

No. 2010-1406

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**United States Court of Appeals**  
for the Federal Circuit

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*THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, AND KATHLEEN RAKER,*  
*Plaintiffs-Appellees,*

*v.*

*UNITED STATES PATENT AND TRADEMARK OFFICE,*  
*Defendant,*

*and*

*MYRIAD GENETICS, INC.,*  
*Defendant-Appellant,*

*and*

*LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, AND MICHAEL K. YOUNG, IN THEIR OFFICIAL CAPACITY AS DIRECTORS OF THE UNIVERSITY OF UTAH RESEARCH FOUNDATION,*  
*Defendants-Appellants.*

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**Appeal from the United States District Court for the Southern District of New York  
in case no. 09-CV-4515, Senior Judge Robert W. Sweet.**

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**BRIEF OF AMICUS CURIAE**

**ELI LILLY AND COMPANY, IN SUPPORT OF NEITHER PARTY**

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## CERTIFICATE OF INTEREST

Counsel for the amicus curiae Eli Lilly and Company certifies the following:

1. The name of every party or amicus represented by me is:

Eli Lilly and Company.

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

Eli Lilly and Company.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

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

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**I. STATEMENTS OF IDENTITY, INTEREST, AND AUTHORITY TO FILE; STATEMENTS IN COMPLIANCE WITH RULE 29(c)(5)**

Eli Lilly and Company is a research-based biopharmaceutical company headquartered in Indianapolis, Indiana.

Lilly has no stake in the result of this appeal. However, Lilly's ability to invest in research to discover and bring new medicines to patients is greatly dependent upon the exclusivity accorded under U.S. patents. Lilly depends upon a strong patent system in which patents, once issued, can be reliably enforced. A strong patent system requires that patents merit respect because they fully comply with each of the requirements for a valid patent, including patent eligibility. The viability of patent-dependent companies such as Lilly is enhanced when the requirements for valid patenting are expressed through legal principles and concepts that are readily understandable and offer relatively bright lines.

The Court ordered that briefs of amici curiae will be entertained, and any such amicus briefs may be filed without leave of court, so long as they do not exceed 15 pages in length and otherwise comply with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29.

Eli Lilly and Company submits this brief as amicus curiae in compliance with Rule 29 of the Federal Rules of Appellate Procedure and

with this Court's Rule 29. No party, no counsel representing a party, and no person, other than counsel representing Lilly, authored any part of this brief. No party, no counsel representing a party, and no person, other than Eli Lilly and Company, contributed money that was intended to fund preparing or submitting this brief.

## **II. SUMMARY**

For a multi-step process claim, such as appellant's claim 20, a threshold patent-eligibility filter (as detailed below) should be applied as a first step for discerning whether a claim is directed to patent-ineligible "laws of nature, natural phenomena, and abstract ideas." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 1293 (2012); *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218, 3225 (2010); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

This threshold filter would reject patent eligibility whenever one or more "mental steps" are set out in a multi-step process claim. For this purpose, a "mental step" is defined as a process step drafted in a sufficiently broad manner such that the step includes embodiments that can be carried out mentally. In particular, a "mental step" is present if no limitation in the step precludes the possibility of the human mind performing the step.

This threshold “mental step” filter for multi-step process claims is not only appropriate as a first step to discern patent ineligibility, but its use is dictated under Supreme Court precedents because it is an unavoidable corollary to a broader patent-eligibility principle relating to processes. This fundamental principle is that an entirely mental process, i.e., a process comprising nothing more than human thought to carry out the steps, would invariably be found to be patent-ineligible under the abstractness criteria laid out in both *Bilski* and *Mayo*. The threshold filter is a corollary to this fundamental principle, being deduced by applying to this principle “poison species” and “poison step” rules that constrain patentability of all process claims.

First, under the “poison species” rule, generically expanding the scope of an unpatentable claim by adding patentable species to broaden the embodiments being claimed should never secure patentability for the more generic claim. The presence of patent-ineligible species in an otherwise patentable generic claim can operate to poison eligibility for the generic claim. An entirely mental—and thus patent ineligible—process should not, therefore, be deemed patentable because it was generically broadened to introduce additional, patent-eligible species, i.e., species that require a



specific machine or other non-mental means to carry out the steps of the process.

In a similar manner, the “poison step” rule applies to multi-step process claims to poison the claim’s patentability where even one step fails to meet even one requirement for patentability (other than novelty/non-obviousness, where the patent statute dictates a contrary rule). The “poison step” rule means that patentability requirements are assessed separately for each step of a process, such that a single step drawn to subject matter excluded from eligibility for patenting results in a patent-ineligible process. Hence, any multi-step process found to have even a single step that contains embodiments that are not precluded from being performed mentally contains a patentability-poisoning “mental step.” The patent statute itself confirms the necessity of applying such an eligibility filter.

A multi-step process is a “combination” invention for which 35 U.S.C. § 112(f) dictates that each step of the combination must either explicitly set out one or more acts or be limited to the corresponding acts set forth in the specification of the patent. Failing either alternative (that is, in the absence of any acts to be found for a step), the patentability of the entire multi-step process is destroyed. The “structure, material or acts” limitation in § 112(f) thusly excludes the possibility that any step in a multi-step

process could be a mental step. A “thinking” or thought-process step is not an act in the statutory sense of being the type of concrete subject matter—the structures, materials, or acts—to which this section of the patent statute limits discrete process steps, or other discrete elements, of all combination claims.

### **III. INTRODUCTION**

At one extreme, it appears well-accepted that a method of treating a patient with a medicine epitomizes a patent-eligible process. *Mayo*, 566 U.S. \_\_\_, 132 S. Ct. at 1302. At the other extreme, claims that are directed to or that effectively preempt laws of nature, natural phenomena and abstract ideas are excluded from patenting, notwithstanding that applying this exclusionary language to real-world patent claims can be frustratingly difficult. Amicus describes herein a threshold eligibility filter grounded on fundamental patenting principles derived from Supreme Court decisions that avoids the confusion caused by conflation of novelty, inventiveness, and patent-eligibility considerations evident in Supreme Court dicta. *Mayo*, 566 U.S. \_\_\_, 132 S. Ct. at 1299.

In circumstances where the proposed filter dictates patent ineligibility of a process claim, it would moot the need for any further analysis. On the other hand, if a claimed process passed through such a threshold filter, then

patent eligibility under a *Bilski-Mayo* inquiry might typically be a *fait accompli*.<sup>1</sup>

#### IV. ARGUMENT

##### **A. This Court Should Seize This Opportunity to Create a Simple, Bright Patent-Eligibility Line.**

It is at best intellectually challenging to meaningfully apply the tripartite exclusions from patenting for laws of nature, natural phenomena and abstract ideas. Robert Armitage, *Subject-Matter Eligibility for Patenting Post-Chakrabarty and Bilski: How Should Human Thinking and Information Content Be Treated?*, University of Illinois Chakrabarty Symposium (2011), <http://www.law.illinois.edu/pdf/RobertArmitagePatent%20Eligibility.pdf>.

It is clear that ideas themselves cannot be patented. *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874). It is, therefore, confusing to posit that only “abstract ideas” are excluded from eligibility for patenting. That said, there is a useful analytical kernel that can be extracted from this exclusion. The “idea” exclusion indicates that claims can be drafted in such

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<sup>1</sup> Amicus addresses only the appealed process claim because *Mayo* appears to be irrelevant to the manifest patent-eligibility of man-made materials that are nowhere to be found as such in nature.

excessively conceptual or otherwise abstract terms that they can thereby fall short of the hurdle for patent-eligible subject matter.

The exclusions for natural phenomena and laws of nature are equally burdened with a potential for creating confusion. *All inventions depend upon natural phenomena for their operation, and no invention can operate other than in harmony with all laws of nature.* Defining what is to be ineligible for patenting in terms of what every invention must embody is a problematic basis for devising any line to separate eligibility and ineligibility, much less a bright one.

There is again a useful analytical kernel to be discerned from these two exclusions. What are understood as “laws of nature” are mental concepts that are uniformly expressed symbolically—sometimes in words, other times in mathematical relationships. Natural phenomena—gravity being one example—are again concepts.

Thus, given the difficulty of any direct application of these traditional exclusionary criteria, but recognizing the essentially *conceptual* character of what these criteria seek to exclude from patenting, a simpler, clearer threshold filter for multi-step process claims, with the potential to largely supersede the need for the traditional tripartite test for exclusion, presents a compelling jurisprudential opportunity.

**B. Entirely Mental Processes Epitomize Inventions That Are Patent-Ineligible as Conceptual and Abstract.**

There can be little doubt that the patent laws were never intended to sanction patentability for inventions that are embodied specifically and exclusively in human thought, human thinking, or human thought processes. Infringement of a process patent cannot sensibly arise from thinking alone; there can be no act of infringement—because there is no act, just thought. The imponderability of enforcing an injunction against “infringing” thoughts, let alone licensing the right to think or determining a reasonable royalty for thinking more than suffices as proof that Congress could never have contemplated opening the door to patenting a process consisting solely of mental steps.

Indeed, this Court’s predecessor once held a clear view of the patent law’s limits on mental patenting. In *In re Heritage*, a “purely mental process” was commingled with additional non-mental process steps. 150 F.2d 554, 556 (CCPA 1945) (“Owing to the fact that claims 1 and 2 are essentially directed to a purely mental process ... they do not define patentable subject matter.”). Indeed, the dissenters in *Diehr* cited what could well be viewed as the subsequent *Bilski-Mayo* rationale for denying patentability to an entirely mental process. The *Diehr* dissenters noted that a mental-steps exclusion “was based on the familiar principle that a scientific

concept or mere idea cannot be the subject of a valid patent.” 450 U.S. at 195.

Standing by itself, the bar to patenting entirely mental processes is profoundly significant because of what it necessarily implies for broader issues of patenting all process inventions containing even a single step that fails to exclude the possibility of performing the step mentally. Such implications have even greater force given the admonition by the Supreme Court in *Mayo* that mere claim-drafting tactics should not be the basis for restoring a patent-ineligible claim to patent eligibility. *Mayo*, 566 U.S. \_\_\_\_, 132 S. Ct. at 1294.

**C. Broadening an Entirely Mental Process Claim by Adding Non-Mental Embodiments Cannot Render the Claim Patent-Eligible.**

The patenting rules—whether subject-matter eligibility, written description, enablement, novelty or non-obviousness—share a common feature. They are tested based upon the full generic reach of the claim. Commingling unpatentable species together with patentable ones can poison patentability of the generic claim encompassing both (“poison species” rule).

This is most categorically applied for novelty and non-obviousness. A claimed invention is not novel unless every claimed embodiment is novel. *Eli Lilly & Co. v. Barr Indus., Inc.*, 222 F.3d 973, 987 (Fed. Cir. 2000). A

claimed invention is not non-obvious if even a single claimed embodiment is obvious. The same notion, with nearly the same rigor, applies under 35 U.S.C. § 112(a). For both written description and enablement, a “commensurateness” test applies—the broader the scope of embodiments covered by the claim, the greater written description and enablement that must be present to support the broader claim scope. *In re Moore*, 439 F.2d 1232, 1236 (CCPA 1971); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1360 (2010) (Newman, J., concurring) (“[T]he patentee is obliged to describe and to enable subject matter commensurate with the scope of the exclusionary right.”).

The standard for patent-eligibility cannot sensibly operate differently. The Supreme Court in *Mayo* would see only a patent draftsman’s machinations at work if an entirely mental, single-step process could be restored to patent eligibility by the trick of generically extending the reach of the claim to encompass embodiments to be performed by a machine, rather than the human mind. If this Court has any doubt about whether to apply a “poison species” rule for patent eligibility, that doubt should be resolved by considering the inaptness of a commensurateness assessment for patent eligibility and, as discussed *infra*, the statutory mandate in § 112(f), limiting individual process steps to acts. The “poison species” rule thus should apply

to a process encompassing any embodiment that could be performed solely in the human mind. Adding non-mental embodiments is no antidote.

**D. A Multiple-Step Process Claim Cannot Be Patent-Eligible if the Claim Contains One or More Patent-Ineligible Steps.**

Having to consider the conventionality of steps—meaning their novelty or inventiveness—and having to analyze pre- and post-solution activity complicate eligibility analysis of multiple-step claims. However, such complexity is unknown for other key patentability-limiting doctrines.

No one would ever contend that a multi-step process was enabled or described under § 112(a) or that it complied with § 112(b) if even one step was non-enabled, was inadequately described, or was insolubly ambiguous.<sup>2</sup> The specific requirements under § 112(f)<sup>3</sup> apply element by element such that if any one element of the combination claim fails the § 112(f) test, the

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<sup>2</sup> Novelty and non-obviousness work differently, but in each case they work differently because a mandate in the patent statute itself requires a different analysis. Under 35 U.S.C. § 102, novelty is preserved whenever the claimed invention as a whole is “not identically disclosed” in the prior art and non-obviousness is dictated solely based on the “claimed invention as a whole.” 35 U.S.C. § 103, Pub. L. No. 112-29, 125 Stat. 284 (2011).

<sup>3</sup> “An element in a claim for a combination may be expressed as a ... step for performing a specified function without the recital of ... acts in support thereof, and such claim shall be construed to cover the corresponding ... acts described in the specification and equivalents thereof.” 35 U.S.C. § 112(f), Pub. L. No. 112-29, 125 Stat. 284 (2011).



entire claim is rendered invalid. *See generally Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 948 n.1 (Fed. Cir. 2007) and authorities cited therein. In other words, a single step failing these patentability tests poisons patentability for any process including such a step (“poison step” rule).

Under the “poison species” and “poison step” rules, a process claim that contains a step that may be performed mentally can be no more patent-eligible than an entirely mental process would be. The “poison species” and “poison step” rules admit of no other possibility. Had Congress permitted a broader berth for patenting processes, § 112(f) would have been drafted quite differently.

**E. A Multiple-Step Process Claim Is a “Combination” Claim in Which Each Step Must Be Confined to “Acts.”**

Multiple-step process claims are “combination” claims as that term is used in § 112(f). The clear implication of § 112(f) is that each discrete element of a claim drawn to a combination must expressly recite the “structure, material or acts” to which the claim is to be limited, or the claim will be nonetheless limited to the “corresponding structure, material or acts” described in the specification of the patent.

Every multi-step process claim is, therefore, to be subject to a step-by-step analysis for the *acts* to which the step is to be limited. The word “acts”

was not used in isolation in § 112(f), but in conjunction with the words “structure” and “material.” Each of the three words underscores a common concept—claims to combination inventions must be set forth in *sufficiently concrete* terms.

For a multi-step process invention, the requirement for “acts” in § 112(f) can be meaningfully understood as differentiating acts from thoughts or concepts. Thus, § 112(f) is more than a strong clue from Congress that individual steps of a multi-step process are intended to be confined to acts to the exclusion of thoughts. It is impossible to read this statutory provision to yield any other outcome than that processes must be limited to those constituted through acts set out for each and every step.

**F. If a Step in Claim 20 Does Not Preclude Being Performed Mentally, the Claim Fails to Pass the Threshold Filter and Is Patent-Ineligible.**

Whenever a process claim is construed as having at least one step not limited to exclude the possibility of being performed mentally, then the Court should, without further inquiry, hold the claim ineligible for patenting. In resolving the present appeal, the Court may construe multi-step process claim 20 as containing a mental step. Specifically, the steps of “determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound” and

“comparing the growth rate of said host cells” may not sufficiently exclude being performed mentally. If the clause “wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic” is construed to be a “step,” then it too may permit mental activity, and therefore not be eligible for patenting.

## V. CONCLUSION

A claimed invention must be sufficiently concrete to be patent-eligible; it cannot be expressed in terms that are excessively conceptual or otherwise abstract. Applying this principle to multi-step process claims, by recognizing a “mental steps” exclusion, provides a bright-line filter for testing a multi-step process claim for patent eligibility. Such a threshold filter, dictated by the *Mayo* holding, yet conceptually simple and consistent with other patent doctrines, would serve the broader policy objective of providing a clearer, more understandable demarcation between the subject matter that can and cannot be protected through patents.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

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