes sufficient "error" to support a reissue application to change a patent's claims.[208] In *Scripps Clinic*, the court adopted a liberal approach. Scripps used reissue to add pure product claims to its original Factor VIII:C patent's process and product-by-process claims.[209] In their reissue declaration, the inventors stated they had always viewed the Factor VIII:C product as their invention, pointing to the specification's statement that the invention's objective was to produce highly purified Factor VIII:C.[210] The accused infringer did not contest that an error occurred or assert that the inventors' attorney's initial view that product claims were unavailable involved deceptive intention. The district court interpreted the reissue statute, 35 U.S.C. § 251, to require a showing that the error could not have been avoided.[211] The Federal Circuit, however, disagreed, holding that the statute does not dictate such a stringent showing.[212] The court noted that one of the most prevalent defects supporting a reissue application is an attorney's failure to claim the invention sufficiently broadly.[213]

The standard for determining whether the statutorily required error has been met is objective, and does not require evidence of subjective state of mind.[214] Thus, proof that the applicants intended to claim less than they had a right to claim is not necessary.[215]

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207. *Id.* at 1582, 18 U.S.P.Q.2d at 1015.

208. *Compare In re* Wilder, 736 F.2d 1516, 1519, 222 U.S.P.Q. 369, 372 (Fed. Cir. 1984) (holding patent attorney's declaration that he did not understand invention's scope satisfies statutory error requirement), *cert. denied*, 469 U.S. 1209 (1985) *with In re* Weiler, 790 F.2d 1576, 1580 n.4, 229 U.S.P.Q. 673, 677 n.4 (Fed. Cir. 1986) (rejecting allegations that inventor's ignorance of patent claim drafting techniques and of patent counsel's ignorance of invention was sufficient to constitute error).

209. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1568, 18 U.S.P.Q.2d 1001, 1003, *petition for reh'g denied and petition for reh'g in banc under consideration*, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).

210. *Id.* at 1575, 18 U.S.P.Q.2d at 1008-09.

211. *Id.*, 18 U.S.P.Q.2d at 1009.

212. *Id.* ("The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue.").

213. *Id.* (citing *In re* Wilder, 736 F.2d 1516, 1519, 222 U.S.P.Q. 369, 371 (Fed. Cir. 1984)).

214. *Id.*; *see also In re* Amos, 953 F.2d 613, 618, 21 U.S.P.Q.2d 1271, 1275 (Fed. Cir. 1991) (affirming lower court's use of objective test for determining whether new claims submitted during reissue are for invention originally disclosed).

215. *Scripps Clinic*, 927 F.2d at 1575, 18 U.S.P.Q.2d at 1009 (citing *In re* Weiler, 790 F.2d 1576, 1581, 229 U.S.P.Q. 673, 676 (Fed. Cir. 1986)).

In *Green v. Rich Iron Co.*,[216] the court held that a district court may not compel a patentee to seek reissue to resolve patent validity and enforceability questions. Green, the patentee, sued Rich Iron and two individuals, claiming they infringed his patent.[217] The defendants asserted that the patent was (a) invalid because of a public use or on sale bar, and (b) unenforceable because of inequitable conduct in the procurement process. The district court stayed the suit and ordered the patentee to seek PTO reissue, citing "the special expertise of the U.S. Patent Office regarding the validity of patents and concerns of judicial economy . . . ."[218] The district court then confirmed the order after the patentee directed its attention to a PTO Commissioner notice stating that it would neither investigate nor reject reissue applications based on inequitable conduct.[219] In reversing, the Federal Circuit noted that ordering a patentee, who insists there is no error in the patent, to seek reissue compels the patentee to attest to error the patentee believes is nonexistent.[220]

C. Reexamination

The court has yet to resolve a number of problems that arise when a patent is simultaneously involved in district court litigation involving its validity and a PTO reexamination. Because of different proof burdens and claim interpretation standards, the two tribunals may well reach different conclusions—the court upholding the patent claim's validity and the PTO canceling it for unpatentability. In *Standard Havens Products, Inc. v. Gencor Industries, Inc.*,[221] the district court held a patent not invalid after full trial, and the infringer appealed to the Federal Circuit.[222] Meanwhile, in a reexamination, the examiner rejected the patent's claims and, while the Federal Circuit appeal was pending, the Board of Appeals affirmed the rejection.[223] The Federal Circuit raised the question whether it should stay the appeal pending judicial review of the PTO action, which could lead to cancellation of the patent claims, but decided not to do so in part because neither party wanted a stay.[224]

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216. 944 F.2d 852, 20 U.S.P.Q.2d 1075 (Fed. Cir. 1991).
217. Green v. Rich Iron Co., 944 F.2d 852, 853, 20 U.S.P.Q.2d 1075, 1076 (Fed. Cir. 1991).
218. *Id.*
219. *Id.* (explaining that notwithstanding notice, PTO remained best forum for resolving technical considerations inherent in public use and sale).
220. *Id.*
221. 953 F.2d 1360, 21 U.S.P.Q.2d 1321 (Fed. Cir. 1991).
222. Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1363, 21 U.S.P.Q.2d 1321, 1323 (Fed. Cir. 1991).
223. *Id.* at 1366, 21 U.S.P.Q.2d at 1325-26.
224. *Id.* at 1366 n.2, 21 U.S.P.Q.2d at 1326 n.2.

If the patentee makes a "substantive" change in a patent claim during reexamination or reissue, it cannot assert the claim against pre-reexamination or reissue conduct. Patentees therefore frequently argue that a change was merely a "clarification." In *Laitram Corp. v. NEC, Corp.*,[225] the court held, in response to a certified question, that claims are not per se substantially changed when they are amended during reexamination following a rejection based on prior art.[226] The court stated that "[t]o determine whether a claim change is substantive it is necessary to analyze the claims of the original and the reexamined patents in light of the particular facts, including the prior art, the prosecution history, other claims, and any other pertinent information."[227]

IV. INFRINGEMENT ISSUES

Infringement is the unauthorized invasion of a patent owner's statutory exclusive rights in the invention, as defined by the patent's claims.[228] Determining infringement involves interpreting the claim language, assessing the nature of the accused infringer's acts, and applying the interpreted claims to those acts. Only *acts*, such as unauthorized manufacture or sale, constitute infringement. It is, however, commonplace to say that a device "infringes" when discussing the relationship of an accused device to a patent claim.

A. Exclusive Rights

In *Intel Corp. v. International Trade Commission*,[229] the court held that if a patent claim only requires an *ability* to perform a function, selling a device with that ability infringes even though the seller never told customers how to use the function.[230] The patent claimed an EPROM memory chip with page mode addressing capability.[231] The court concluded that capability to operate in page mode was sufficient to constitute infringement under the doctrine of equivalents.[232] The accused infringer argued that it did not infringe because, although its chips were capable of performing page mode

225. 952 F.2d 1357, 21 U.S.P.Q.2d 1276 (Fed. Cir. 1991).
226. Laitram Corp. v. NEC, Corp., 952 F.2d 1357, 1362, 21 U.S.P.Q.2d 1276, 1280 (Fed. Cir. 1991).
227. *Id.*
228. 35 U.S.C. §§ 154, 271 (1991).
229. 946 F.2d 821, 20 U.S.P.Q.2d 1161 (Fed. Cir. 1991).
230. Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 832, 20 U.S.P.Q.2d 1161, 1171 (Fed. Cir. 1991).
231. *Id.* The claim referred to "programmable selection means" and specifically stated "*when* said alternate addressing mode is selected," meaning that the accused device need only be capable of operating in page mode to constitute infringement. *Id.* (emphasis in original).
232. *Id.*

addressing, customers were never told how to convert the chip to page mode operation or that conversion was possible.[233] Moreover, the infringer cited *Fromberg, Inc. v. Thornhill*[234] to argue that intent to use the parts in an infringing manner is required.[235] The court, however, disagreed, stating that *direct* infringement has no intent element.[236] Because *Fromberg* dealt with induced and contributory infringement, the court deemed it inapplicable.[237]

B. Claim Interpretation

1. Generally

Interpreting patent claim language is critical to any decision about patent or patent application patentability and coverage. As with all documents that humans draft, patent claims vary in clarity. Rules on deriving patent claim meaning can never remove the necessity for judgment and interpretation or the prospect for dispute. The Federal Circuit issues a steady stream of claim interpretation decisions, and the year 1991 provided its fair share.[238]

In *Intel*, the disclosed invention, a radiation shield, allowed a normally erasable EPROM cell to be converted to a UPROM (unerasable programmable read-only memory) cell.[239] The claims included the phrase "whereby said EPROM cell can be *permanently programmed* so that said redundant elements are always used in place of said defective elements."[240] The specification stated that the invention's goal was a UPROM cell that could withstand 300 hours of ultraviolet light exposure without erasing. Following the estab-

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233. *Id.*

234. 315 F.2d 407, 137 U.S.P.Q. 84 (5th Cir. 1963).

235. *Id.* (citing Fromberg Inc. v. Thornhill, 315 F.2d 407, 415, 137 U.S.P.Q. 84, 89 (5th Cir. 1963) (stating that intent and purpose of infringer is critical for finding of contributory infringement)).

236. *Id.*

237. *Id.*

238. *See, e.g.*, Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 836, 20 U.S.P.Q.2d 1161, 1174 (Fed. Cir. 1991) (rejecting defendant's argument that limitation should be read into claims of life span of UPROM cells and accepting Commission's claim interpretation); Tol-O-Matic, Inc. v. Proma Produk-Und Marketing Gesellschaft m.b.H., 945 F.2d 1546, 1552, 20 U.S.P.Q.2d 1332, 1338 (Fed. Cir. 1991) (concluding that accused device did not infringe patent claims for rodless piston cylinder because normal operation of device did not meet lateral support claim limitation); Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1564-65, 19 U.S.P.Q.2d 1500, 1505 (Fed. Cir. 1991) (explaining that claim for fabric sheet mounting framework cannot include linear pieces with mitered ends because merger of two concepts would be redundant and violate "all elements" rule); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1580, 18 U.S.P.Q.2d 1001, 1013 (noting that when construing claims, words of claim are looked at "independent of the accused product, in light of the specification, the prosecution history, and the prior art"), *petition for reh'g denied and petition for reh'g in banc under consideration*, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).

239. *Intel*, 946 F.2d at 832, 20 U.S.P.Q.2d at 1171.

240. *Id.* (emphasis in original).

lished rule that claims should be interpreted in light of the specification, the accused infringer argued that "permanently programmed" should require that an infringing cell tolerate 300 hours of exposure. The court, however, disagreed because the specification did not require such a limitation.[241] Consequently, the court would not read such a limitation into the claims.[242]

2. Product-by-process claims

In *Scripps Clinic*, the court held that product-by-process claims are to be construed in the same manner for validity and infringement.[243] Accordingly, product-by-process claims are "not limited to products prepared by the process set forth in the claims."[244]

Scripps' patent described a method for purifying and concentrating Factor VIII:C, the blood clotting factor, from natural sources by using a monoclonal antibody. It contained process claims, such as claim 1, which provided "[a]n improved method of preparing Factor VIII pro-coagulant activity protein comprising the steps of . . ." and "product-by-process" claims, such as claim 13, which provided "[h]ighly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1."[245] Genentech, the accused infringer, produced Factor VIII:C by a process different from that in the Scripps specification. It used recombinant DNA technology, i.e., isolating the gene encoding the protein, inserting it into a host cell, replicating the cell, causing the cell to excrete the protein into a culture medium, and purifying the protein from the medium using Factor VIII:C monoclonal antibodies.[246]

The district court found that, unless the same process was used, product-by-process claims are not infringed.[247] In reversing the summary judgment of invalidity, the Federal Circuit commented that the district court's statement that the process must be identical for infringement to exist was inconsistent with precedent.[248] There-

241. *Id.*

242. *Id.* ("The 'permanently programmed' limitation only requires that the shielded UPROM cells remain programmed for the normal life of the EPROM.").

243. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1583, 18 U.S.P.Q.2d 1001, 1016, *petition for reh'g denied and petition for reh'g in banc under consideration*, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).

244. *Id.*

245. *Id.* at 1570, 18 U.S.P.Q.2d at 1005.

246. *Id.* at 1580 n.9, 18 U.S.P.Q.2d at 1013 n.9.

247. *Id.* at 1583, 18 U.S.P.Q.2d at 1016.

248. *Id.* (citing *In re* Thorpe, 777 F.2d 695, 697, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985) (holding that prior art pertinent only to product is proper ground for rejecting product-by-process claims); *In re* Brown, 459 F.2d 531, 535, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972) (explaining that, in product-by-process claims, patentability of product must be established independent of process); *In re* Bridgeford, 357 F.2d 679, 682 n.5, 149 U.S.P.Q. 55, 58 n.5

fore, "the correct reading of product-by-process claims is that they are not limited to products prepared by the process set forth in the claims."[249]

3. Means-plus-function limitations

Section 112's final paragraph authorizes "means-plus-function" limitations and provides a statutory claim construction rule. It provides that:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.[250]

This provision was Congress' response to the Supreme Court's 1946 decision in *Halliburton Oil Well Cementing Co. v. Walker*.[251] The facts in *Halliburton* resemble many current controversies over means-plus-function clauses. *Halliburton* involved Walker's invention of a method to measure oil well depth by sonic probing which improved on prior art techniques of Lehr and Wyatt by using a conventional device, a mechanical acoustical resonator, to distinguish tube collar and catcher echoes from other noises.[252] The claim described the apparatus' echo distinguishing aspect as "means . . . for tuning said receiving means to the frequency of echoes from the tubing collars . . . to clearly distinguish the echoes from said couplings from each other."[253] The accused infringer used an electric filter rather than a mechanical resonator.[254] The Supreme Court invalidated the claim as "too broad" and "functional."[255]

(C.C.P.A. 1966) (recognizing that some courts in infringement litigation have construed product-by-process claims as limited to particular process, but holding that patentability is determined independent of process)).

249. *Id.*

250. 35 U.S.C. § 112 (1988).

251. 329 U.S. 1, 71 U.S.P.Q. 175 (1946); *see* Charles J. Zinn, *Commentary on New Title 35, U.S. Code, "Patents"*, 1952 U.S.C.C.A.N. 2507, 2514 (stating that new final paragraph of section 112 "offsets the theory of the *Halliburton* case").

252. Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 5-6, 71 U.S.P.Q. 175, 177 (1946).

253. *Id.* at 9, 71 U.S.P.Q. at 178.

254. *Id.* at 12, 71 U.S.P.Q. at 180.

255. *Id.* ("What [Walker] claimed . . . is that his patent bars anyone from using in an oil well any device heretofore or hereafter invented which combined with the Lehr and Wyatt machine performs the function of . . . catching and recording echoes from tubing joints with regularity. Just how many different devices there are of various kinds and characters which would serve to emphasize these echoes, we do not know. The Halliburton device, alleged to infringe, employs an electric filter for this purpose. In this age of technological development there may be many other devices beyond our present information or indeed our imagination which will perform that function and yet fit these claims. And unless frightened from the

Halliburton was poorly reasoned.[256] The patentee, however, may have invited the error by suggesting that its claim covered every means of achieving the designated function, not simply those means that were equivalent to his disclosed means.[257] The dispositive issue should have been whether the defendant's electric filter was the technological equivalent of the patentee's disclosed means, a mechanical resonator. A negative answer should have led to a conclusion of noninfringement, not invalidity. In enacting the 1952 Act, Congress included section 112's last paragraph to restore the law to its pre-*Halliburton* state.[258]

Three significant 1991 Federal Circuit cases addressed means-plus-function limitation interpretation. In *Symbol Technologies, Inc. v. Opticon, Inc.*,[259] the court held that the patentee presented a prima facie infringement showing by offering expert opinion testimony that the accused device met each claim limitation, even though the limitations were in a means-plus-function format and the expert did not discuss the structural equivalency between the allegedly infringing devices and the patent specifications in detail.[260] The court noted that a patentee bears the burden of showing section 112(6) means and structure equivalency, but Rule 705 of the Federal Rules of Evidence allows a patentee to meet that burden by presenting expert opinion testimony without disclosing the factual foundation.[261] The court conceded, however, that it is not easy to apply a claim drafted under section 112(6) to an accused device because

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course of experimentation by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose.").

256. *See* 2 DONALD S. CHISUM, PATENTS § 8.04[1], at 8-62 (1991) (arguing that *Halliburton* created unreasonably high standard of definiteness for patent claims). Prior to *Halliburton*, means-plus-function was a common style of claim language and had received the apparent approval of the Supreme Court in Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 (1908). *Id. Halliburton* ran against the prevailing notions that a patentee need not describe every possible variation of the invention in its specification and that a patent would include later specific improvements if they "stood on the shoulders" of the first patent. *Id.*

257. *See Halliburton*, 329 U.S. at 12, 71 U.S.P.Q. at 180 (explaining that Walker's claim bars anyone from using any device which combined with Lehr/Wyatt machine records and catches echoes from tubing joints).

258. *See In re* Fuetterer, 319 F.2d 259, 264 n.11, 138 U.S.P.Q. 217, 221 n.11 (C.C.P.A. 1963) (quoting statement of Rep. Joseph R. Bryson (S.C.) that "this provision in reality will give statutory sanction to combination claiming as it was understood before the *Halliburton* decision. *All the elements of a combination now will be able to be claimed in terms of what they do as well as in terms of what they are.*" (emphasis in original)).

259. 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991).

260. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1575, 19 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1991).

261. *Id.* at 1576, 19 U.S.P.Q.2d at 1246.

paragraph six allows "an element in a claim to be expressed as a means or step for performing a specified function."[262]

In *Laitram Corp. v. Rexnord, Inc.*,[263] the court held the interpretation of section 112(6), that "means" be limited to equivalents of specification-disclosed corresponding structure, applicable to means-plus-function clauses that recite some structure.[264] Moreover, the court stated that the statute overrides claim differentiation.[265]

The patent at issue in *Laitram* claimed a conveyer belt consisting of plastic modules pivotally connected at their link ends which "allows smooth transfer of containers to and from the head and tail ends of a conveyor via a transfer comb."[266] The claim required, inter alia:

> Subparagraph 1: "a plurality of like modules", each including "first and second like *pluralities of link* ends of substantially identical width", each end circumscribing "a pivotal hole through said width"; and
>
> Subparagraph 2: "*means for joining said pluralities* to one another so that the axes of said holes of said first plurality are arranged coaxially, the axes of said holes of said second plurality are arranged coaxially and the axes of respective holes of both pluralities of link ends are substantially parallel."[267]

The patent's specification described the link end joining means as requiring at least one, and preferably a pair, of spaced cross-members and the illustrated structure formed an "H-shaped" grid.[268] The accused structure had a "V-shape" or squared zig-zag configuration and no cross member joining the link ends. It lacked a means equivalent to that in the patent specification for performing the designated function.[269]

The Federal Circuit found the district court's holding of infringement was based on erroneous claim interpretation.[270] It held that the lower court erred as a matter of law by not interpreting subparagraph 2 of the claim 21 in accordance with section 112, paragraph

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262. *Id.* at 1575, 19 U.S.P.Q.2d at 1245 ("[T]he statutory provision prevents an overly broad claim construction by requiring reference to the specification, and at the same time precludes an overly narrow construction that would restrict coverage solely to those means expressly disclosed in the specification.").

263. 939 F.2d 1533, 19 U.S.P.Q.2d 1367 (Fed. Cir. 1991).

264. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538, 19 U.S.P.Q.2d 1367, 1371 (Fed. Cir. 1991).

265. *Id.*

266. *Id.* at 1534-35, 19 U.S.P.Q.2d at 1368-69.

267. *Id.* (emphasis added).

268. *Id.* at 1536, 19 U.S.P.Q.2d at 1370.

269. *Id.* at 1539, 19 U.S.P.Q.2d at 1372.

270. *Id.* at 1534, 19 U.S.P.Q.2d at 1368.

six, and by holding that "this limitation was met merely because there was some means in the accused device that performed the stated function."[271] The court stated that:

> The recitation of some structure in a means-plus-function element does not preclude the applicability of section 112, paragraph six. For example, in this case, the structural description in the joining means clause merely serves to further specify the function of that means. The recited structure tells only what the means-for-joining does, not what it is structurally.[272]

The patentee in *Laitram* argued that claim "differentiation" prevented limiting the claimed "means" to cross members because claim 24, which was dependent upon the claim in suit, specifically required a cross member.[273] Claim differentiation directs that "[w]here some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement."[274] The court rejected this argument because it would allow an easy avoidance of section 112, paragraph six.[275]

In *Intel Corp. v. International Trade Commission*, the court stressed that section 112, paragraph six, means equivalency and, unlike the doctrine of equivalents, does not require consideration of prior art.[276] Section 112, paragraph six, only requires that the means employed by the accused and the allegedly infringed device be equivalent, not identical.[277] Equivalence is determined in the same way that any other type of claim language is interpreted—by considering "the specification, the prosecution history, other claims in the patent, and expert testimony."[278]

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271. *Id.* at 1536, 19 U.S.P.Q.2d at 1370.
272. *Id.*, 19 U.S.P.Q.2d at 1369.
273. *Id.* at 1538, 19 U.S.P.Q.2d at 1371.
274. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054-55, 5 U.S.P.Q.2d 1434, 1441 (Fed. Cir. 1988).
275. *Laitram*, 939 F.2d at 1538, 19 U.S.P.Q.2d at 1371 ("[T]he judicially developed guide to claim interpretation known as 'claim differentiation' cannot override the statute. A means-plus-function limitation is not made open-ended by the presence of another claim specifically claiming the disclosed structure which underlies the means clause or an equivalent of that structure.... The patentee's argument, if adopted, would provide a convenient way of avoiding the express mandate of section 112(6).... [O]ne cannot escape that mandate by merely adding a claim or claims specifically reciting such structure or structures.").
276. Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 842, 20 U.S.P.Q.2d 1161, 1179 (Fed. Cir. 1991).
277. *Id.* ("It is only necessary to determine what is an equivalent to the structure disclosed in the specification which is performing the function at issue.").
278. *Id.* at 842-43, 19 U.S.P.Q.2d at 1179-80.

C. *Claim Application—Literal and Equivalent Infringement*

The final step in infringement analysis is to apply the interpreted patent claim to the accused device or process. If the claim literally covers the accused product or process, there is literal infringement. If the claim does not literally cover the accused product or process but the accused product or process is substantially the same as that claimed, there might be infringement under the doctrine of equivalents.[279]

The doctrine of equivalents accommodates the basic, opposing concerns for clear notice to potential infringers and fairness to inventors.[280] In 1991, the Federal Circuit affirmed infringement judgments based on equivalency,[281] but emphasized that patentees bear a strict burden of proof.[282] As the wag says, "it's not enough that it's the same—or *really* the same; to be equivalent, it must be *really, really* the same!"

The traditional tripartite equivalency test is whether a device or process falling outside a claim's literal scope "performs substantially the same function in substantially the same way to obtain the same result."[283] This test, however, rarely provides a clear guide to determining infringement by equivalency because it does not control the level of generality that may be used in characterizing the invention's "way," "function," and "result." Patentees in litigation, therefore, broadly characterize "way," "function," and "result" to show similarity between the patented invention and the accused product; accused infringers narrowly characterize "way" to show

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279. *See* Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535, 19 U.S.P.Q.2d 1367, 1369 (Fed. Cir. 1991) (stating that infringement may occur either when every limitation in patent claim is found in accused device or when there is substantial equivalence).

280. *See* London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538, 20 U.S.P.Q.2d 1456, 1458 (Fed. Cir. 1991) ("On the one hand, claims must be 'particular' and 'distinct,' . . . so that the public has fair notice of what the patentee and the Patent and Trademark Office have agreed constitute the metes and bounds of the claimed invention. Notice permits other parties to avoid actions which infringe the patent and to design around the patent. . . . On the other hand, the patentee should not be deprived of the benefits of his patent by competitors who appropriate the essence of an invention while barely avoiding the literal language of the claims.").

281. *See, e.g.*, Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 20 U.S.P.Q.2d 1161 (Fed. Cir. 1991); Uniroyal, Inc. v. Rudkin-Wiley Corp., 939 F.2d 1540, 19 U.S.P.Q.2d 1432 (Fed. Cir. 1991).

282. *See* Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1327, 21 U.S.P.Q. 1161, 1166 (Fed. Cir. 1991) (concluding that testimony about function, way and result achieved by accused device is insufficient to determine equivalency because testimony was conclusory and thus "the jury was left to its own imagination on the technical issue of equivalency"); Slimfold Mfg. Co. v. Kinkead Indus., Inc., 932 F.2d 1453, 1457, 18 U.S.P.Q.2d 1842, 1846 (Fed. Cir. 1991) (holding that district court committed clear error in finding that accused device accomplished its result in same "way" as patented invention because changes were not "so insubstantial as to result in 'a fraud on the patent' ").

283. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950).

differences. The Federal Circuit, however, continues to emphasize the importance of the traditional test. In *Malta v. Schulmerich Carillons, Inc.*,[284] a sharply divided three-judge panel followed *Lear Siegler, Inc. v. Sealy Mattress Co.*[285] in holding that a patentee must offer specific testimony and argument, not general opinions and conclusions, in support of the function, way, and result prongs.[286]

Patentees asserting equivalency face two limitations: the prior art and prosecution history estoppel. In *Wilson Sporting Goods Co. v. David Geoffrey & Associates*,[287] Judge Rich adopted new approach to prior art constraint. The court suggested that the limitation on the scope of equivalents should be conceptualized by imagining a patent claim of sufficient scope to literally cover the accused product and then by asking whether the claim could have been allowed by the PTO over the prior art.[288] Several 1991 decisions purported to apply the *Wilson Sporting Goods* hypothetical claim approach.[289] In one decision, however, the court slipped into a comparison of the accused infringer's product or process with the prior art.[290]

Prosecution history estoppel precludes expansion of the scope of a claim to resurrect subject matter surrendered during PTO proceedings to obtain a patent.[291] This issue commonly arises when the inventor files broad claims that would literally cover a product or process later accused of infringement, narrows the claims in response to a rejection by a PTO examiner on the grounds of prior art, and later asserts infringement through equivalency, arguing that the accused product or process is more similar to the patented in-

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284. 952 F.2d 1320, 21 U.S.P.Q.2d 1161 (Fed. Cir. 1991).

285. 873 F.2d 1422, 10 U.S.P.Q.2d 1767 (Fed. Cir. 1989).

286. Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1327, 21 U.S.P.Q. 1161, 1166 (Fed. Cir. 1991).

287. 904 F.2d 677, 14 U.S.P.Q.2d 1942 (Fed. Cir.), *cert. denied*, 111 S. Ct. 537 (1990).

288. Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684, 14 U.S.P.Q.2d 1942, 1948 (Fed. Cir.), *cert. denied*, 111 S. Ct. 537 (1990).

289. *See* Jurgens v. McKasy, 927 F.2d 1552, 1561, 18 U.S.P.Q.2d 1031, 1038 (Fed. Cir.) (applying hypothetical claim approach to windsock decoy patent infringement), *cert. denied*, 112 S. Ct. 281 (1991); Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449, 17 U.S.P.Q.2d 1806, 1810 (Fed. Cir. 1991) (explaining hypothetical claim rationale as acknowledging that prior art limits coverage available under doctrine of equivalents); Insta-Foam Prods., Inc. v. Universal Foam Sys., Inc., 906 F.2d 698, 704, 15 U.S.P.Q.2d 1295, 1299 (Fed. Cir. 1990) (explaining that hypothetical claim drawn to encompass object would not have been unpatentable under 35 U.S.C. § 103); *cf.* We Care, Inc. v. Ultra Mark, Int'l Corp., 930 F.2d 1567, 1571, 18 U.S.P.Q.2d 1562, 1565 (Fed. Cir. 1991) (vacating preliminary injunction and remanding for determination of whether range of equivalents sought by patentee encroaches on prior art).

290. *See* Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449, 17 U.S.P.Q.2d 1806, 1810 (Fed. Cir. 1991) (comparing defendant's decorative caps for wheel nuts with prior art and finding no infringement under doctrine of equivalents).

291. Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1362, 219 U.S.P.Q. 473, 481 (Fed. Cir. 1983).

vention than to the prior art distinguished by the amendment. The Federal Circuit vacillates between a hardline approach, refusing to "speculate" whether an amendment in response to a prior art rejection is necessary to distinguish the prior art, and a flexible approach, emphasizing the amendment's nature and purpose and the prior art.[292]

292. *Compare* Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.p.A., 944 F.2d 870, 20 U.S.P.Q.2d 1045 (Fed. Cir. 1991) (explaining that courts must consider what was changed and reason for change, but when record does not indicate that limitation was added to avoid prior art, prosecution history estoppel does not apply) *with* Dixie USA, Inc. v. Infab Corp., 927 F.2d 584, 17 U.S.P.Q.2d 1969 (Fed. Cir. 1991) (affirming summary judgment in favor of alleged infringer on grounds that lower court properly considered nature of prior art and amendment in applying doctrine of prosecution history estoppel).