Intellectual Property Technology Law Journal

ELECTRONICALLY REPRINTED FROM JULY 2012

Recent Intellectual Property Developments in The Chemical Industry

By Steven M. Zager and Sarah J. Ring

Over the last several years, the Federal Circuit has focused its lens on the chemical industry from a variety of angles. Although there have been a disproportionate number of cases pertaining to inventorship or priority of invention under Title 35 U.S.C. § 102(g)(2), there have also been significant cases related to written description, double patenting, and anticipation. This article provides an overview of the most notable Federal Circuit cases since 2010 that could have a wide-reaching effect on intellectual property in the chemical industry.

For Claims Directed to a Genus of Chemical Compounds, a Written Description Failing to Disclose a Variety of Species is Insufficient

In *Ariad Pharm., Inc. v. Eli Lilly and Co.*,[1] the Federal Circuit granted Ariad's petition for rehearing *en banc* in light of the controversy concerning (1) whether Title 35 U.S.C. § 112, Paragraph 1, contains a written description requirement separate from an enablement requirement, and (2) if a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

The patent-in-suit relates to the regulation of gene expression and recites methods encompassing a genus of materials achieving a stated useful result (functional language),[2] but the specification does not disclose a variety of species that accomplish the result.[3]

Ariad argued that because the original claims are part of the original specification, the original claim language discloses the subject matter that it claims and satisfies the written description requirement, and that the only question left is whether the invention is enabled.[4]

The Federal Circuit held that, although many original claims will satisfy the written description requirement, certain claims may not.[5] The court went on to state that a generic claim, for example, may define a vast genus of chemical compounds, and the question may remain whether the original specification (including the claims) demonstrates that the applicant has invented a species sufficient to support a claim to a genus.[6] The problem is exacerbated when the patentee claims a genus using functional language.[7] In such a case, "the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus."[8]

Sufficient written description of a genus requires "the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."[9] "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and the complexity and predictability of the relevant technology."[10]

The Federal Circuit recognized that, although in some fields, there is little difference between describing an invention and enabling a person to make and use it (and thus written description and enablement rise and fall together), this is not always the case, particularly in regard to chemical inventions.[11]

An Individual Responsible for Developing a Method for Making a Genus of Compounds is a Properly Named Inventor of Broadly Drafted Claims

In *Falana v. Kent State University,*[12] the Federal Circuit held that, for claims broadly drafted to

Steven M. Zager, a partner in the New York and Longview, Texas, offices of Akin Gump Strauss Hauer & Feld LLP, serves as the global head of the firm's intellectual property practice and is a member of the firm's Management Committee. He can be reached at szager@akingump.com. **Sarah J. Ring,** counsel in the firm's Houston office, practices intellectual property litigation and prosecution, with a focus on patent litigation and patent and trademark prosecution. She can be reached at sring@akingump.com.

cover an entire genus of compounds, the individual responsible for developing a synthesis protocol for making the genus is a properly named inventor.

Oleusegun Falana filed an action to correct inventorship of the patent-in-suit under Title 35 U.S.C. § 256, alleging that he was an omitted as a named co-inventor of that patent, which relates to chiral additives used to improve the performance of liquid crystal displays (LCDs).[13]

Kent Displays, Inc. (KDI), a spinoff from Kent State, started a research program to develop chiral additives and hired Falana to synthesize and develop these additives.[14] Falana developed a synthesis protocol for making a novel genus of compounds (napthyl substituted TADDOLs) and synthesized Compound 7 (a species within that genus) using that protocol.[15] Although it represented great progress, Falana's Compound 7 did not completely satisfy the temperature-independence goals of the project.[16] Falana subsequently resigned from KDI, and another KDI employee synthesized Compound 9, which was also a napthyl substituted TADDOL synthesized using Falana's synthesis protocol.[17] Compound 9 exhibited substantial temperature independence and therefore satisfied the goals of the project.[18]

KDI filed a patent application (which led to the patent-in-suit) disclosing the synthesis protocol developed by Falana but did not list Falana as an inventor.[19] The claims were drafted broadly to include the entire genus, as opposed to only the Compound 9 species.[20]

Based on the broad claims of the patent-in-suit, the Federal Circuit upheld the district court's determination that Falana should be named as a joint inventor.[21] This holding shows the importance of narrowly tailoring claims to what is actually conceived by the named inventors.

Claims to a Narrow Species May be Anticipated by the Disclosure of the Broad Genus

Despite the Federal Circuit's having previously held that the prior art's teaching of a broad genus does not anticipate every species within that genus, the Federal Circuit held in *ClearValue, Inc. v. Pearl River Polymers, Inc.* that claims to a more-narrow species are anticipated by disclosure of a broader genus when the patentee fails to establish that the different portions of the broad range would work differently,[22] that is, when the patentee fails to establish that its narrower range or species is critical to invention or fails to provide any evidence demonstrating any difference across the broad range.[23]

The claims of the patent-in-suit related to process for clarifying water with alkalinity of 50 ppm or less, and the prior art patent granted to Hassick disclosed a composition for clarifying water with alkalinity of 150 ppm or less.[24] The plaintiff, ClearValue, relied upon *Atofina v. Great Lakes Chem. Corp.*[25] to argue that the 150 ppm disclosed in Hassick's patent was too broad to anticipate the 50 ppm limitation of the claims at issue.[26]

The patent in *Atofina* claimed a method for synthesizing dithoromethane at a temperature between 330–450°C and also that the prior art taught a broad temperature range of 100–500°C.[27] The Federal Circuit distinguished *Atofina* on the facts: The patent in *Atofina* claimed a method for synthesizing dithoromethane at a temperature between 330–450°C and stated that only that narrow temperature range enables the process to operate as claimed and that problems occur outside that temperature range.[28] Also, during the prosecution of the *Atofina* patent, Atofina described the temperature range as "critical."[29] The *Atofina* court explained that the prior art's teaching of a broad genus (100–500°C) does not disclose every species within that genus.[30]

After distinguishing *Atofina*, the Federal Circuit found anticipation of the ClearValue patent because ClearValue did not argue that the 50 ppm limitation was "critical" or that the claimed method works differently within the prior art range of 150 ppm or less.[31]

Prior Inventor Must Prove Appreciation of What its Invention was but not Understanding of Everything About How or Why it Worked

In *Teva Pharma. Indus. v. AstraZeneca Pharm. LP,*[32] the Federal Circuit held that, while a party must prove that it appreciated what it had made so as to establish prior invention under Title 35 U.S.C. § 102(g), it did not have to understand everything about how or why its invention worked.

Teva's patent-in-suit claimed statin formulations (useful in treating dyslipidemia, or high cholesterol) that were stabilized exclusively by an amino-group

containing polymeric compound (AGCP) compound.[33] AstraZeneca asserted invalidity based on its prior invention under Title 35 U.S.C. § 102(g).[34] AstraZeneca's prior invention consisted of a stabilized statin (rosuvastatin calcium) designed with tribasic calcium phosphate (not an AGCP compound) as a stabilizer.[35] AstraZeneca's prior invention also contained crospovidone, which is an AGCP compound, as a disintegrant.[36] AstraZeneca, however, did not understand crospovidone to have a stabilizing effect.[37]

AstraZeneca conceded infringement for the limited purpose of advancing the summary judgment motion, and there were no issues of fact, only an issue of law: "whether AstraZeneca had to understand that crospovidone stabilized its drug so as to win a priority dispute under Title 35 U.S.C. § 102(g)(2)."[38] Teva argued that the district court had misapplied § 102(g)(2) by failing to require AstraZeneca to prove that it appreciated the stabilizing effect of crospovidone in its formulation.[39]

The Federal Circuit held that, to establish prior invention, a party must prove that it appreciated what it had made.[40] The party does not need to know everything about how or why its invention worked, nor must it conceive of its invention using the same words as the patentee.[41] Therefore, the court held that, despite AstraZeneca's not understanding the stabilizing effect of crospovidone and despite the claim language "stabilizing effective amount," AstraZeneca had established prior invention under Title 35 U.S.C.§ 102(g)(2).

A Double Patenting Inquiry Looks to Disclosure as Well as to What is Claimed

In *Sun Pharm. Indus. v. Eli Lilly and Co.,*[42] the Federal Circuit held that a claim to a method of using a composition (for the treatment of cancer) is invalid for obviousness-type double patenting over an earlier claim to the identical composition in a patent disclosing (but not claiming) that use (treatment of cancer). In a dissenting opinion to a decision denying a petition for rehearing *en banc*, however, Justices Newman, Rader, Laurie, and Linn argued that this decision violates a vast body of precedent that the issue of obviousness-type double patenting is directed to whether the invention *claimed* (and not disclosed) in a later patent is an obvious variant of the invention claimed in an earlier patent.[43]

Eli Lilly's patents-in-suit related to gemcitabine, a pharmaceutical composition used for treating cancer. Its U.S. Patent No. 4,808,614 claims gemcitabine and the method of using gemcitabine for treating viral infections, and the later-issued U.S. Patent No. 5,464,826 claims a method of using gemcitabine for treating cancer.

In support of its invalidity finding, the Federal Circuit court held that for "a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes."[44]

The dissenting opinion to the court's denial of the petition for rehearing *en banc* opined that,"[u]ntil recently it was beyond dispute that the law of double patenting is concerned only with what is patented—that is, what is claimed."[45] The dissenting opinion argued that the double-patenting analysis occurs only when the earlier patent is not prior art against the later patent and that "[t]he specifications of the patents are irrelevant to the double patenting analysis, other than to guide in construing the claims."[46]

The applications that led to the patents-in-suit were filed on the same day, but the 5,464,826 patent expired two and a half years after the 4,808,614 patent. The result, the dissenting opinion argued, is that, "Lilly would be entitled to a separate patent on the anticancer use" if it had not included the disclosure of anticancer use in the specification filed on the same day.[47] The dissenting opinion claimed that such disclosure does not "improperly extend" any patent.[48]

Title 35 U.S.C. § 102(G): Prior Invention is not Established by Reduction to Practice Prior to Priority Date

In *Solvay S.A. v. Honeywell Int'l, Inc.,*[49] the Federal Circuit held that an invention reduced to practice by another person or entity in the United States before the priority date of the patent-in-suit is insufficient to establish a prior invention defense under Title 35 U.S.C. § 102(g)(2).

The Federal Circuit reversed the district court's finding of invalidity, holding that Honeywell was a prior inventor of the claimed process.[50] The Federal Circuit ruled that, under the rules governing the determination of priority of invention, which are

often applied to prior inventions under Title 35 U.S.C. § 102(g)(2), Honeywell must prove that it *conceived* of the invention and reduced it to practice in the United States.[51]

The patent-in-suit was directed to methods for making HFC-245fa, which is advantageous as a blowing and insulation agent in the preparation of expanded polymeric materials, the type commonly used in refrigeration and heat-storage systems.[52] Honeywell entered into a research contract with the Russian Scientific Center for Applied Chemistry (RSCAC), pursuant to which (1) RSCAC performed in Russia a process that corresponds to the patent claims at issue; (2) RSCAC transmitted to Honeywell in the United States complete instructions for the process; and (3) Honeywell replicated the Russian process by following the information provided by RSCAC, thereby practicing the invention in the United States before the priority date.[53]

Based on these facts, Honeywell argued that it qualified as "another inventor" under Title 35 U.S.C. § 102(g)(2) and that the fact that the claimed invention was previously reduced to practice in the United States by someone other than the patentee was sufficient to establish a prior invention defense under Title 35 U.S.C. § 102(g)(2).[54] This Section states that a person is not entitled to a patent if, before the applicant's invention thereof, "the invention was made in this country by another inventor who had not abandoned, suppressed or concealed it."

Honeywell argued that "as a matter of policy, it would contradict the purpose of § 102(g)(2) to allow Solvay to have a patent covering subject matter that Solvay was not the first to invent."[55] In rejecting this argument, the Federal Circuit reasoned that, "Whether the holding ignores the realities of globalization and outsourcing by modern-day research companies . . . is not the question before us," but rather whether Honeywell qualified as "another inventor" under Title 35 U.S.C. § 102(g)(2).[56] The Federal Circuit found that Honeywell did not conceive of the invention but merely followed another inventor's instructions and therefore was not "another inventor" under Title 35 U.S.C. § 102(g)(2).[57]

Burden of Proof For Invalidity is Based On Priority of Invention

Creative Compounds, LLC v. Starmark Labs[58] presented several interesting issues, including whether the burden of proof is lowered for invalidity when the issue is priority of invention, whether the accused infringer has the burden to establish that its product is not made pursuant to the patented method, and whether declaratory judgment jurisdiction exists when accusatory communications were only sent to customers, as opposed to being sent directly to the declaratory judgment plaintiff.

Creative Compounds sued Starmark and sought a declaratory judgment that Starmark's U.S. Patent No. 7,109,373 was invalid and not infringed.[59] Starmark alleged infringement of the patent and sought a declaration that Creative Compounds' U.S. Patent No. 7,129,273 was invalid.[60] Both patents relate to formulations of the dietary supplement creatine, which increases bioavailability.[61]

Invalidity: Burden of Proof

Creative Compounds argued that the correct burden of proof on invalidity is the preponderance of the evidence, as opposed to clear and convincing evidence, because preponderance is the standard for priority of invention as between copending interfering patents.[62]

The Federal Circuit distinguished two other Federal Circuit cases that applied the preponderance of the evidence standard to priority determinations.[63] The *EnvironProd., Inc. v. Furon Co.* case was distinguishable because the parties stipulated that the same invention was common to the copending patent applications and agreed on the description of the common subject matter that would serve as the basis for determining who the original inventor was.[64] The *Slip Track Sys., Inc. v. Metal-Lite, Inc.* case was distinguishable because it was a Title 35 U.S.C. § 291 action (civil patent interference), in which common claimed subject matter must be identified.[65]

Therefore, in *Creative Compounds,* the Federal Circuit held that an accused infringer cannot obtain the benefit of the lower burden of proof applied in interference proceedings (preponderance of the evidence) simply by alleging that the asserted patent is invalid based upon a copending patent (Title 35 U.S.C. § 102(g)(2)) *unless* common claimed subject matter is first identified.[66]

Infringement

As to infringement of the method claims of the 7,109,373 patent (Creative Compounds conceded

infringement of compound claims), the court affirmed the district court's infringement finding.[67] Starmark submitted expert testimony that the process most likely used to manufacture the claimed compound is the method claimed in the claims at issue.[68] Starmark also sought discovery on the manufacturing process, but Creative Compounds failed to produce documentation.[69] The court held that the burden of establishing that the product was not made by the method claims at issue was properly on Creative Compounds, which offered no evidence as to how or why the process did not infringe the 7,109,373 patent.[70]

Jurisdiction

The Federal Circuit reversed the district court's determination that declaratory judgment jurisdiction existed as to the invalidity of the 7,129,273 patent.[71] Despite letters from Creative Compound's patent counsel opining that the 7,109,373 patent was invalid in light of the 7,129,273 patent and letters from Creative Compounds to purchasers of dicreatine malate alleging infringement of the 7,129,273 patent, the Federal Circuit held that there was no jurisdiction because Creative Compounds had never accused Starmark directly of infringement of the 7,129,273 patent.[72] The court noted that Starmark had no indemnity obligation to its customers, so Starmark had only an economic interest in clarifying its customers' rights, which alone is not enough to form the basis of an actual controversy.[73]

Notes

1. Ariad Pharm., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1342 (Fed. Cir. 2010) (*en banc*).
2. *Id.* at 1340-1341. Specifically, the patent-in-suit related to a genus encompassing the use of all substances that achieve the desired result of reducing the binding of NF-êB to NF-êB recognition sites.
3. *Id.* at 1350.
4. *Id.* at 1349.
5. *Id.*
6. *Id.*
7. *Id.*
8. *Id.*
9. *Id.* at 1350.
10. *Id.* at 1351.
11. *Id.* at 1352.
12. Falana v. Kent State University, No. 2011-1198, 2012 WL 171550 (Fed. Cir. Jan. 23, 2012).
13. *Id.* at *1.
14. *Id.*
15. *Id.* at *2.
16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.*
20. *Id.* at *9.
21. *Id.*
22. ClearValue, Inc. v. Pearl River Polymers, Inc., __ F.3d __, 2012 WL 517488, *3-4 (Fed. Cir. Feb. 17, 2012).
23. *Id.* at *4.
24. *Id.* at *1, 3.
25. Atofina v. Great Lakes Chem. Corp., 441 F.3d 991 (Fed. Cir. 2006).
26. ClearValue, 2012 WL 517488 at *3.
27. *Id.*
28. *Id.*
29. *Id.*
30. *Id.*
31. *Id.* at *4.
32. Teva Pham. Indus. v. AstraZeneca Pharm. LP, 661 F.3d 1378 (Fed. Cir. 2011).
33. *Id.* at 1380.
34. *Id.* at 1381.
35. *Id.* at 1380-1381.
36. *Id.*
37. *Id.*
38. *Id.* at 1382.
39. *Id.* at 1381-1382.
40. *Id.* at 1384.
41. *Id.*
42. Sun Pharm. Indus. v. Eli Lilly and Co., 611 F.3d 1381 (Fed. Cir. 2010).
43. Sun Pharm. Indus. v. Eli Lilly and Co., 625 F.3d 719 (Fed. Cir. 2010).
44. Sun Pharm., 611 F.3d at 1387.
45. Sun Pharm., 625 F.3d at 721.
46. *Id.*
47. *Id.* at 723.
48. *Id.*
49. Solvay S.A. v. Honeywell Int'l, Inc., 622 F.3d 1367 (Fed. Cir. 2010).
50. *Id.* at 1379.
51. *Id.*
52. *Id.* at 1370.
53. *Id.* at 1371, 1374-1375.
54. *Id.* at 1374.
55. *Id.* at 1379.
56. *Id.*
57. *Id.*

58. Creative Compounds, LLC v. Starmark Labs, 651 F.3d 1303 (Fed. Cir. 2011).
59. *Id.* at 1306.
60. *Id.*
61. *Id.*
62. *Id.* at 1309.
63. *Id.* at 1310-1311 (distinguishing *Environ Prod., Inc. v. Furon Co.,* 215 F.3d 1261 (Fed. Cir. 2000) and *Slip Track Sys., Inc. v. Metal-Lite, Inc.,* 304 F.3d 1256 (Fed. Cir. 2002)).
64. *Id.* at 1310-1311.
65. *Id.*
66. *Id.* at 1311.
67. *Id.* at 1315.
68. *Id.*
69. *Id.*
70. *Id.*
71. *Id.* at 1317.
72. *Id.* at 1315-1317.
73. *Id.*