Looking at Federal Circuit Developments 2005: The Year in Review*

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Cite as: 6 J. High Tech L. 113

The Federal Circuit's much-awaited *en banc* pronouncements about claim construction in *Phillips* [1] overshadowed many of the court's other decisions this year, both in the press and on the conference circuits. But the court has issued a number of decisions in other areas of patent law in 2005 that both clarify, and in some cases confuse, existing law under Federal Circuit precedent. This paper looks at some of the notable developments by the court this year in four areas of law: the extraterritorial reach of U.S. patent law, claim construction, inequitable conduct and enablement.

I. Extraterritorial Reach of 35 U.S.C. §271(f)

Within the past year, the Federal Circuit has refined the contours of the extraterritorial reach of U.S. patent laws under 35 U.S.C. §271(f) in a series of cases that highlights the court's unease in construing this statutory provision.[2] Losing parties in all four of the court's §271(f) cases this year have sought review by way of petitions for rehearing, rehearing *en banc*, or *certiorari*.

 ISSN 1536-7983.
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1. Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005).

2. Section 271(f) imposes liability on anyone who "supplies or causes to be supplied . . . any component of a patented invention . . . where such component is uncombined in whole or in part, knowing that such component is [ ] made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States." 35 U.S.C. § 271(f)(2000).

A. Components of Patented Inventions Under §271(f) Need Not Be Tangible

The Federal Circuit in *Eolas Technologies Inc. v. Microsoft Corp*.[3] considered the issue of whether software code contained on a "golden master" disk (manufactured in the United States and exported to Original Equipment Manufacturers (OEMs) abroad), was a "component" under §271(f) sufficient to sustain a damages award for Microsoft's foreign sales of Windows® with Internet Explorer®. Foreign OEMs use the golden master disk to replicate the software code onto computer hard drives for sale outside of the United States. The golden master disk itself does not end up as a physical part of an infringing product[4] and the software code *per se* was *unpatented*; rather, the claims were directed to a computer program product.[5] The district court determined that the software code on the golden master disks constituted a "component" of an infringing product for combination outside of the United States under section 271(f), and held that Eolas' royalty for Microsoft's infringement should include foreign sales of the patented computer code. The Federal Circuit agreed, construing "patented invention" in §271(f) broadly to mean any "invention or discovery,"[6] including a process.[7] Contrary to arguments offered by Microsoft, neither the statutory language nor the legislative history of the enactment of §271(f) (overruling *Deepsouth*[8]) limited "components" under §271(f) to machine components or structural or physical components. According to the

3. 399 F.3d 1325 (Fed. Cir. 2005)(Rader, J.).

4. *Id*. at 1331.

5. The claimed computer program product included a client workstation, a network server, a network environment, and *e.g*., a computer usable medium having computer readable program code physically embodied therein. *Id.* at 1330-31.

6. The court's interpretation was based on the definition of "invention" in the definitions section of Title 35, 35 U.S.C. § 100(a). *Eolas* at 1338.

7. The court also relied on the definition of "invention" under 35 U.S.C. §101, which encompasses "any new and useful process, machine, manufacture or composition of matter." *Eolas* at 1338-39 (citing 35 U.S.C. § 101 (2000)) ("Without question, software code alone qualifies as an invention eligible for patenting under these categories, at least as processes." *Id.*, citing *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994)).

8. Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 32 L. Ed. 2d 273, 92 S. Ct. 1700 (1972). *Deepsouth* recognized that unauthorized manufacturers of patented products could avoid liability for infringement by manufacturing the unassembled components infringing products in the United States and then shipping them outside the United States for assembly. Section 271(f) closed that loophole in the statutory protections for patented inventions. *Eolas* at 1340.

court, the software code on the golden master disk was not only a component, it was "probably the key part of [the] patented invention."[9] By any metric, the *Eolas* case involved an extraordinary extension of § 271(f) to capture foreign sales.

Both Microsoft and a surprised *amici* community petitioned for rehearing or rehearing *en banc*.[10] There is no decision on the petition as of yet. Just weeks after Microsoft's petition was filed, it argued nearly the same issues again in *AT&T v. Microsoft*.[11]

B. "Supplied" Under §271(f) Includes Foreign Replication of Exported Components That Are Sold Exclusively to Foreign Users

Microsoft supplies a limited number of master versions of the Windows® software to foreign computer manufacturers and authorized foreign "replicators," who, pursuant to their licensing agreements with Microsoft, replicate the master versions in generating multiple copies of Windows® for installation on foreign-assembled computers that are then sold to foreign customers.[12] After a district court found Microsoft liable for infringement of AT&T's Reissue '580 patent based on copies of the Windows® operating system replicated abroad, Microsoft again argued that software could not be a "component" of a patented invention within the meaning of § 271(f). The court squarely disposed of this argument based on *Eolas*, decided only three months earlier.

Microsoft also argued that no actual "components" had been "supplied" from the United States as required by §271(f) because the copies of Windows® installed on the foreign-assembled computers had all been made abroad. But the Federal Circuit, per Judge Lourie, was unpersuaded. Because software was typically "supplied" by transmitting an exact copy, the court reasoned that the act of copying was subsumed in the act of "supplying," such that sending a single copy abroad with the intent that it be replicated invoked §271(f) liability for those foreign-made copies.[13] The court rejected Microsoft's argument that §271(f) liability should attach only to disks shipped and incorporated into a foreign-assembled computer, because inherent in the nature of software is its replicability from a single

9. *Eolas* at 1339.

10. *Amicus curiae* briefs were filed by Bentley Systems, Inc. et al., Shell Oil Corp., AOL & Intel, and the Business Software Alliance (BSA).

11. 414 F.3d 1366 (Fed. Cir. 2005) (Lourie, J.).

12. *Id.* at 1368.

13. *Id.* at 1370.

disk. According to the court, all such resulting copies had essentially been supplied from the United States.

Dissenting, Judge Rader disagreed that "supplied" in §271(f) included copying, replicating, or reproducing - in effect *manufacturing*.[14] To give such a broad interpretation of "supplied" was – according to Judge Rader – (1) an unwarranted extraterriorial expansion of U.S. patent law, (2) violative of both Supreme Court and Federal Circuit precedent, (3) discriminatory based on the field of the inventive technology, and (4) inconsistent with Congress' intent in enacting §271(f).[15]

To be certain, Judge Lourie's expansion of "supplied" to encompass sending a copy of software abroad with the intent that it be replicated (based on the nature of software itself) has telling implications on a U.S. biotechnology industry whose members may produce domestically but thereafter export products capable of self-replication. Left unchecked, the *AT&T* case may, *sub silentio*, be one of the most important decisions for biotech companies this year.

C. The Domestic Sale of Blackberry® Devices is not the "Supply" of a "Component" of a Patented Method

In early August, the court again revisited the outer edges of §271(f) in *NTP v. RIM*[16] a re-do of last December's notorious Blackberry® case.[17] In *NTP*, the court held that RIM's supply of Blackberry® devices to customers in the US was not the statutory "supply" of any "component" steps for combination into NTP's patented methods and thus did not constitute infringement under §271(f).[18] NTP's method claims at issue recited a series of steps for transmitting information from an originating processor in an electronic mail system to at least one destination processor. One of the steps in the process in each asserted method claim recited an "interface" or "interface switch," which was only met by the use of RIM's Blackberry® relay located in Canada.[19] The district court found infringement of all asserted claims of NTP's patents and denied RIM's JMOL motions seeking

14. *Id*. at 1372-73 (Rader, J., dissenting).
15. *Id*. at 1373-75.
16. 418 F.3d 1282 (Fed. Cir. 2005) (Linn, J.).
17. Per order of August 2, 2005, the court denied RIM's (Research In Motion's) petition seeking rehearing *en banc* and granted a limited panel rehearing for the limited purpose of revising the original panel decision. The substituted panel decision in *NTP* issued August 2, 2005, and replaced the previous panel opinion of Dec. 14, 2004, in which an opposite result was reached on the §271(f) issue.
18. *NTP*, 418 F.3d at 1322.
19. *Id*. at 1318.

relief.[20]

In its initial panel opinion, the Federal Circuit affirmed the judgment of the district court, stating that that the location of the RIM's infringement *was* within the territorial United States, not abroad as in *Deepsouth*.[21] The court held that even though one of the accused components in RIM's Blackberry® system was located in Canada, the beneficial use and function of the whole operable system assembly was within the United States. According to the court, it was immaterial whether the messages exchanged between Blackberry® users were transmitted outside of the United States at some point.[22]

Reversing direction, the Federal Circuit vacated its original panel opinion and held that although Congress did not expressly limit §271(f) to a specific type of invention, (citing *Eolas*), "RIM's supply of the Blackberry handheld devices and Redirector products to its customers in the United States is not the statutory "supply" of any "component" steps for combination into NTP's patented methods."[23] By merely supplying products to its U.S. customers, RIM did not supply or cause to be supplied any steps of a patented process invention for combination outside the U.S. and did not infringe NTP's asserted method claims under section 271(f) as a matter of law.

D. The Foreign Sale of Catalysts IS a "Supply" of a "Component" of a Patented Method

Just weeks after *NTP* was decided, the Federal Circuit in *Union Carbide*[24] reached an opposite result from the *NTP* decision regarding the sale of a component of a patented method practiced abroad. Shell manufactures unpatented silver catalysts used in the production of ethylene oxide (EO). It sells these catalysts to customers abroad, who make EO but do not sell EO in the United States. Union Carbide's U.S. patent is directed to the EO manufacturing process, but not the catalysts themselves. The district court ruled *in limine* that § 271(f) was not directed to process claims and therefore excluded all evidence at trial pertaining to foreign processes using Shell's catalysts. On appeal, the Federal Circuit

20. *Id*. at 1290-92.
21. Slip.Op. at 54-56 (Fed. Cir. Dec. 14, 2004).
22. *Id*.
23. 418 F.3d at 1322 (citing *Standard Havens Prods., Inc. v. Gencor Indus., Inc.,* 953 F.2d 1360, 1374 (Fed. Cir. 1991)) (holding that the sale in the United States of an apparatus for carrying out a claimed process did not infringe the process claim under §271(f) where the customer practiced the process abroad).
24. Union Carbide Chemicals & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005)(Rader, J.).

reversed, because "the statute makes no distinction between patentable method/process inventions and other forms of patentable inventions."[25]

The court attempted to distinguish *NTP* by noting that: (1) Blackberry® devices were used both within and outside the United States; and (2) RIM did not supply any component of the Blackberry® device to a foreign affiliate. In contrast, the court noted, Shell's infringing catalysts sold abroad were used in processes abroad, and damages were separately calculated from those based on domestic sales.[26] Cognizant of the court's earlier pronouncements in *Eolas*, *AT&T* and *NTP*, the Federal Circuit analogized the facts in *Union Carbide* to *Eolas* by stating that in both cases the exportation of a component (*i.e.,* a computer disc with program code in *Eolas* and a catalyst in *Union Carbide*) used in the performance of a patented process or method (*i.e.,* the method steps executed by the computer in response to the computer readable program code in *Eolas* and the commercial production of EO in *Union Carbide*) justified application of §271(f) in each case.[27]

Unlike *NTP*, where RIM sold Blackberry® devices domestically which were used, in part, outside the U.S., Shell supplied catalysts from the U.S. directly to foreign customers. This fact alone was held to be sufficient to impose liability under §271(f).[28]

Union Carbide is difficult to reconcile with the statutory language of §271(f) and the Federal Circuit's earlier decision in *Standard Havens*,[29] which was not even cited in *Union Carbide*. It is equally difficult to reconcile with *NTP*, considering that the Blackberry® device itself is the component used to carry out the claimed step of "transmitting" a signal to a relay in Canada.

What impact will these case have on the biotechnology industry? Is the manufacturer of a host cell transformed in the U.S. and thereafter exported for protein expression and production liable for infringement of a patent claiming a method of producing proteins under §271(f)? Does it make a difference (under §271(f)) if the customer is domestic? Given the likelihood that at least one of the cases will be reviewed, hope remains that companies engaged in trans-national manufacturing and sales will not be mortgaged with the uncertain threat of infringement liability, given the fine

25. *Id*. at 1379.
26. *Id.* at 1379-80.
27. *Id.* at 1379.
28. *Id*. at 1379-80.
29. Standard Havens Prods., Inc. v. Gencor Indus., Inc*.,* 953 F.2d 1360, 1374 (Fed. Cir. 1991).

distinctions made this year.

II. Claim Construction After *Phillips*

In *Phillips*, the Federal Circuit sitting *en banc* held: (1) claims define the scope of invention;[30] (2) the words of a claim are given their ordinary and customary meaning to a person of ordinary skill in the art *at the time of the invention*, (*i.e.,* as of the effective filing date of the patent application);[31] (3) claim terms are read in the context of the claim in which it arises, the other claims, and the specification;[32] and (4) the widely accepted meaning of commonly understood words may be used where the meaning is readily apparent, and general purpose dictionaries may be helpful to this end.[33]

According to *Phillips*, where the meaning is not readily apparent, it is appropriate look to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean, which include: (1) the words of the claims themselves; (2) the specification; (3) the prosecution history; and (4) extrinsic evidence.[34] Extrinsic evidence is always less relevant than intrinsic evidence because (1) it is not part of the patent; [35](2) it may not reflect the understanding of a skilled artisan in the field of the patent;[36] (3) it may be litigation inspired;[37] (4) it may be only marginally relevant;[38] and (5) the public notice function of patents is important.[39]

Finally in *Phillips*, the court concluded that expert testimony is extrinsic evidence, but can be useful to (1) provide background on the technology at issue, (2) explain how an invention works, (3) ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, and (4) establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.[40] Expert testimony is discounted where it (1) contains conclusory, unsupported assertions or (2) is clearly at odds with the claim construction mandated by the claims

30. 415 F.3d at 1312.
31. *Id*. at 1312-13.
32. *Id*. at 1313-14.
33. *Id*.
34. *Id*. at 1314.
35. *Phillips* at 1318.
36. *Id*.
37. *Id*.
38. *Id*.
39. *Id*. at 1318-19.
40. *Phillips* at 1318.

themselves, the written description, and the prosecution history.[41]

While the holdings in *Phillips* are straightforward, it remains to be seen whether it be followed or ignored, leaving the patenting community with the same fractured body of claim construction doctrine that led to the *en banc* rehearing to begin with. An early review of the court's claim construction decisions for the first 3-4 months after *Phillips* is optimistic, revealing a surprising fidelity to the principles set forth by the *en banc* court. Perhaps even more surprising, but gratifying, is the fact that many of the post-*Phillips* decisions adhering to its principles were authored by circuit judges who, prior to *Phillips*, employed different and even *opposite* claim construction methodologies.

For example, Judge Linn, who authored *Texas Digital Systems*,[42] held in *Terlep*[43] that "clear" meant "transparent" according to the specification and the prosecution history, not the broader definition "translucent" contained in Webster's Dictionary as argued by Terlep.[44] In *Pause Technology*[45], he rejected the proffered broad definition of "circular storage buffer" as set forth in the Encyclopedia of Computer Science as inconsistent with the narrower interpretation present in the claim language, the written description, and the prosecution history; he also rejected a proposed claim interpretation based on expert testimony that conflicted with the intrinsic record.[46] In *Nystrom*,[47] the Federal Circuit vacated an earlier (2004) panel opinion in which the claim term "board" was construed broadly to include wood and other materials (the specification was held not to have disavowed or disclaimed any part of the broader definition).[48] In the recently-issued substituted opinion, Judge Linn limited the

41. *Id*.

42. Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002)(Linn, J.). In *Texas Digital*, the court noted that "dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms." 308 F.3d at 1202. Those texts, the court explained, are "objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art. *Id.* at 1203. The *Texas Digital* approach thus limited the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term if the specification requires the court to conclude that fewer than all the dictionary definitions apply, or if the specification contains a sufficiently specific alternative definition or disavowal. *See, e.g.*, *Texas Digital,* 308 F.3d at 1202.

43. Terlep v. Brinkmann, 418 F.3d 1379 (Fed. Cir. 2005) (Linn, J.).

44. *Id*. at 1383-84.

45. Pause Technology v. TiVo, 419 F.3d 1326 (Fed. Cir. 2005)(Linn, J.).

46. *Id*. at 1329-33.

47. Nystrom v. Trex, 424 F.3d 1136 (Fed. Cir. 2005)(Linn, J.).

48. Nystrom v. Trex, 374 F.3d 1105 (Fed. Cir. 2004).

construction of "board" to "wood sawn from a log" based on repeated references to that meaning in the specification, rejecting a broader Webster's Dictionary definition.[49] Each of these recent decisions has faithfully followed the claim construction methodology of *Phillips,* with primacy given to the intrinsic evidence.

Judge Dyk in *Free Motion Fitness*[50] considered two different dictionary definitions for "adjacent," and concluded that the definition "not distant" was more consistent with the specification. Citing *Phillips*, he observed that "[t]he court must ensure that any reliance on dictionaries accords with the intrinsic evidence: the claims themselves, the specification, and the prosecution history."[51] Again in *Cytologix*,[52] Judge Dyk interpreted "heating station" to refer to devices in which only a single slide can be accommodated; the alternative interpretation would have rendered another claim of the patent meaningless.[53] In *Network Commerce*,[54] Judge Dyk construed "download component" to include a boot program that interacts directly with the computers operating system, and rejected as inconsistent with the intrinsic evidence Network's proffered expert testimony that a boot program was not required.[55]

In *Ocean Innovations*,[56] Judge Schall construed "flotation units' as both "hollow" and "airtight" based on repeated passages in the specification. He rejected Jet Dock's claims that the "hollow" requirement constituted an erroneously imported limitation from the specification into the claims.[57]

Judge Plager in *Biagro*[58] rejected expert declarations as extrinsic evidence as a basis to construe "phosphorous-containing acid" as including a "chemical equivalent amount of phosphorous-containing acid;" neither the claims nor the specification referred to the amount

49. *Id*. at 1142-46.

50. Free Motion Fitness v. Cybex Intenational*,* 423 F.3d 1343 (Fed. Cir. 2005)(Dyk, J.).

51. *Id*. at 1348 (citing *Phillips* at 1322, quoting *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996)).

52. Cytologix Corp. v. Ventana Medical Systems, 424 F.3d 1168 (Fed. Cir. Sept. 21, 2005)(Dyk, J.).

53. *Id*. at 1173-74.

54. Network Commerce v. Microsoft Corp., 422 F.3d 1353 (Fed. Cir. 2005)(Dyk, J.).

55. *Id*. at 1362.

56. Ocean Innovations v. Jet Dock Systems*,* 2005 U.S. App. LEXIS 17775 (Fed. Cir. August 19, 2005)(Schall, J.).

57. *Id*. at *7-*12.

58. Biagro Western Sales v. Grow More, Inc., 423 F.3d 1296, 2005 U.S. App. LEXIS 19680 (Fed. Cir. 2005)(Plager, J.).

of phosphorous-containing acid as an *equivalent* amount.[59]

Judge Bryson in *Tap Pharmaceuticals* [60]interpreted "comprising a copolymer . .. of lactic acid and... of glycolic acid" as not limited to the particular method of reaction based lack of any such limitation in the other claims and in the specification. He rejected the argument that the copolymers must be made *directly* from lactic acid and glycolic acid as starting materials, as opposed to other indirect methods.[61]

Judge Mayer in *Aquatex*[62] construed the claim term "fiberfill" to refer to synthetic materials based on the patentee's consistent use of that term throughout the written description to refer to synthetic materials. Although the written description indicated that the composition of the fiberfill was not known to be critical, the court held that the context of the specification made clear that the patentee did not intend the term fiberfill to encompass natural materials.[63]

The post-*Phillips* panels have thus far responded to the pleas of the parties, *amici*, the patent bar and the inventing community for predictability in claim construction methodology and adherence to the principles of *stare decisis*. Court members previously disposed toward the primacy of, *e.g.,* dictionary definitions for use in interpreting claims have since relied on the intrinsic evidence in the sprit and letter of *Phillips*. Hopefully the pre-*Phillips* panel-dependent outcomes of claim construction disputes are relegated to the history books. Left for another day, however, are forecasts about the impact of *Phillips* on patent procurement and enforcement, particularly when applied in the context of other doctrines.

III. The Inequitable Conduct Phoenix

Inequitable conduct has fallen and out of favor with the Federal Circuit almost since the creation of the court in 1982. Indeed Professor Lisa Dolak stated in 2002 that "[t]he 'heyday' of inequitable conduct has come and gone," citing the court's more restrictive requirement for proving intent in the 1990s than had been employed previously.[64] But hidden behind the *Phillips* and *Merck*

59. *Id*. at 1302.

60. Tap Pharmaceutical Prods. V. Owl Pharmaceuticals, 419 F.3d 1346 (Fed. Cir. 2005)(Bryson, J.).

61. *Id.* at 1349-50.

62. Aquatex Industries v. Techniche Solutions, 419 F.3d 1374 (Fed. Cir. 2005) (Mayer, J.).

63. *Id* at 1379-81.

64. Lisa A. Dolak, *The Inequitable Conduct Doctrine: Lessons From Recent Cases*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 719 (2002).

leviathans that have occupied the headlines in 2005, the inequitable conduct phoenix has arisen again.

A. Prophetic Examples Written in the Past Tense Support Intent to Deceive

The judicial censure of a patent's reference to prophetic results in a manner suggesting they were, in fact, experimental continues as a basis of inequitable conduct.[65] Applicants are advised to avoid the use of past-tense language used to describe prophetic examples.

In *Purdue*,[66] the Federal Circuit upheld the finding of inequitable conduct with respect to Purdue's oxycodone patents. By representing to the PTO that Purdue had "discovered" that oxycodone acceptably controlled pain over a four-fold dosage range, while withholding from the PTO the fact that the discovery was based on insight *without scientific proof*, Purdue failed to disclose material information. The court rejected Purdue's argument that the lack of scientific proof was not material because the inventors never stated during prosecution that the discovery had been clinically tested, and thus did not expressly misrepresent a material fact. Rather, the court held that Purdue relied on its discovery of the four-fold dosage range throughout prosecution as a prominent argument in favor of patentability, and the failure to explain that the discovery was based on insight was inconsistent with Purdue's arguments for patentability.[67]

The court inferred the intent element from Purdue's carefully chosen language suggesting that it had obtained clinical results, which was left unclarified by any disclosure that discovery of the dosage range was untested.[68]

In *Pharmacia*,[69] applicants submitted a Rule 132 declaration in support of the patentability of the claimed 17-phenyl drug compound (Xalatan) over an asserted prior art genus that included the 17-phenyl compound.[70] Paragraph 10 of the declaration touted the superiority of the 17-phenyl compound over a preferred member of the asserted genus, said to be inoperative at a particular dosage range. But the statement conflicted with an earlier article coauthored by the declarant, as well as two Japanese articles cited in the declarant's article. Neither the declarant's article nor the Japanese articles were

65. Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003).
66. Purdue Pharma v. Endo Pharmaceuticals, 410 F.3d 690 (Fed. Cir. 2005).
67. *Id*. at 697-98.
68. *Id*. at 701.
69. Pharmacia v. Par Pharmaceutical, 417 F.3d 1369 (Fed. Cir. 2005).
70. *Id*. at 1371.

brought to the attention of the PTO. Pharmacia argued a translation error in the declaration, and that replacing "does not" with "did not" would limit this the declarant's comments to only those tests actually conducted, rather than including conflicting tests by other researchers. [71] The Federal Circuit affirmed the district court's conclusion that the misrepresentation was material and intent could be inferred. Elsewhere in the declaration, the language contained the "implicit suggestion" that the declarant conducted a test on a certain dose of the prior art compound which he never conducted. The Federal Circuit did not reach this second basis of affirming the inequitable conduct determination.[72]

More recently, in *Novo Nordisk*,[73] the Federal Circuit affirmed a finding of inequitable conduct based on evidence showing that an example provided in a priority application, written in the *past tense*, was never successfully used to produce human growth hormone (hGH). The example described the use of the LAP enzyme to cleave the bacterial portion from the pre-hGH fusion protein, resulting in "ripe" hGH. The Federal Circuit rejected Novo's argument that it successfully used the LAP enzyme to produce hGH *after* the application was filed.[74] The evidence showed that the LAP enzyme used was contaminated with DAP 1 enzyme, a different enzyme that would later be successfully used in producing hGH.[75] According to the court, Novo's post-filing unintentional use of the DAP I enzyme present only as a contaminant in the inoperative LAP enzyme described in the example was insufficient to support Example 1 as of filing.[76]

According to the court, Novo knew or should have known that the examiner during prosecution (and later, the Board in an interference) would have considered the prophetic nature of the data in Example 1 important in evaluating whether the claimed invention was enabled.

B. Intent to Deceive Based on Failure to Disclose

In prosecuting claims to a "Z" lens, applicant in *Frazier*[77] argued the superiority of the depth of field achievable with the claimed

71. *Id*. at 1371-72.
72. *Id*. at 1373.
73. Novo Nordisk v. Bio-Technology General, 2005 U.S. App. LEXIS 21518 (Fed. Cir. 2005).
74. *Id.* at *36-37.
75. *Id*. at *39-43.
76. *Id.* at *37.
77. Frazier v. Roessel Cine Photo Tech, 417 F.3d 1230 (Fed. Cir. 2005).

invention as compared with the prior art. In support, the applicant submitted a video to demonstrate the features and uniqueness claimed optical system. The relevant video portions were not shot with the claimed Z lens, but rather with a prior art "AI Lens", a normal, wide-angle objective lens, or an L-shaped Lens. The district court found inequitable conduct based in part on the misstatement as to which lens was used to make the video.[78] The Federal Circuit affirmed, holding that the submission of the footage shot with other than the claimed lens constituted a sufficiently material misrepresentation without regard to whether the claimed lens *could* create the same shots.[79] Intent was properly inferred where applicant submitted a video in order to represent the capabilities of the claimed lens, knowing that portions of the video were shot with a different lens.[80]

In *Bruno*[81] the applicants failed to submit certain prior art references to the PTO during prosecution based on their argument that the references were cumulative of art already of record. But the Federal Circuit concluded that there was inequitable conduct because applicants argued during prosecution that one of the "novel and nonobvious attributes" of the claimed stairlift invention was the swivel seat with an off-center pivot. That very feature was disclosed in the withheld prior art reference. According to the court, Bruno could not have touted the front offset swivel as a point of novelty of the claimed invention had the examiner known about the disclosure of the prior art reference.[82] The Federal Circuit also considered probative of materiality (1) Bruno's submission of the stairlift reference to the FDA in seeking approval of its stairlift and (2) Bruno's statement that the prior art stairlift and its own product were "substantially equivalent."[83] The court held that there was sufficient evidence of intent to deceive, based on the high degree of materiality of the withheld reference and the failure to submit to the PTO the same reference that was provided to FDA.[84]

A. But No Intent to Deceive Where the Explanation is Credible

Patentees in *Warner Lambert*[85] discovered how to stabilize their

78. *Id.* at 1233-34.
79. *Id.* at 1234-35.
80. *Id.* at 1236.
81. Bruno Independent Living Aids v. Acorn Mobility Services, 394 F.3d 1348 (Fed. Cir. 2005).
82. *Id.* at 1353-54.
83. *Id.* at 1352.
84. *Id.* at 1354.
85. Warner-Lambert v. Teva Pharmaceuticals, 418 F.3d 1326 (Fed. Cir. 2005).

Accupril® (quinapril) formulation using sodium bicarbonate and lactose. Warner-Lambert discovered that Merck stabilized its previously-marketed Vasotec® (elanapril) formulation with sodium bicarbonate and lactose, but did not disclose Merck formulation the PTO during prosecution of its quinapril application. (Merck's stabilizing formulation was a trade secret.[86]) The Federal Circuit held there was no inequitable conduct for Warner-Lambert's failure to disclose Merck's stabilizing formula.[87] Although Claim 16 of Warner-Lambert's '450 patent read on much of the Vasotec® formulation, the district court credited the testimony of the '450 patent inventors who stated that the mere knowledge of sodium bicarbonate as one of the ingredients of Vasotec® in no way informed them as to *how* sodium bicarbonate was used to stabilize the Vasotec® formulation.[88] The inventors' explanation as to why Vasotec® was not cited was sufficient to refute any showing of intent to deceive.

IV. The *Rasmusson* Enablement Standard

In *Rasmusson*,[89] the Federal Circuit suggested that a claim to a cancer treatment is invalid unless data or other proof of utility is found *in the original application.* The court affirmed the denial of Rasmusson's claim of priority (for lack of enablement) to his first three of nine applications directed to the use of finasteride in treating prostate cancer.

Both parties agreed that a person of ordinary skill in the art at the time of Rasmusson's applications would have recognized that finasteride was a selective 5αR inhibitor, yet disagreed as to whether a person of ordinary skill in the art would have believed, before Rasmusson's ninth application, that finasteride would be effective in treating prostate cancer.[90] Rasmusson argued that data demonstrating the efficacy of finasteride was not required to comply with §112 based evidence showing that certain multi-active 5αR inhibitors were effective in treating prostate cancer. But the Board and the Federal Circuit disagreed, stating that Rasmusson's evidence was dated too late or pertained only to the use of multi-active inhibitors to treat

86. *Id.* at 1331.
87. *Id.* at 1346-47.
88. *Id.*
89. Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318 (Fed. Cir. 2005)(Bryson, J.),
90. *Id.* at 1323.

prostate cancer.[91] According to the court, a person of skill in the art as of the filing date of Rasmusson's eighth application, would not have concluded that a selective 5αR inhibitor would have any anti-tumor effects, because the anti-tumor effects shown by published experiments involving multi-active 5αR inhibitors could be attributable to contaminating activities having no relation to 5αR inhibition. The court relied on articles and testimony to show that it was unclear whether DHT or testosterone caused prostate cancer.[92] If testosterone and not DHT caused the disease, then the anti-tumor effects resulting from multi-active 5αR inhibitors were not due to 5αR inhibition, but rather to anti-testosterone mechanisms such as the inhibition of testosterone receptor binding.[93]

The decision contrasts with the court's earlier decision in *Jolles*,[94] which addressed the sufficiency of the utility disclosure in the original application under 35 U.S.C. § 101 for a cancer drug. In *Jolles*, the PTO found that the asserted utlitiy of Jolles' anticancer compounds to be incredible.[95] In experimentation conducted *post*-filing, Jolles established that one of the compounds within the claimed genus was operative as a cancer treatment, and that several others within the genus were active in tests conducted in mice. [96] Like *Jolles*, the claimed invention in *Rasmusson* was directed to an anticancer compound whose original statement of utility at the priority date was found to be incredible. Thereafter, Rasmusson's statement of utility was accepted by persons skilled in the art, establishing the correctness of the originally filed utility statement.

Does *Rasmusson* establish a means of attacking the validity of patents under §112 by permitting evidence that the "how to use" element of §112 would not have been believed at the time of original application without scientific proof? Must a disclosure of all claimed utility in an original application be substiantiated scientifically at the time of filing in order to comply with §112? The decision amplifies the need for careful application preparation, particularly in fields where claims for treating illnesses or disease states are based on a mode of action of the claimed compounds or species.

V. Conclusion

91. *Id.* at 1324.
92. *Id.* at 1323-24.
93. *Id.*
94. In re Jolles, 628 F.2d 1322 (C.C.P.A. 1980).
95. *Id.* at 1324-25.
96. *Id.* at 1323-25.

The Federal Circuit has issued a number of important decisions this year. The state of the law over the reach of U.S patent laws under §271(f) is at best unclear, and at worst, not over yet. Certainly, further refinements on the *Union Carbide* or *NTP* cases may yet be forthcoming. The application of claim construction principles after Phillips has been uniform and consistent with the methodology set forth in *Phillips*. Inequitable conduct is on the rise, and the Federal Circuit continues its application as a basis of unenforceability for prophetic examples written in the past tense. Where a person of skill in the art would not find the "how to use" portion of §112 credible as of the filing date, the claims may be found to be deficient for lack of enablement.