Written Description of the Invention: *Ariad* (2010) and the Overlooked Invention Priority Principle

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In *Ariad Pharmacueticals, Inc. v. Eli Lilly & Co.* (No. 2008-1248, En banc, March 22, 2010), the Federal Circuit reaffirmed two propositions about the meaning of the "written description of the invention" language in 35 U.S.C. Section 112, first paragraph. First, written description of the invention is a requirement independent of the enablement requirement. Second, original claims do not necessarily comply with the written description of the invention requirement. The majority confirmed its prior, controversial decision, *Regents of the University of California v. Eli Lilly & Co*., 119 F.3d 1559 (Fed. Cir. 1997).

Much has been and will be written about *Ariad*. The primary problem with the *Lilly-Ariad* doctrine, as pointed out by the dissenting judges and by commentators, is that it creates confusion and uncertainty by perpetuating the written description of the invention (WDI) requirement as a generally applicable co-regulator of patent claim *scope* along with the enablement (E) requirement.

There may be a solution: application of an established patent law priority principle. The principle focuses on a specific embodiment of a generically

claimed invention as a constructive reduction to practice, that is, as a completion of the inventive process. Adopting this solution would preserve WDI's independence and applicability to original claims but would remove WDI as a standard for assessing the *scope* of a patent claim. WDI would continue to govern whether, at the time an applicant files an application, he or she has completed the inventive process, that is, "possesses" the invention. But only E would govern how broadly the applicant is entitled to claim that invention. It may be possible to implement this priority principle interpretation of *Ariad* without contradicting its clear holdings.

In *Ariad*, the majority opinion, by Judge Lourie, who also authored *Lilly* (1997), reviews the statutory language and Supreme Court precedent at length and reaffirms WDI's independence and applicability to original claims. Turning to the question of the standard for WDI compliance, the majority decrees that WDI requires that the specification, as filed on its priority date, "show that the inventor *actually invented the invention* claimed." But what does "invented the invention" mean? The court makes little effort to link that phrase to basic patent law principles on "invention," in particular, those on setting the date of invention and on resolving priority contests between rival inventors who rely on both generic and specific conceptions of their "inventions." Had the court

done so in *Ariad*, it may well have still concluded that WDI is an independent requirement and that it applies to original claims. However, WDI would apply *only* to determine whether a filed specification constituted a constructive reduction to practice, for priority purposes, of the subject matter claimed, originally or by amendment, either specifically or generically. WDI would be satisfied as to a claim if the specification adequately discloses an example or embodiment that falls within the claim and has sufficient utility.

Consider a hypothetical. In 2010, inventor A discovers that dipping a tree-ripened peach in a 5% mint oil solution retards the rapid rotting that such peaches undergo. Inventor A immediately files an application, which includes, as an example, a detailed description of her successful testing of a peach with the 5% solution. The application includes both a broad, generic claim, "A method of retarding ripening of a fruit comprising dipping said fruit in a mint oil solution," and more specific claims limited to methods using 5% solutions and peaches. In 2011, inventor B makes the same discovery and files an application. B's application is much more detailed than A's, giving examples of ten different fruits, including peaches and strawberries, and even exotic tropical fruits such as mangosteens. She also includes extensive information on how the mint oil content must be adjusted for particular fruit characteristics. Inventor B

includes a generic claim essentially the same as inventor A's.

Who wins priority as to the generic claim, A or B? The answer is inventor A, even though inventor B provides a much fuller disclosure. A's prior disclosure of the peach example is a constructive reduction to practice of a species that defeats B's priority to the genus. In patent law, an earlier species trumps a later genus. It is important that this is so without regard to whether the generic claim is patentable to A. See *In re Zletz*, 893 F.2d 319, 323 (Fed. Cir. 1989) ("Priority as to a genus may ... be shown by prior invention of a single species, ... but the genus will not be patentable to an applicant unless he has generic support therefor."). See generally CHISUM ON PATENTS § 10.04[1][e].

These priority principles should apply not only to interferences but also to determinations of patentability and validity. In the hypothetical, the court should hold that A's disclosure of a species (the 5% mint oil and peach example) satisfies WDI for the generic claim. Inventor A has shown that she has more than a "research plan" or a desired "useful result." She has crossed over from theory to application. She has indicated that she possesses a generic conception of her invention and has reduced it to practice constructively by an adequate description of an embodiment, to wit, the peach example.

Whether inventor A is actually entitled to a generic

claim of broad scope is *another* matter. The scope question turns on time-honored principles of enablement, articulated as early as 1853 in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), and enumerated as factors in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). See generally CHISUM ON PATENTS § 7.03.

The added detail in B's later-filed specification suggests that the particular art was unpredictable at the time of A's filing and that the disclosure of a single simple example on a common fruit (a peach) at one concentration (5%) might not suffice to support a generic claim to all "fruits" at whatever concentration is effective. For a discussion of fruit varieties and ripening characteristics, see Gollner, THE FRUIT HUNTERS (Schribner 2008).

Now alter the hypothetical and assume that inventor A included only a general discussion of the fruit and mint oil process with no working or prophetic example (peach or otherwise). Here, *Ariad* dictates that A's disclosure would be only a "research plan" and not sufficient to establish priority over inventor B. See *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). In a similar way, in an *ex parte* situation, A's genus claim is unpatentable for want of written description.

How would this priority principle interpretation of WDI apply to the two key cases, *Lilly* (1997) and *Ariad* (2010)? Considering the two cases solely on the basis of

the facts stated by the Federal Circuit, the result would likely have been the same in *Ariad*, where no embodiment of the generic method claims was adequately disclosed in the prior application, but different in *Lilly*, where an embodiment of a species (a sequence of DNA encoding for rat insulin) within the generic claim (DNA sequences encoding for insulin of a vertebrate or mammal) was adequately disclosed.

Some argue that a generic claim held unpatentable under the Federal Circuit's controversial interpretation of the WDI requirement would also be unpatentable under the E requirement. That may not have been so in either *Lilly* or *Ariad*. In *Lilly*, the accused infringer Lilly did not even challenge the patent claims for lack of enablement. Evidence that a person of ordinary skill could have easily isolated human or other mammal DNA coding for insulin in light of the disclosed rat DNA sequence and known homology between rat and human DNA could well have carried the day on enablement for the patent owner.

In *Ariad*, both WDI and E were at issue. The court suggests that the patent owners (Harvard, MIT and Whitehead Institute for Biomedical Research) came close to satisfying the WDI requirement and may have satisfied the E requirement. Based on the inventors' discovery of a factor (NF-κB) that regulates gene expression, the inventors disclosed and claimed methods for reducing NF-κB expression. They postulated three potential ways

of accomplishing that reduction, the first being use of a specific inhibitor, such as I-κB, a naturally occurring molecule. In their 1989 priority application, the inventors included only a "vague functional description" of I-κB. In 1991, the inventors filed a continuing application that added a figure disclosing DNA encoding the I-κB. The figure, unfortunately, was not accurate, which led to a charge of inequitable conduct. Moreover, the patent owners relied on the 1989 application for priority at trial and only argued for use of the more complete 1991 application on appeal. In other words, the patent owners might have met the WDI requirement by doing a little more in order to disclose an embodiment. That the enablement requirement would have been met was suggested by, inter alia, the fact that others actually used, soon after the 1989 filing, the second suggested way of accomplishing expression reduction, to wit, use of "dominantly interfering molecules."

Does *Ariad* actually reject the priority-principle approach to WDI? Some language in the opinion supports the view that disclosure of a sufficient embodiment or example would satisfy WDI. In one passage, the opinion describes one of the "a few broad principles that hold true across all cases" as follows:

> We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive

> reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006).

This passage properly links WDI compliance to the priority concept, constructive reduction to practice. It suggests that "examples" are not *necessary* but it leaves open the safe harbor that a specific example falling within a claim is a *sufficient* description for written description purposes.

On the other hand, different language in the *Ariad* opinion suggests that, at least in some instances, a single example will not suffice. Consider the following passage:

> Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. *Compare Eli Lilly*, 119 F.3d at 1567 (holding an amino acid sequence did not describe the DNA sequence encoding it), *with In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (discussing how it is now a "routine matter" to convert an amino acid sequence into all the DNA sequences that can encode it). *Thus, whatever inconsistencies may appear to some to exist in*

the application of the law, those inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts. (Emphasis added).

The first sentence's indication that the "number" of species can vary cuts against a rule that a single concrete example will suffice. But the "compare ... with" citation and the "Thus ...." sentence in the quoted passage suggest that the court is open to "arguments" that will allow it to avoid past inconsistencies.

In response to the court's invitation, I propose to reduce conceptual confusion in the law of written description by distinguishing carefully three questions.

The first question is: when does a specification that recites one or more species but does not explicitly define a genus nevertheless implicitly support a claim to the genus? This is a classic written description problem. It arises when an applicant adds claims to a genus after a priority filing date. Case law discussed in *Ariad* confirms that the applicant need not have set forth the genus in exact words (*in ipsis verbis*) but must provide some adequate indication of possession of the genus. An enabling disclosure, as such, does not suffice.

The second question is: can a specification that expressly describes a genus and adequately discloses one or more species fail to satisfy WDI because it does not show, in the court's judgment, sufficient "possession" of

the genus invention? Under the priority principle approach, the answer should be "no." The *Ariad* opinion does not clearly repudiate this approach. Indeed, the court invites arguments that will reduce "inconsistencies." Application of the priority principle will not undermine the court's two clear holdings: that there is a distinct written description and that it applies to original claims.

The third question is: are some apparent verbal descriptions of generic inventions not descriptions at all because they are excessively functional? In other words, is a description not a description when it defines a generic class in terms of a desired result and what species of the genus *do* instead of what they *are*? In 1997, *Eli Lilly* answered affirmatively. The answer disturbs many, and for good reason. Classes of methods and things are often described quite clearly in terms that are partially or even wholly functional. They are not for that reason imprecise or indefinite in scope. An ordinarily skilled person will know whether a given embodiment is within or without the class.

In *Ariad*, discussing *Lilly*, the court states:

> We held that a sufficient description of a genus instead 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. [119 F.3d] at 1568-69. We explained that an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials. [119 F.3d] at 1568 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). We have also held that functional claim language can meet the written description requirement when the art has established a correlation between structure and function. *See Enzo*, 323 F.3d at 964 (quoting 66 Fed. Reg. 1099 (Jan. 5, 2001)). *But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species*. (Emphasis added).

The court's explanation of when a description is not a description is conclusory and unsatisfactory. To show why this is so, let us return to the hypothetical fruit example. Is "fruit" an adequate description of a "variety of materials"? One would think so, but let us analyze the issue a bit more. "In botanical parlance, a fruit is the developed ovary of a flower, alongside any other structure that ripen with it and form a unit with it."

Gollner, *supra*, at 21. The "fruit" genus includes species such as cucumbers that are not sweet and are commonly referred to as vegetables, not fruits. See, e.g., *Nix v. Hedden*, 149 U.S. 304 (1893) (a tomato, which is botanically a fruit, is, for tariff purposes, *not* a fruit because, inter alia, people eat "fruits" but not tomatoes for dessert). In what sense does the word "fruit," botanically-defined, allow a person to "visualize or recognize" all fruit varieties? As Gollner and others demonstrate, there are tremendous variation in fruits; they are linked primarily by a function, ripening together with surrounding structure. Given a plant structure, a person might find it necessary to observe how it reacts in nature to determine whether it is a "fruit."

Perhaps the *Eli Lilly* notion that a clear written description of a genus is not a description of the genus should be cabined to a special circumstance and a special technology: "DNA encoding" for an identified protein And even "DNA encoding" might no longer be deemed special given developments in biotechnology since 1997. Cf. *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009) (rejecting a pharmaceutical structural-focused approach to determining nonobviousness of DNA claims).

A final question: how would the Federal Circuit's rulings in *Ariad* fare in the Supreme Court? It seems unlikely that the Supreme Court would approve of any primarily policy-driven approach to the question whether

a description shows that an "the inventor actually invented the invention claimed." Quite relevant is the Supreme Court's decision, *Pfaff v. Wells Electronic*, 525 U.S. 55 (1998). The issue in *Pfaff* was completion of an "invention" for purposes of triggering the Section 102(b) "on sale" bar. The Supreme Court affirmed that completion of an invention was linked to the general patent law concepts of reduction to practice and conception. The Court criticized the Federal Circuit's nontextual "special interpretation of the word `invention' as used in § 102(b)"and its "totality of the circumstances" approach as contrary to the need for a definite and certain standard. The same criticism can be, and has been, leveled at the *Eli-Lilly-Ariad* doctrine on written description of "the invention," with its multi-factored approach, disclaimer of "bright-line rules" and admitted "inconsistencies" in application.

A final historical note. Prior to the enactment in the 1952 Act of Section 103 as defining the nonobviousness standard, courts used the vague concept "invention" to assess patentability. The "invention" concept was criticized as conferring too much discretion on courts. See Rich, *Laying the Ghost of the Invention Requirement*, 1 APLA Q.J. 26-45 (1972). Such an elastic standard allowed courts to cycle through alternating periods of positivity and negativity toward the patent system. See CHISUM ON PATENTS § 5.02. In 1952, Congress opted to

replace the judicially created "invention" standard in favor of the more objective Section 103 standard. Ironically, by overlooking the invention priority principle, the *Eli Lilly* and *Ariad* decisions resurrect an amorphous and subjective standard of "invention" to determine written description compliance comparable to that previously governing patentability over the prior art.

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In the interest of full disclosure, it should be noted that the author was co-counsel for the University of California in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and therefore on the losing side of the written description issue in that case. The author presented (he thought) the priority-principle approach to the court in the appellant's brief, urging that written description concerned only timing and priority and that claim scope questions were governed by the distinct enablement requirement.