Appeal No. 2008-1130
FOR HEARING *EN BANC*

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ARIAD PHARMACEUTICALS, INC. ET AL.,
Plaintiffs-Appellees

v.

ELI LILLY & CO.,
Defendant-Appellant

APPEAL FROM THE UNITED STATE DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS, 02-CV-11280 (JUDGE RYA W. ZOBEL)

BRIEF OF *AMICUS CURIAE* PUBLIC PATENT FOUNDATION IN SUPPORT OF DEFENDANT-APPELLANT ELI LILLY & CO.

Joshua D. Sarnoff
Glushko-Samuelson Intellectual
Property Law Clinic
Washington College of Law
American University
4801 Massachusetts Avenue, N.W.
Washington, D.C. 20016
(202) 274-4165
jsarnoff@wcl.american.edu
Counsel of Record for Amicus Curiae
Public Patent Foundation

November 19, 2009

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Public Patent Foundation certifies the following:

1. The full name of every party or *amicus curiae* represented by me is Public Patent Foundation.

2. The name of the real parties in interest (if the party named in the caption is not the real party in interest) represented by me is Public Patent Foundation.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are: None.

4. There is no such corporation as listed in paragraph 3. Yes.

5. The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this court are:

Joshua D. Sarnoff
Glushko-Samuelson Intellectual Property Law Clinic
Washington College of Law
American University
4801 Massachusetts Avenue, N.W., Room 446A
Washington, D.C. 20016
(202) 274-4165 (phone)
(202) 274-0659 (facsimile)
jsarnoff@wcl.american.edu

Signed: /Joshua D. Sarnoff/ Date: November 19, 2009

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes and Government Documents

Foreign Authorities

Other Authorities

INTEREST OF AMICUS CURIAE[1]

The Public Patent Foundation ("PUBPAT") at Benjamin N. Cardozo School of Law is a not-for-profit legal service organization that represents the public interest in the patent system. In this case, the public interest lies in preserving the current written description requirement, which prevents claims for research plans that–if allowed–would create notice and fairness problems and breed litigation and increase legal transaction costs, impede research and impose excessive costs on the public, and unjustly enrich applicants. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education. PUBPAT has argued for sound patent policy before this Court, the Supreme Court, the United States Congress, the United States Patent and Trademark Office, the United Nations, and the European Union Parliament, among other judicial, governmental and political bodies.

PUBPAT has an interest in this matter because the decision of the Court will have a significant effect on the public interest that PUBPAT represents.

[1] This brief is filed pursuant to this Court's Order of August 21, 2009 and consent has been obtained from the parties. No part of this brief was authored by counsel for any party and no party, person, or organization contributed to this brief besides *amici* and their counsel. Marcela Shirsat and Brian Rockwell, students in the Glushko-Samuelson Intellectual Property Law Clinic, and Nikhil Palekar, Research and Writing Fellow, assisted in researching, drafting, and filing this brief.

RESPONSE TO EN BANC QUESTIONS PRESENTED

The Court has asked (a) whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement; and (b) if a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement. The answers are: (a) yes, a separate written description requirement has existed since at least 1822; and (b) it is the conceptual predicate of any patent system based on an objective disclosure of an invention, and it exists both to protect researchers and the public from numerous harms that would result from broad and uncertain claims to research plans, and to prevent the unjust enrichment of applicants who pretend in their claims to have invented more than they themselves conceived or than they objectively and recognizably disclosed in their specification. To meet the written description requirement, applicants must disclose either a sufficient structure-function correlation for a species or genus or a representative number of species of a genus.

SUMMARY OF THE ARGUMENT

The written description requirement is the conceptual predicate of a patent system based on disclosure of an invention. Since at least 1822, the written description requirement has assured adequate notice of the invention, protecting the public from unintentional infringement. It has also prevented applicants from unjustly enriching themselves, by pretending that their inventions are broader than what they subjectively conceived (despite expansive claiming language) or than they disclosed in their specifications as the objectively recognizable inventive contributions to the art. In the 1952 Act, Congress re-codified in different paragraphs of Section 112 three related aspects of the written description requirement: (1) a requirement to disclose an objectively recognizable invention that is as broad as the construed claim language; (2) a prohibition against an applicant claiming more than he or she subjectively regarded as the invention; and (3) a restriction on the scope of functional claim language, limiting construction to the objectively disclosed structures corresponding to the claimed function. Both before and after 1870, when Congress required precise peripheral claiming, the written description requirement has prohibited patenting of broad claims to research plans that are not yet inventions. To meet the written description requirement, applicants must identify and disclose either a sufficient correlation

between the structure and function of a claimed species or genus or a representative number of species of a claimed genus.

Abandoning the requirement for an objectively recognizable disclosure of the claimed invention would encourage broad claims to research plans and would thereby create notice and fairness problems, breed litigation, and increase legal transaction costs. Because of uncertainty regarding what would fall within the scope of the claims, researchers and the public would be unable to recognize in advance whether their activities will result in infringement, subjecting researchers and the public to unfair ex-post liability when they later learn that their activities constituted infringement. This superfluous layer of patent protection would create a need for costly legal evaluations and licenses to avoid such liability. The liabilities and legal transaction costs would deter investments in research and would increase the overall costs of identifying, producing, and using inventions. Commercial researchers would be deterred by the reduced revenues resulting from having to enrich applicants by paying them to follow the research plan. Researchers also would be deterred by having to share profits with applicants for products or processes developed within the scope of the claims (through blocking patent licenses) or beyond that scope (through reach-through royalties). Even if some researchers were not deterred, the public would pay excessive costs and

would suffer serious delays. Thus, the public would be forced to pay a terrible price to applicants who would reap the consequent windfall.

Neither the enablement doctrine nor the utility doctrine is sufficient to protect the public against these harms, particularly under the current permissive standards for those doctrines. Applicants seeking broad genus claims to research plans may sometimes enable the research to be performed and may identify a useful function or result that the research will achieve. However, they will not themselves have made the inventive contributions required to justify the broad claims sought and the correspondingly large benefits provided.

ARGUMENT

I. The Written Description Requirement Prohibits Claims For Research Plans That Are Broader Than The Disclosed Inventions.

A. The Plain Language of Section 112 Shows That The Written Description Requirement Is Separate From Enablement, And It Is The Conceptual Predicate To All Patentability Evaluations.

A requirement for a written description separate from enablement exists in the Patent Act. Section 112, paragraph 1 provides that:

> [t]he specification shall contain **a written description of the invention, and** of the manner and process 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.

35 U.S.C. § 112. para. 1 (emphasis added). As is evident from the linguistic structure of paragraph 1, the requirement for a description of the invention is separate from the requirement for a disclosure that enables "the same" to be made and used. *See* Lilly Br. at 25-31. Moreover, a separate description is required as the conceptual predicate for determining whether "the invention" is enabled, as the specification might enable a wide range of potential inventions that could be described. Virtually all patentability doctrines—including claim interpretation doctrines—refer to "invents" or "the invention." *See, e.g.,* 35 U.S.C. §§ 101, 102, 103, 112. Thus, a description of the invention is always necessary in any patent system based on an objective disclosure of an invention, and is a prerequisite for any other patentability evaluation regarding the invention, including whether the scope of an original or amended claim corresponds to what the applicant actually invented and disclosed. *See* Lilly Br. at 31-35.

B. The Written Description Requirement Assures Adequate Notice Of The Invention, Protecting The Public And Preventing Unjust Enrichment.

Both the existence and purpose of a requirement for a written description of the invention, separate from enablement, were articulated very early by the Supreme Court in *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822).

> The specification, then, has **two objects**: one is make known the manner of constructing the machine (if the invention is of a machine)

> so as to enable artisans to make and use **it**, and thus to give the public the full benefit of the discovery after the expiration of the patent. **The other object** of the specification is, **to put the public in possession of what the party claims as his own invention,** so as to ascertain if he claim anything that is in common use, or is already known, and **to guard against prejudice or injury from** the use of an invention which the party may otherwise **innocently suppose not to be patented.**

Id. at 433-34 (emphasis added). As the Supreme Court recognized, the written description requirement ensures that the public receives adequate notice of the invention. When the public can recognize the full scope of the claimed invention from reading the specification, its members can avoid unintentional infringement.

Significantly, the Court emphasized that the written description requirement prohibits an inventor from "**pretending that his invention is more than what it really is.**" *Id.* at 434 (emphasis added). The invention that is objectively recognizable from the written disclosure thus is not necessarily co-extensive with the scope of the written claims for which exclusive rights are sought.[2] Allowing the applicant to obtain a claim that is broader than the recognizable invention would provide exclusive rights to a research plan and would unjustly enrich the

[2] This is particularly true given that claim language is not necessarily construed to be limited to corresponding embodiments disclosed in the specification. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

applicant, as the public would not be in possession of an invention as broad as claimed.

Although all inventions originate as subjective conceptions of the mind, it is the **objective** disclosure of the **recognizable** invention in the specification that governs whether the applicant has met the "quid pro quo" for the breadth of the exclusive rights claimed. *Bonito Boats, Inc. v. Thunder-Craft Boats*, 489 U.S. 141, 161 (1989). It is this disclosure—the written description—that measures whether the claim is broader than the invention, given that it is only when an invention is objectively disclosed in a specification that our patent system—drawn from our English history—grants rights to inventors. *See Liardet v. Johnson,* 62 Eng. Rep. 1000 (K.B. 1780). *See generally* Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents* (pt. 3), 77 J. PAT. & TRADEMARK OFF. SOC'Y 771, 793-97 (1995). *Cf. Genentech*, [1989] R.P.C. 147, 236–37 ("[I]t is undesirable to allow claims the subject of which is to cover a wide and unexplored field or where there is no disclosure in the specification which is in any way coterminus with the monopoly indicated in the claims.").

Although applicants have been required to identify the scope of their claim of exclusive rights with increasing precision since *Evans,* claim language may be intelligible without necessarily disclosing a patentable invention of commensurate scope. Claim language may disclose a research plan, or a wish, for an invention,

claiming by function or result what has not yet been adequately identified by structure to correspond to the function. *See* Lilly Br. at 17-23 (citing cases). For example, using chemical nomenclature, an applicant (or computer) could claim and disclose an almost infinite variety of compounds (by species or by genus). No one could credibly argue that such an applicant had invented all of the claimed compounds that the nomenclature permits disclosing, without having first identified which of the compounds exhibit some reasonable correlation to some identified function. Whether the specification also enables the making and using (in some way) of the full scope of the claimed compounds, given the state of the art, is simply beside the point. *See id.* at 11-17, 36 (citing cases).

C. The Written Description Requirement Performs Three Functions That Congress In 1952 Separated Into Three Paragraphs Of Section 112.

The objectively recognizable disclosure protects the public against uncertainties that a broad claim to a research plan would impose. But the Patent Act **also** requires that the claim reflect what the applicant **subjectively** "regards as the invention." 35 U.S.C. § 112, para. 2.[3] This additional requirement directly enforces *Evans'*s prohibition against applicants pretending that their claims are

[3] In recent years, this Court has limited the ability to use testimonial evidence after issuance of a patent to prove such a variance of the claim from the inventor's subjective understanding of the scope of the invention. *See Solomon v. Kimberly-Clark*, 216 F.3d 1372, 1377-79 (Fed. Cir. 2000).

more than what they recognized, by using broad functional language directed to an as-yet unmade invention. This requirement also applies without regard to whether the applicant actually enabled whatever invention it had conceived or claimed.

Because applicants may use broad functional language to claim more than they disclose or invent, the Patent Act **also** directly limits the construed scope of functional language. 35 U.S.C. § 112, para. 6. (When enacted in 1952, this provision was paragraph 3 of Section 112.[4]) Such claims otherwise could easily be construed to extend beyond the actual disclosed invention, particularly when functional language is employed at the point of novelty.[5] The Act limits functional language in claims to the recognizable, objectively disclosed "corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, para. 6. By requiring correspondence (*i.e.*, an identified and disclosed correlation) between a claimed function and a disclosed structure, Congress ensured that claims using functional language would not merely be research plans that identified a desired function without recognizably disclosing the structures (or the steps of the process) that would accomplish the function.

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[4] Act of July 19, 1952, ch. 950, Pub. L. No. 82-593, 66 Stat. 799.

[5] *See, e.g., Halliburton Oil Well Cementing Co. v. Walker,* 329 U.S. 1, 8-9 (1946). The Court expressly noted the lack of an adequate written description for the invention as claimed by its function. *See id.* at 13. Section 112, paragraph 3 was explicitly enacted to revise *Halliburton's* absolute prohibition on functional claiming at the point of novelty. S. Rep. No. 82-1979, at 19 (1952); H.R. Rep. No. 82-1923, at 6 (1952).

In 1952, Congress placed the separate restrictions in the three paragraphs of Section 112 to emphasize what was implicit in the unitary structure of its predecessor provision.[6] Each paragraph imposes a different requirement that restricts the claims from being mere research plans, requiring a disclosed correlation between or correspondence of structure and function. The restrictions are: (1) to the objectively disclosed invention; (2) to what the applicant subjectively regarded as the invention; and (3) to the disclosed structures corresponding to the functionally claimed part of the invention. And for good measure, Congress directly prohibited patents–under the "Conditions for patentability"–when the applicant "did not himself invent the subject matter sought to be patented," which applies both to derivation and to overbroad claims to research plans. 35 U.S.C. § 102(f).

D. The Supreme Court Has Recognized The Statutory Prohibition On Claiming Research Plans, Both Before And After Strict Peripheral Claiming Was Codified.

In *O'Reilly v. Morse,* 56 U.S. (15 How.) 62, 113 (1853), the Supreme Court prohibited applicants from claiming more than they invented and thus more than they were capable of disclosing in the specification. *See* Lilly Br. at 7-8.

[6] Congress also loosened the restrictive rule on functional claiming that the Supreme Court had adopted in *Halliburton Oil Well Cementing Co.* under the unitary provision.

Significantly, in Claim 8 Morse sought to patent a claimed function or a result, rather than an invention that could accomplish that function or result. Similarly, in *Corning v. Burden,* 56 U.S. (15 How.) 252 (1853), the Court held that a claim to a function or result, rather than to an invention, is invalid. "His patent having a title which claims a machine and his specification describing a machine, to construe his claim as for the function, effect, or result of his machine, would certainly endanger, if not destroy, its validity." *Id.* at 269. Numerous subsequent cases have held that broad, research-plan claims to a function or a result are invalid, even if the applicant has disclosed one way of accomplishing the function.[7]

In particular, the Supreme Court in *Holland Furniture Co. v. Perkins Glue Co*., 277 U.S. 245 (1928), echoed *Evans* concerns with inadequate public notice, consequent social harm, and unjust enrichment that result from broad claims to research plans that lack an identified and disclosed structure-function relationship. *See* Lilly Br. at 9-10 (quoting *Holland Furniture*'s restatement of *Corning*'s prohibition on claiming a function or result). The Court's language regarding the harms to research and competition (with the obvious consequent harms to the public) bears repeating:

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[7] *See, e.g., Waxham v. Smith*, 294 U.S. 20, 21 (1934); *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 384-85 (1908); *Westinghouse v. Boyden Power Brake Co*., 170 U.S. 537, 554 (1897); *Risdon Locomotive Works v. Medart*, 158 U.S. 68, 79 (1894). *See also* Lilly Br. at 17-23, 33-37.

> A claim so broad, if allowed, would operate to enable the inventor, who has discovered that a defined type of starch answers the required purpose, to exclude others from all other types of starch, and so foreclose efforts to discover other and better types. The patent monopoly would thus be extended beyond the discovery, and would discourage rather than promote invention.

Holland Furniture, 277 U.S. at 257. This is true even if the applicant alone enabled and motivated others to perform the research.

Holland Furniture was decided long after the 1870 Act required strict peripheral claiming.[8] Thus, the Plaintiffs-Appellees' argument that the requirement for distinct claims—also placed in paragraph 2 of Section 112 by the 1952 Act, 35 U.S.C. § 112, para. 2—is the *sole* requirement that addresses notice concerns in the statute is meritless. *See* Ariad Br. at 14-15. Peripheral claims may clearly define their boundaries without identifying what lies within them; central claims may identify the core concept without identifying how far the concept extends. If the distinct claiming requirement were the sole standard for notice, there would be no need either for the "and" in paragraph 1 or for paragraph 3 of Section 112.

The fact that claims can be construed intelligibly[9] and applied in infringement actions after research or other activity has been performed only

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[8] *See, e.g., Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996).

[9] Under this Court's current test for indefiniteness, the claims must merely avoid being "insolubly ambiguous" without a proper narrowing construction. *See, e.g., Exxon Res. & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

emphasizes the notice concerns. Researchers and the public cannot know in advance what things or activities ultimately will fall within the boundaries of a claimed research plan.

E. A Sufficient Written Description Of A Patentable Species Or Genus Requires An Identified Correlation Between Structure And Function.

The actual test of an adequate written description has never been able to be reduced to a formula, because sufficiency of the description in each case depends on what the invention is and on whether the language used to describe it corresponds in scope to the language separately used to claim it. As this Court stated in *Enzo Biochem, Inc. v. Gen-Probe, Inc*., 323 F.3d 956 (Fed. Cir. 2002), the written description requirement can be met when the disclosure provides a "complete or partial structure, other physical and/or chemical properties, functional characteristics **when coupled with a known or disclosed correlation between function and structure,** or some combination of such characteristics." *Id.* at 964 (emphasis added). The disclosed structure-function correlation is sufficient when it permits the person of ordinary skill in the art to recognize what structures are contemplated **and** that the structures have the functions claimed. Merely reciting claims for unspecified things that perform the function "usually does not suffice." *Id.* at 968. *See, e.g., Biogen v. Medeva*, [1997] R.P.C. 1, 49, 51-52 (a patent fails to provide a sufficient description under Article 83 of the European Patent

Convention if it claims "every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention") (citing *O'Reilly v. Morse,* 56 U.S. 62 (1853) and *British United Shoe Mach. Co. Ltd. v. Simon Collier Ltd*., [1908] R.P.C. 21).

Nothing in the statute or case law, however, clearly defines when the applicant's understanding of the structure-function correlation is sufficiently developed and adequately identified and disclosed. By requiring a written description the statute places the burden of identifying and disclosing a sufficient structure-function correlation on the applicant. That burden is necessarily heavier in unpredictable fields of technology such as chemistry and biotechnology, as it is more difficult for the person of ordinary skill in such fields to recognize what structures will exhibit the claimed function. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("The disclosure must allow one in the art to visualize or recognize the identity of the subject matter purportedly described."). *See also Capon v. Eshhar,* 418 F.3d 1349, 1358 (Fed. Cir. 2005); *In re Storrs,* 245 F.2d 474, 478 (C.C.P.A. 1957). Functional descriptions for claimed structures or processes for using them are sufficient "only if there is also a structure-function relationship known to those of ordinary skill" that permits such recognition. *See, e.g., In re Wallach*, 378 F.3d 1330, 1335 (Fed. Cir. 2004).

Although the precise quantum of disclosure of the requisite correlation is uncertain, what is abundantly clear is that one cannot claim a species or genus by function without *any* disclosed relationship of the function to the structure. For example, in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 918 (Fed. Cir. 2004), *reh'g denied*, 375 F.3d 1303 (Fed. Cir. 2004), Rochester claimed a method of achieving a result by administering unspecified compounds that could perform a specific function. *See id.* at 918, 927. Rochester thus had claimed only a research plan for unspecified, wished-for compounds and had not identified any correlation of the structure of particular compounds to that function. Whether or not making, identifying, and using such compounds was enabled, there was no actual invention recognizably disclosed in Rochester's application. Nor did drafting the claim as a method of administering compounds having the function (rather than as the unspecified, functionally claimed compounds themselves) save the claim.

F. Disclosure Of A Representative Number Of Species May Provide An Adequate Written Description For A Genus Claim.

In order to properly claim a genus invention, an applicant must either sufficiently describe the structure-function correlation that identifies the functional species within the genus or provide a representative number of species of the genus that perform the identified function. *See, e.g., Eli Lilly & Co.*, 119 F.3d at 1569;

Capon, 418 F.3d at 1358-59 (Fed. Cir. 2005) (citing cases). *See also* MYCOGEN/ Modifying plant cells, T 694/92, [1998] E.P.O.R. 114, 120 ("[M]ore technical details and more than one example may be necessary in order to support claims of a broad scope…when doubt exists that the…effect can be readily obtained over the whole range of applications claimed."). This second method of providing a disclosure that is recognizably commensurate with the scope of the claims is particularly important for process claims that do not require the use of particular structures in performing the steps of the process. It is possible to satisfy the requirements of a broad process invention without fully understanding how it works. But the applicant must still provide researchers and the public with sufficient notice of the variety of ways of performing the process to accomplish the function, thereby both providing notice of the breadth of the claim and justifying the grant of such broad exclusive rights.

Unless the process is clearly specified through such examples, it may merely reflect a broad research plan using functional claim language and will thereby cover innumerable structures that may or may not work. Without either disclosing a sufficient structure-function correlation or a sufficiently representative number of species of a genus, the public cannot objectively recognize what is claimed except as a research plan to be followed. *See, e.g.*, *Wallach*, 378 F.3d at 1335. Such an extra layer of patent protection may sometimes motivate, but will invariably

precede, the actual identification and invention of the developed species and thus the entitlement to claim the genus.

In contrast, pioneering process patents that disclose sufficiently representative species may dominate sequential species inventions directed to or that employ non-obvious, previously undisclosed structures. Thus, the broad method claims in *Dolbear v. Am. Bell Tel. Co.,* 126 U.S. 1 (1888) were permissible, because the aplicant had also described specific devices for "transmitting vocal or other sounds telegraphically" and had described the process with sufficient "clearness and precision" to demonstrate objectively that he had invented its full (and operative) scope. *Id.* at 531, 536-37; Lilly Br. at 16-17. *See also Morley Sewing Mach. Co. v. Lancaster,* 129 U.S. 263, 273 (1889).

In contrast, the claims at issue in the present case involve the use of specific, functionally identified compounds, and **no** such compounds were identified and disclosed by the applicant or were known in the art to actually perform those functions. *See Ariad Pharms. Inc. v. Eli Lilly & Co.,* 560 F.3d 1366, 1371 (Fed. Cir. 2009). This case thus presents no opportunity to explore the important question of when a sufficiently representative number of species are disclosed to claim a broad genus for a method, when the structure-function correlation is not identified and disclosed. Nevertheless, it is clear that the less a structure-function

correlation is and the fewer the species that are disclosed, the less a specification will provide notice of what falls within the scope of a broad genus claim.

This case does provide the opportunity to make clear that claims lacking **any** disclosed structure-function correlation and **any** representative examples are not valid. The Court will thereby deter the filing, prosecution, and litigation of similar claims in the future. Until such claims are clearly held invalid, they will require researchers and the public to pay tribute to the applicant when performing the research plan, deterring or adding to the costs of socially beneficial activities.

II. Abandoning The Written Description Requirement Would Impose Serious, Avoidable Harms And Unjustly Enrich Applicants.

A. Claims To Research Plans Would Create Uncertainty And Provide Inadequate Notice, Imposing Unfair Liability And Breeding Litigation And Other Transaction Costs.

Unlike indefinite claims that provide inadequate notice of claim boundaries, broad claims to research plans provide inadequate notice of the inventive contents that fall **within** the identified boundaries. Broad genus claims with disclosures that identify neither a sufficient structure-function correlation nor a sufficiently representative number of species do not tell subsequent researchers or the public what the invention actually is. Instead, they disclose only how to make and use things or perform processes that *may subsequently* be determined to fall within claims boundaries, after those things or processes are developed through research.

Other researchers thus are highly likely to unintentionally infringe the claims. For example, in *University of Rochester*, Pfizer and Searle had no way to know in advance that the medicines they were developing would infringe Rochester's future broad claims to a research plan, particularly as they initiated their research before the patent was issued. *See* 358 F.3d at 918.

As recognized by *Evans*, the lack of notice may unfairly impose liability and breed litigation and transaction costs for researchers and the public. In many cases, subsequent researchers will run a risk, the extent of which cannot be assessed from the patent itself, that their activities will fall within the boundaries of broad research claims. To avoid such liability, researchers and the public who are aware of the patents either will have to incur substantial legal transaction costs for patent-scope evaluations before and after identifying the structures found to perform the functions or will have to negotiate and pay the costs of licenses that will avoid such liability or avoid having to make such legal determinations.

Those who risk going forward will face unfair ex-post liability and litigation costs. This is true both when they are unaware of the application or granted patent–which frequently occurs with important research for which research-plan claims are sought–and when they are aware of the application or patent and continue the research because of its importance, to identify what the plan covers, or to design improvements based on it. The uncertainty of claim scope also would

encourage applicants to improperly threaten liability and litigation, expanding the scope of the unjustified rights to exclude even further.

As recognized by the Supreme Court in *Markman v. Westview Instruments, Inc.*, uncertain claim boundaries (like the uncertain claim contents at issue here) "'would discourage invention only a little less than unequivocal foreclosure of the field.'" 517 U.S. at 390 (quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942)). *See United Carbon Co.*, 317 U.S. at 228 ("The inventor must 'inform the public...of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.'") (quoting *General Elec. Co. v. Wabash Corp.*, 304 U.S. 364, 369 (1938)). The costs of such uncertainty include either additional liability or the opportunity costs of foregone innovation and public domain activity. Without a written description requirement, moreover, there may be no effective misuse or antitrust limits to such extensions of exclusive rights beyond the disclosed invention,[10] as liability costs might appear warranted and the opportunity costs might be invisible because of the broad but unjustified claim scope.

Consider, for example, the claim for "all 'non-naturally occurring'" erythropoietin ("EPO"), which followed the applicant's invention of a particular production method for isolated human EPO in hamster cells. *See Amgen Inc. v.*

[10] *See, e.g., Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997); *Mallinckrodt, Inc. v. Medipart, Inc*., 976 F.2d 700, 708 (Fed. Cir. 1992).

Hoechst Marion Roussel, 314 F.3d 1313 (Fed. Cir. 2003); James Bessen & Michael J. Meurer, *Patent Failure* 66 (Princeton Univ. Press 2008). Researchers who did not rely on the patent's teaching found a different way to make non-naturally occurring EPO by tricking human cells into producing it directly. *See* Bressen & Meurer, *supra*, at 66. Amgen succeeded because its claim was read broadly to include the entire genus of species that they had not identified or invented, and thus should have been in the public domain to identify even if that identification was itself a patentable invention. The species were neither recognizably contemplated by the applicant nor objectively disclosed by the applicant, without regard to whether the claimed genus was enabled by or despite the disclosure and without motivating the research (given that a "race for the prize" was involved). *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 579 F. Supp. 2d 199, 201 (D. Mass. 2008). Hoechst and Transkaryotic Therapies, Inc. have had to pay huge costs (that will be transferred to the public) for litigation that has been ongoing since 1997. *See id.* at 210. Further, after Amgen's patent was found to be infringed, the product was enjoined and will likely remain so until the expiration of two of Amgen's patents, thereby reducing competition. *See id*. Other researchers will face similar difficulties from, and the public will pay the price for, such broad research-plan claims. *See generally* Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents,* 11 B.U. J. Sci. & Tech. L. 1, 13-14 (2005).

B. Claims To Research Plans Would Discourage Sequential Invention And Impose Excessive Blocking-Patent And Reach-Through-Royalty Costs On The Public.

The additional legal transaction costs created by research-plan claims create disincentives to engaging in sequential invention and impose unfair costs on sequential researchers and the public. Consequently, researchers may be deterred from developing inventions within the claims (dominated by the upstream patent) or outside of the claims (for which research royalties must be paid). Worse yet, the patent holder simply may refuse to license or to perform the research itself, and the public will pay the costs of foregone innovation. *See, e.g.*, Andrew Pollack, *Bristol-Myers and Athersys Make Deal on Gene Patents*, N.Y. Times, Jan. 8, 2001 at C2 ("[T]here are more than 50 proteins possibly involved in cancer that the company was not working on because the patent holders either would not allow it or were demanding unreasonable royalties.").

Consider, for example, the claims at issue in *Enzo*, which dealt with a dispute over three DNA sequences identified to have the useful function of hybridizing to gonorrhea bacteria. 323 F.3d at 960-61. The sequences (as recombinant DNA molecules within a bacterial host) were then deposited, and the applicant filed various claims to a genus of nucleotide sequences selectively hybridizing in various ratios (with two claims more closely limited to the specific deposited sequences but encompassing "'astronomical' numbers of mutated

variations"). *Id.* at 961-62, 966. The District Court rejected all of the claims for lack of written description because they disclosed the claimed sequences only by their activity or function. *Id.* at 962. On appeal, this Court held that the description of the availability of the specific sequences in a public depository and the ability of skilled artisans to obtain the claimed sequences and to test their function may have avoided an inadequate description. *Id.* at 966. The Court also remanded to determine if the broader claims were adequately described, based on the three deposited sequences constituting representative species. *Id.* at 967. But before performing the research to identify the species and test them against the deposits, the public could not know what the claims covered.

The claims at issue in *Enzo* dramatically illustrate both the manner in which research would be deterred and the consequent opportunity costs – or the additional costs that would be imposed for those not so deterred – absent the written description requirement. The "astronomical" numbers of species of nucleotide sequences that might be identified were not actually recognizable from the description of having made a deposit. In short, the applicant pretended in its claim to have invented all the species, simply by identifying three species having the function and describing a way to isolate others, claiming broadly and thereby shifting the costs of its research plan to others.

Given the potential for infringement liability and legal transaction costs, few researchers would choose to perform the research to identify what the claim covers. Merely performing the research would trigger liability, as it was necessary to obtain and use the deposited sequences to test hybridization and function of any newly identified species. If the newly identified species turned out to fall within the claims, the researchers would also be liable both for making and for using (and possibly also for selling or importing) the patented invention. *See* 35 U.S.C. § 271(a).

As if the threat of liability were not enough, commercial researchers also would be deterred by the reduced revenues that would result from having to enrich applicants and to share profits by performing the applicant's research for them. The costs to such researchers (and thus the increase in market prices for their products or processes) would include licensing costs for making or using patented sequences (or for avoiding having to assess liability for the newly identified species). Such added costs and reduced revenues would apply to the researchers' own patentable inventions, which would create blocking patents,[11] and to products

[11] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 860-68 (1990); Robert P. Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 Tenn. L. Rev. 75, 82-92 (1994). *See also* John H. Barton, *Antitrust Treatment of Oligopolies with Mutual Blocking Patent Portfolios*, 69 Antitrust L.J. 851, 851-53, 860-61 (2002) (discussing barriers to entry and effects on incentives for research of blocking patents).

or processes that do not infringe the claim, but for which applicants may demand reach-through royalties.[12]

The public would also suffer serious delays and opportunity costs through the time incurred for licensing, or from other delays that may result while performing the research. Significantly, applicants are best situated to follow their own disclosed research plans to make the actual inventions at earlier times, and in many cases having identified the research plan they may be able to follow it more effectively and at lower costs than sequential and actual inventors. In the case of *Enzo*, having identified some sequences, the applicant could have continued its research to demonstrate that it possessed (and could describe) the entire genus claimed. The public would have received the disclosure of the invention without having to pay again for the same research, which effectively gave the applicant a windfall by the grant of exclusive rights for what it had not itself invented.

Finally, some researchers will not be deterred from performing the research, either because they do not know of the patent or because the potential benefits may still justify any liability costs. But whether they are or are not so deterred, the public will pay excessive costs for the additional, unnecessary layer of patent protection.

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[12] *Compare Engel Indus., Inc. v. The Lockformer Co.*, 96 F.3d 1398, 1407-09 (Fed. Cir. 1996) (voluntarily negotiated reach-through royalty was not patent misuse); *with Bayer AG v. Housey Pharm. Inc.*, 228 F. Supp. 2d 467, 470-71 (D. Del. 2002) (license not "conditioned" on covering unpatented product was not patent misuse).

C. The Threat Of Harm To Research And To The Public Is Real And Would Be Greater Were The Written Description Requirement Eliminated.

These sequential-invention and public-cost concerns are real and serious. A recent survey, conducted by the American Association for the Advancement of Science ("AAAS") in 2006, found that since 2001 forty percent (40%) of responding members had difficulties in obtaining patented technologies; most were in the biosciences. *See* Stephen Hansen, et al., *The Effects of Patenting in the AAAS Scientific Community* 21 (AAAS 2006). Seventy-two (72) respondents out of the forty percent (40%) stated that difficulties acquiring the technology had significantly affected their research. *See id.* Fifty-eight percent (58%) had delayed their work; fifty percent (50%) had to change their research; and twenty-eight percent (28%) abandoned their research. *See id.* at 22. The reasons noted for changing or abandoning research were the overly complex licensing negotiations, high royalties, and the fact that some patents were not being licensed. *See id*. *See also* Jon F. Merz et al., *Diagnostic testing fails the test*, 415 Nature 577–79 (2002) (describing additional costs to the public, foregone research and testing, and wasteful expenditure of resources to develop alternatives tests for haemochromatosis because of gene sequence patents); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 Journal of Molecular Diagnostics 3-8 (2003) (discussing increased

costs of and consequent reduced access to medical care). Eliminating the written description requirement would dramatically exacerbate these problems, because claims for research plans without sufficient disclosures currently are prohibited and thus are only infrequently asserted and litigated.

III. The Enablement And Utility Doctrines Are Not Sufficient Protection Against Improper Claims To Research Plans.

Neither the enablement doctrine nor the utility doctrine adequately prohibits overly broad genus claims. Many inventions can be enabled by a specification that still may not satisfy the written description requirement. *See* Lilly Br. at 35-37. The enablement standard, moreover, has gradually evolved from the restrictive "independent experiments" standard,[13] through a more permissive "unreasonable experimentation" standard,[14] to the current "undue experimentation" standard articulated by this Court.[15] Under the "undue experimentation" standard, a patent disclosing a research plan could easily be found valid on enablement grounds, without providing any description of a correlation between disclosed structure and claimed function. But even if the law were restored to the more restrictive "independent experiment" standard, the patent would still cover the results of the future work that is enabled but has not been performed to identify the species.

[13] *Consol. Elec. Light Co. v. McKeesport Light Co*., 159 U.S. 465, 474 (1895).
[14] *Mineral Separation, Ltd. v. Hyde*, 242 U.S. 270-71 (1916).
[15] *In re Wands*, 858 F.2d 731, 736-41 (Fed. Cir. 1988).

Similarly, the utility doctrine cannot prevent broad genus claims for research plans. So long as a patentee can identify just a single, identifiable "specific and substantial" utility for a single species, the patentee will receive exclusive dominion over all future and potentially more valuable but currently unknown and undisclosed uses of the species invention. *In re Fisher,* 421 F.3d 1365, 1371 (Fed. Cir. 2005).[16] A disclosure of such an identified utility may motivate the further research needed to identify other species of the genus, as well as other uses, but does not thereby perform that research and may actually prevent or delay it. As the Supreme Court recognized in *Brenner v. Manson,* 383 U.S. 518 (1966), "to the extent that the patentee has power to enforce his patent, there is little incentive for others to undertake a search for uses." The same is true for additional species. *Id.* at 534-35.

[16] *See* 35 U.S.C. § 271(a); 2 R. Carl Moy, *Moy's Walker on Patents* § 6:18 & n.20 (4th ed. on-line Nov. 2008) (discussing the problem of disclosing "'relatively trivial'" uses to obtain claims that cover the many more substantial uses "that remain to be investigated") (quoting G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project,* 22 AIPLA Q.J. 27, 51 (1994)). *Cf. In re Brana,* 51 F.3d 1560, 1564 (Fed. Cir. 1995) (lacking any disclosed utility, a specification cannot enable use of an invention).

CONCLUSION

For the foregoing reasons, this Court should reaffirm that a written description requirement separate from enablement exists in Section 112, paragraph 1, and that it prohibits claims to research plans, without regard to whether the research is enabled.

Respectfully submitted,

/Joshua D. Sarnoff/
Counsel of Record for *Amicus Curiae*
Public Patent Foundation

November 19, 2009

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I certify that the foregoing Brief of *Amicus Curiae* Public Patent Foundation in Support of Defendant-Appellant Eli Lilly & Co. complies with the type volume limitations of Rule 29(d) of the U.S. Court of Appeals for the Federal Circuit and this Court's August 21, 2009 Order. I further certify that the body of this brief – not including the cover page, table of contents, table of authorities, Appendix, and certificates – contains 6,999 words as determined by Microsoft Word 2007, including the statement of interest, summary of argument, headings, footnotes, quotations, signature lines, and date.

/Joshua D. Sarnoff/
Glushko-Samuelson
Intellectual Property Law Clinic
Washington College of Law
American University
4801 Massachusetts Avenue, N.W.
Washington, D.C. 20016
Counsel of Record for Amicus Curiae
Public Patent Foundation

November 19, 2009

CERTIFICATE OF SERVICE

I, Joshua D. Sarnoff, hereby certify that I caused two copies of the foregoing Brief of *Amicus Curiae* Public Patent Foundation in Support of Defendant-Appellant Eli Lilly & Co. to be served this 19th day of November, 2009, by first class mail, postage prepaid, upon each of the following Counsel for the parties:

James W. Dabney
Fried Frank Harris
Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004
(212) 859-8000

Attorney for Plaintiffs-Appellees

Charles E. Lipsey
Finnegan, Henderson, Farabow,
Garret & Dunner, LLP
2 Freedom Square
11955 Freedom Drive
Reston, VA 20190
(571) 203-2399

Attorney for Defendant-Appellant

November 19, 2009

/Joshua D. Sarnoff/
Glushko-Samuelson Intellectual
Property Law Clinic
Washington College of Law
American University
4801 Massachusetts Avenue, N.W.
Washington, D.C. 20016
Counsel of Record for Amicus Curiae
Public Patent Foundation