

No. 10-1150

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*In the Supreme Court of the United States*

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MAYO COLLABORATIVE SVCS. (D/B/A MAYO MEDICAL LABO-  
RATORIES) AND MAYO CLINIC ROCHESTER, *Petitioners*,  
v.  
PROMETHEUS LABORATORIES, INC., *Respondent*.

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**On Writ of Certiorari to the  
U.S. Court of Appeals for the Federal Circuit**

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**BRIEF OF *AMICI CURIAE*  
CATO INSTITUTE, REASON FOUNDATION, AND  
COMPETITIVE ENTERPRISE INSTITUTE  
IN SUPPORT OF PETITIONERS**

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CHRISTINA MULLIGAN  
Information Society Project  
Yale Law School  
127 Wall St.  
New Haven, CT 06511  
(617) 797-8605

MANUEL S. KLAUSNER  
Law Offices of Manuel S.  
Klausner, P.C.  
One Bunker Hill Building  
601 W. Fifth St., Suite 800  
Los Angeles, CA 90071  
(213) 617-0414

ILYA SHAPIRO  
*Counsel of Record*  
JAMES W. HARPER  
Cato Institute  
1000 Mass. Ave., N.W.  
Washington, DC 20001  
(202) 842-0200  
ishapiro@cato.org

SAM KAZMAN  
Comp. Enterprise Institute  
1899 L St., N.W., 12<sup>th</sup> Floor  
Washington, DC 20036  
(202) 331-2265

*Counsel for Amici Curiae*

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**QUESTION PRESENTED**

Whether someone can patent the process of observing correlations between blood test results and patient health—effectively preempting all uses of the naturally occurring correlations—simply because the methods used to administer prescription drugs and test blood may involve “transformations” of body chemistry.

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**INTEREST OF *AMICI CURIAE***<sup>1</sup>

The Cato Institute was established in 1977 as a nonpartisan public policy research foundation dedicated to advancing the principles of individual liberty, free markets, and limited government. Cato's Center for Constitutional Studies was established in 1989 to help restore the principles of limited constitutional government that are the foundation of liberty. Toward those ends, Cato publishes books and studies, conducts conferences and forums, publishes the annual *Cato Supreme Court Review*, and files *amicus* briefs. This case is of central concern to Cato because it implicates an overreach of the federal power to establish patents, thus stifling free markets and infringing on individual liberty.

Reason Foundation is a national, nonpartisan, and nonprofit public policy think tank, founded in 1978. Reason's mission is to promote liberty by developing, applying, and communicating libertarian principles and policies, including free markets, individual liberty, and the rule of law. Reason promotes policies that allow and encourage individuals and voluntary institutions to flourish. Reason advances its mission by publishing Reason Magazine, as well as commentary on its websites, [www.reason.com](http://www.reason.com) and [www.reason.tv](http://www.reason.tv), and by issuing policy research reports that promote choice, competition, and a dynamic market economy as the foundation for human dignity

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<sup>1</sup> Pursuant to this Court's Rule 37.3(a), letters of consent from all parties to the filing of this brief have been submitted to the Clerk. Pursuant to this Court's Rule 37.6, *amici* state that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amici* or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

and progress. To further its commitment to “Free Minds and Free Markets,” Reason participates as *amicus curiae* in cases raising significant issues.

The Competitive Enterprise Institute is a non-profit, nonpartisan public interest organization dedicated to empowering individuals to make their own choices in a free market. Founded in 1984, CEI has been involved in a wide range of policy debates, from energy and economic issues to technology and medical care. CEI’s interest in this case is based on our view that government efforts to “promote the progress of science and useful arts” must protect freedom of thought and preserve a rich public domain.

### SUMMARY OF ARGUMENT

Prometheus’s patents are two among thousands of abstract process patents which have been improvidently granted since the 1990s. The patents at issue present an opportunity for the Court to restore the original meaning of patentable “process” and reverse an expansion of patentable subject matter that has discouraged innovation and harmed U.S. industries.

The patents at issue are not “processes” as the term was understood when section 101 of the Patent Act of 1952 was adopted. The Patent Act’s legislative history explains that the term “process” meant “art,” as it had been used in earlier patent statutes. Patentable arts were limited to processes which aimed to produce an effect on matter, and these patents do not.

Moreover, the patents at issue here do not describe a process by either a historic or general definition of the term. A process is a series of actions, and

the “indication” element of the claims does not describe an action.

Enforcing the patents here will have a deleterious economic effect on the healthcare and medical research industries and will retard innovation. Empirical evidence shows that other abstract process patents, such as software and business-method patents, have resulted in aggregate financial losses for American firms and have discouraged rather than encouraged innovation. The effect of abstract process patents on software and financial firms will spread to the healthcare and medical research industries if patents such as Prometheus’s are permitted.

Prometheus’s patents will also impermissibly restrict public domain activity. These patents’ final step is entirely mental. Patents whose final step is mental have the effect of transforming non-infringing, public domain activity into infringing activity for those who are aware of the thought that triggers infringement. This effect discourages the dissemination of knowledge, because access to patented knowledge places individuals in situations where they must elect to cease doing what was previously a public domain activity—such as reading the results of medical tests—or inadvertently infringe a patent.

For similar reasons, the patents at issue unconstitutionally restrict freedom of thought, by putting parties at risk of incurring damages for patent infringement when they recognize the correlations described in the patents at issue. The First Amendment protects freedom of thought and places limits on patent protections, just as it does on copyright protections. As the Court stated in *Eldred v. Ashcroft*, 537 U.S. 186 (2003), copyrights could require First Amend-

ment scrutiny if “the traditional contours of copyright protection” were altered. The patents at issue here represent an unprecedented departure from the traditional contours of patent protection; only recently have parties sought patent protection for claims which final element encompasses pure thought. Even if the patents at issue are otherwise patentable subject matter, these patents unconstitutionally restrict freedom of thought in violation of the First Amendment and should be invalidated.

## ARGUMENT

### **I. The Patents At Issue Are Not Processes Under Section 101 Of The Patent Act**

Prometheus’s patents are two among thousands of abstract process patents which have been improvidently granted since the 1990s. These patents should be invalidated because they do not qualify as “processes” under 35 U.S.C. § 101.

As an historical matter, the patents at issue do not describe activity which would have qualified as a “process” when the Patent Act of 1952 was adopted. The legislative history of the 1952 Act explains that the term “process” is coextensive with the term “art,” as it had been used in earlier patent statutes. Patentable arts were limited to processes which aimed to produce an effect on matter, and these patents do not.

Additionally, the patents at issue here do not describe a process by either an historic or general definition of the term. A process is a series of actions, and the “indication” element of the claims does not describe an action.

**A. The Patents at Issue Are Not Processes under Section 101 because Patentable “Processes” Were Historically Limited to Those Which Aimed to Produce an Effect on Matter.**

**1. “Process” in the Patent Act of 1952 shares the same meaning as “art” in the Patent Act of 1793.**

The meaning of the term “process” in the Patent Act is informed by the historic limitations on process and art patents. These limits show that the patents at issue here are beyond the permissible boundaries of process patents.

The Supreme Court recently considered the meaning of “process” in *Bilski v. Kappos*, 130 S.Ct. 3218 (2010). The majority opinion emphasized *Diamond v. Diehr*’s instructions that “[u]nless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning, . . . and [that] in dealing with the patent laws, . . . courts should not read into the patent laws limitations and conditions which the legislature has not expressed.” 450 U.S. 175, 182 (1981) (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)) (internal quotation marks omitted) (discussed in *Bilski*, 130 S.Ct. at 3226).

In contrast, Justice Stevens’s concurrence emphasized that the term “process” must be understood as a “complex term[ ] of art developed against a particular historical background.” *Bilski*, 130 S.Ct. at 3238 (Stevens, J., concurring). Although some language in *Diehr* suggests that the term “process” can be simply

understood by its lay or dictionary definition alone,<sup>2</sup> the *Diehr* court also acknowledged the relationship between the terms “process” in the 1952 Act and “art” in previous patent statutes. See 450 U.S. at 182 (“[A] process has historically enjoyed patent protection because it was considered a form of ‘art’ as that term was used in the 1793 Act.”); see also *Parker v. Flook*, 437 U.S. 584, 588 (1978) (explaining that a claim may describe a “‘process’ in the ordinary sense of the word” but still not be patentable subject matter).

The term “process” first appeared as a category for patentable subject matter in the 1952 Act, replacing the term “art” which had been a category of patentable subject matter in earlier patent statutes. The report of the Senate Judiciary Committee explained the change was cosmetic and did not alter the scope of patentable subject matter:

“Art” [in prior patent statutes] . . . is interpreted by the courts to be practically synonymous with process or method. The word “process” has been used to avoid the necessity of explanation that the word “art” as used in this place means “process or method,” and that it does not mean the same thing as the word “art” in other places [*e.g.*, sections describing “prior art”].<sup>3</sup>

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<sup>2</sup> Other categories of patentable subject matter, such as “manufacture” and “composition of matter,” have been interpreted in accordance with their lay or dictionary definitions or common usage. See *Bilski*, 130 S.Ct. at 3226 (citing *Chakrabarty*, 447 U.S. at 308).

<sup>3</sup> The committee report also explained, “The definition of ‘process’ has been added in section 100 to make it clear that ‘process

S.Rep. No. 82-1979, at 2398-99 (1952).

Because the change from “art” to “process” in the 1952 Act was cosmetic, the present-day meaning of “process” is substantially informed by the meaning of the term “art” in earlier patent statutes.

The Patent Act of 1793 allowed patents to issue for “any new and useful art, machine, manufacture, or composition of matter.”<sup>4</sup> Ch. 11, 1 Stat. 318, 319. An early authority on patent law,<sup>5</sup> George Ticknor Curtis, described the term “art” as “a new process or method of working or of producing an effect or result in matter.” George Ticknor Curtis, *A Treatise on the*

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or method’ is meant, and also to clarify the present law as to the patentability of certain types of processes or methods as to which some insubstantial doubts have been expressed.” S.Rep. No. 82-1979, at 2399 (1952). The “insubstantial doubts” language referred to dicta in *In re Thuau*, 135 F.2d 344, 347 (C.C.P.A. 1943), and other decisions that suggested a new use of a known machine, manufacture or composition of matter could not be patented. Peter S. Menell, *Forty Years of Wandering in the Wilderness and No Closer to the Promised Land*, 63 Stan. L. Rev. 1289, 1297 (2011) (citing P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1 (West 1954), reprinted in 75 J. Pat. & Trademark Off. Soc’y 161, 176-77 (1993)).

<sup>4</sup> In his concurring opinion in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), Judge Dyk described how “the categories of patentable subject matter closely tracked the English approach, and in certain respects reflected a deliberate choice between competing views prevalent in England [around 1793].” 545 F.3d at 968 (Dyk, J., concurring). In the mid-eighteenth century, England had not yet resolved whether processes for manufacturing were themselves patentable under the statute. In the 1793 Patent Act, Congress resolved this question by including the term “art” in the statute. *Id.* at 970.

<sup>5</sup> Robert Merges & John Duffy, *Patent Law & Policy* 916 (3d ed. 2002) (cited in Menell, *supra*, at 1295).

Law of Patents for Useful Inventions § 9 (Boston, Little, Brown & Co. 3d ed. 1867) (cited in Menell, *supra*, at 1295). He illustrated the definition with examples drawn from case law, each of which referred to improved manufacturing techniques involving physical objects. *See id.* §§ 9-19. A later treatise by William Robinson defined “art” as “an act or a series of acts performed by some physical agent upon some physical object, and producing in such object some change either of character or of condition.” 1 William C. Robinson, *The Law of Patents for Useful Inventions* § 159 (Boston, Little, Brown & Co. 1890). Robinson noted an “art” “is also called a ‘process.’” Robinson, *supra*, at § 159 (citing *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).

Courts’ interpretation of the term “process” remained in accord with the historic understanding of “art,” until around the 1990s.

## **2. The Federal Circuit expanded the scope of patentable subject matter far beyond its historic limits throughout the 1990s.**

The seeds for expanding the scope of patentable subject matter were sown in *Gottschalk v. Benson*, 409 U.S. 63 (1972). *Benson* invalidated a process patent for converting signals from binary-coded decimal into binary, emphasizing that “[p]henomena of nature, . . . mental processes, and abstract intellectual concepts [we]re not patentable.” *Id.* at 67. The Court found that granting the patent “in practical effect would [grant] a patent on the [conversion] algorithm itself,” *id.* at 72, and indicated that patents on software programs were beyond the scope of the patent statute. *See id.* at 72-73 (“It may be that the patent

laws should be extended to cover these programs, a policy matter to which we are not competent to speak. . . . If these programs are to be patentable, considerable problems are raised which only committees of Congress can manage.”).

Following *Benson*, patent drafters attempted to redraft abstract process claims into claims for making a new machine, in the hopes of concealing any resemblance of their claims to those at issue in *Benson*.<sup>6</sup> See Robert Merges & Patrick Duffy, *Patent Law and Policy* 151-52 (4th ed. 2007) [hereinafter Merges &

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<sup>6</sup> The earliest attempt to cast a software invention as a hardware claim actually predated *Benson*. The applicant in *In re Bernhart*, 417 F.2d 1395 (C.C.P.A. 1969), filed a claim for a computer which could depict three-dimension objects in two dimensions, as opposed to filing a claim for a process of depicting three-dimensional objects *using* a computer. The Court of Customs and Patent Appeals upheld the patent, explaining that a computer with the program was, compared to a computer without the program, “a new machine.”

[I]f a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed. If a new machine has not been invented, certainly a ‘new and useful improvement’ of the unprogrammed machine has been, and Congress has said in 35 U.S.C. [§] 101 that such improvements are statutory subject matter for a patent.

*Id.* at 1400. The tactic of recasting a process claim as a machine claim “lay dormant” until it was revived, post-*Benson*, in the 1980s. Robert Merges & Patrick Duffy, *Patent Law and Policy* 152 (4th ed. 2007).

Duffy 4th ed.]. This tactic succeeded when the Federal Circuit upheld machine claims for software in *In re Iwahashi*, 888 F.2d 1370 (Fed. Cir. 1989), and *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (*en banc*). The Federal Circuit in *Alappat* acknowledged that “many, or arguably even all, of the means elements recited in [the claim] represent circuitry elements that perform mathematical calculations.” 33 F.3d at 1544. Nonetheless, the majority concluded, “This [claim] is not a disembodied mathematical concept . . . but rather a specific machine to produce a useful, concrete, and tangible result.” *Id.*

In 1998, the Federal Circuit decided *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). *State Street* eliminated the common-law ban on business-method patents, but also struggled uncomfortably with the legal fiction that software patents could be appropriately characterized as new machine claims. *State Street* attempted to gloss over the issue of whether software patents should be claimed as machines or processes. The majority claimed, “The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to—process, machine, manufacture, or composition of matter—but rather on the essential characteristics of the subject matter, in particular, its practical utility.” *Id.* at 1375.

Between 1994 and September 2007, the Federal Circuit held no claims unpatentable under 35 U.S.C. § 101.<sup>7</sup> Merges & Duffy 4th ed., *supra*, at 153-54.<sup>8</sup>

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<sup>7</sup> Notably, no appellate decisions were rendered on patentable subject matter between 1982 and 1989 either—“which strongly suggests the [Patent and Trademark Office (“PTO”)] was not

During this period, the granting of software patents became the norm. Whereas only 262 software patents were issued between 1978 and 1987, the PTO issued approximately 4,500 software patents in 1994. See Jeffrey J. Blatt, *Software Patents: Myth Versus Virtual Reality*, 17 *Hastings Comm. & Ent. L.J.* 795, 816 (1995); John T. Soma & B.F. Smith, *Software Trends: Who's Getting How Many of What? 1978 to 1987*, 71 *J. Pat. & Trademark Off. Soc'y* 415, 418-19 (1989); Merges & Duffy 4th ed., *supra*, at 154.

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issuing rejections on that basis.” Merges & Duffy 4th ed., *supra*, at 150. During those years, the PTO adopted “a liberal, rather than a conservative, interpretation of [*Diamond v. Diehr*]” and began “issuing patents for algorithms and a wide range of other software-related innovations.” Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 *Emory L.J.* 1025, 1094 (1990).

<sup>8</sup> In September 2007, the Federal Circuit invalidated patents in *In re Comiskey*, 499 F.3d 1365, 1379, 1381 (Fed. Cir. 2007) (finding claims that “describe an allegedly novel way of requiring and conducting arbitration” unpatentable under section 101), and *In re Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (holding a signal to be unpatentable subject matter under section 101). The applicants in *In re Nuijten* argued that *State Street* rendered the four statutory categories of section 101—process, machine, manufacture, or composition of matter—irrelevant to the question of whether an invention was patentable. 500 F.3d at 1353-54. The Federal Circuit disagreed with this characterization of *State Street*, holding, “The four categories together describe the exclusive reach of patentable subject matter. If a claim covers material not found in any of the four statutory categories, that claim falls outside the plainly expressed scope of [section] 101 even if the subject matter is otherwise new and useful.” *Id.* at 1354. *In re Nuijten* marked a return to focusing on the text of section 101, including the meaning of the term “process.”

Because *State Street* de-emphasized the categories for subject-matter patentability, most software and business-method patents are now candidly described as processes. The proliferation of software and business-method patents represented the completion of a twofold change in patentable subject matter. Not only was the term “process” interpreted so broadly as to include processes far beyond the “arts” contemplated in the early patent acts, but the scope of the exceptions to patentable subject matter was narrowed to exclude algorithms instantiated as computer code.

**3. The Court should overturn Federal Circuit precedent that broadens patentable subject matter beyond its historic limits and invalidate the patents at issue because they do not describe a “process” or “art.”**

The term “process” in section 101 is properly limited to processes which aim to have an effect on matter. Although software and business method patents have proliferated over the past two decades, many software and business-method patents, as well as the patents at issue here, should not qualify as patentable subject matter because the purpose of performing the processes is not to have an effect on the physical world.

Prior Supreme Court precedent is consistent with this historic understanding of patentable process. The aim of the *Diehr* patent was to cure synthetic rubber—to effect a physical change in the world—and that patent was upheld. *See* 450 U.S. at 177. In contrast the purpose of the *Benson* patent was to represent a number in binary, 409 U.S. at 64, and the purpose of the *Flook* patent was to calculate updated

alarm limits, 437 U.S. at 585. Although the algorithms in *Benson* and *Flook* would happen to effect a change on a computer, these changes did not transform the claimed algorithms into *patentable* processes because the purpose of performing the claimed processes was not to alter the physical world. The aim of the *Benson* and *Flook* patents was to represent or calculate a number, respectively. Those patents were correctly invalidated.

Similarly, the patents at issue here fail to qualify as patentable processes because the claimed processes do not aim to effect a change in the physical world. Consider, for example, Claim 1 of the '623 patent. The aim of the claim is to reveal whether levels of 6-thioguanine in a patient “indicate” that subsequent doses of a drug should be higher or lower. Recognition of whether a drug dosage should be changed is the last part of the claimed process.

The Federal Circuit observed that the patient is physically changed when the test dose of a drug is administered and that a blood sample is transformed when 6-thioguanine levels are measured. *See Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1356-57 (Fed. Cir. 2010). As with the changes in computers running the *Benson* and *Flook* algorithms, however, these changes in patients and their blood are merely side effects of the claimed process. The purpose of the patents at issue here is to reveal information about whether a drug dosage should be increased or decreased, not to change the patient’s internal state or the state of blood samples.

Prometheus’s claims are aimed not at producing an effect on matter, but at revealing information. They are therefore not patentable processes or art.

**B. The Patents at Issue Do Not Describe a Process because a Process Is a Set of Actions and the Patents’ “Indication” Step Requires No Action.**

The Supreme Court and the Federal Circuit have consistently interpreted the statutory term “process” to require action. *See Benson*, 409 U.S. at 70 (“A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” (quoting *Cochrane*, 94 U.S. at 788)); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1319 (Fed. Cir. 2005) (“[A] process is a series of acts.” (quoting *Minton v. Nat’l Ass’n of Sec. Dealers*, 336 F.3d 1373, 1378 (Fed. Cir. 2003))); *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (“[A] process . . . consists of a series of acts or steps<sup>9</sup> . . . . It consists of doing something, and therefore has to be carried out or performed.”); *In re Nuijten*, 500 F.3d at 1355 (explaining that a patent applicant’s argument that his claims might be covered by the “process” category even if they do not recite acts “lacks merit”).

The patents at issue here do not describe processes, by any dictionary or historic definition of “process,” because the “indication” element does not re-

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<sup>9</sup> A step is “[o]ne of a series of actions, processes, or measures taken to achieve a goal.” American Heritage Dictionary of the English Language 1699 (4th ed. 2000) (also defining a step as “[a] stage in a process”); *see also* Merriam-Webster’s Collegiate Dictionary 1223 (11th ed. 2003) (A step is “a stage in a process” or “an action, proceeding, or measure often occurring as one in a series.”); Oxford American Dictionary & Thesaurus 1281 (2d ed. 2009) (A step is “a measure or action taken to deal with or achieve something.”).

quire action. *See, e.g.*, American Heritage Dictionary of the English Language 1398 (4th ed. 2000) (A process is “[a] series of actions, changes, or functions bringing about a result[,]” or “[a] series of operations performed in the making or treatment of a product.”); Merriam-Webster’s Collegiate Dictionary 990 (11th ed. 2003) (A process is “a series of actions or operations conducing to an end; [especially] a continuous operation or treatment esp[ecially] in manufacture.”); Oxford American Dictionary & Thesaurus 1027 (2d ed. 2009) (A process is “a series of actions or steps taken toward achieving a particular end.”).

Each step of a process must require someone or something to *do* something. But the final “indication” element of the claimed processes is entirely passive. Consider the final portion of Claim 1 of the ‘623 patent. The drug must be administered, and 6-thioguanine levels must be determined,

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject[,] and

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

2JA at 16.

This process claim allegedly has three parts: administration, determination, and indication. But the

“indication” element is not an action; it is merely an observation.

The number representing metabolite levels does not undertake the action of “indicating” anything. More accurately, the claim instructs a party reading lab results to *recognize* something about the number. But “recognizing,” without doing something further based on the recognition, is not an action, and the claims in the patents at issue here, accordingly, do not describe processes.<sup>10</sup>

## **II. Enforcing The Patents At Issue Would Stifle Free-Market Competition, Slow Innovation, And Raise The Costs Of Medical Treatment**

The Federal Circuit’s expansive interpretation of patentable subject matter in the 1990s coincided with patents having a net negative economic effect in most industries, as the forthcoming empirical evidence shows. Broad, abstract process patents are particularly prone to litigation, the costs of which have overwhelmed the profits generated from those patents. Enforcing the patents at issue here will spread the economic harms caused by broad, abstract process patents from the software and financial industries to the healthcare industry.

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<sup>10</sup> Alternatively, the Court could consider the claims as only including two steps—administering the drug and determining the metabolite levels—eliminating the passive element of “recognition” from the claimed process. The administering and determining steps comprise a process according to the term’s common usage, but are otherwise unpatentable as prior art.

**A. The Federal Circuit's Expansive Interpretation of Patentable Subject Matter Has Hurt the Economy and Stifled Free-Market Competition.**

This Court's decision in *Bilski* re-emphasized the limits on patentable subject matter. Nonetheless, the Federal Circuit's validation of the patents at issue here demonstrates that the boundaries of patentable subject matter remain far beyond their appropriate and historic limits in the Federal Circuit.

Granting highly abstract process patents not only deviates from the historic understanding of patentable processes, but also has wreaked tremendous damage on numerous sectors of the economy. This damage will extend to the medical and healthcare industries if medical diagnostic patents, such as the patents at issue, are upheld.

Despite the widely-held belief that stronger patent protection always provides greater incentives to innovate and monetize innovation, empirical economic evidence indicates that patents do not "universally spur innovation and economic growth." See James Bessen & Michael J. Meurer, *Of Patents and Property*, Regulation Mag. 18, 25 (Winter 2008/2009). Bessen and Meurer analyzed the costs and benefits of patenting over the past few decades and concluded that "patents may actually discourage investment in innovation" for public firms in "most industries today." *Id.*

Although patents have consistently provided a positive return on investment to chemical and pharmaceutical firms, patents have had a much more ambiguous effect in other industries. During the 1980s, public non-pharmaceutical and -chemical firms

“might have, at best, broken even from patents.” *Id.* By 1994, however, the costs of litigating patents in other industries had mushroomed far beyond the profits earned from patents. *See* Patents, Profits, and Costs, *infra* App. A, at 1a (Graphs of cost of patent litigation compared to worldwide profits from patents in the 1980s and 1990s.). “By almost any interpretation, the patent system could not [have been] providing overall positive incentives for those . . . firms by the end of the 1990s.” Bessen & Meurer, *Of Patents and Property*, *supra*, at 25; *see also* James Bessen & Michael J. Meurer, Patent Failure 138-42 (2008).

It is no coincidence that the patent system switched from a system which encouraged innovation to one which created economic losses in the 1990s. *In re Iwahashi* and *In re Alappat*, coupled with the PTO’s willingness to grant patents on software and business methods, caused broad, abstract process patents to proliferate. Firms scrambled to acquire patents in newly available areas, either out of belief that patenting would be profitable, or defensively, to prevent competitors from acquiring broad patents that would threaten their existing projects and business models. In 1991, even Bill Gates worried that “some large company w[ould] [acquire a software] patent [on] some obvious thing” and use the patent to “take as much of [Microsoft’s] profits as they want[ed].” *See* Timothy B. Lee, *A Patent Lie*, N.Y. Times, June 9, 2007, at A15.

Software and business method patents presented and continue to present numerous difficulties for firms. Critically, it is almost impossible for a firm to search through existing patents, determine when its own software is infringing existing software patents,

and license the pre-existing patents to clear the rights for its own work. Searching the patent system for patents covering material similar to one's own software can reveal thousands of patents. A recent episode of *This American Life* on National Public Radio demonstrated the problem. The program interviewed David Martin, who runs a company called M-Cam. M-Cam is hired by the government, banks, and other businesses to assess patent quality. Martin demonstrated how M-Cam's software searches existing patents and can detect overlap between them. Martin tested patent no. 5771354, a 1998 patent that covers upgrading software on one's home computer over the internet. He discovered that while the '354 patent was being prosecuted, 5,303 other patents covering the same or very similar material were issued by the PTO. See *This American Life* # 441: *When Patents Attack* (National Public Radio broadcast July 22, 2011), transcript available at [http://www.thisamericanlife.org/sites/default/files/TAL441\\_transcript.pdf](http://www.thisamericanlife.org/sites/default/files/TAL441_transcript.pdf).

As software patents proliferated, patent thickets developed, making it even more impracticable for a company to acquire all of the licenses it would need to market a completely cleared product. For example, there are as many as 250,000 patents relevant to smartphones. See Richard Waters, *Patent Hunting is Latest Game in Tech Bubble Circuit*, Financial Times, July 27, 2011, at 15 (Inside Business section); Richard Waters, *Tech Patent Arms War Reaches New Level of Intensity*, Financial Times, March 31, 2011, at 16 (Inside Business section); see also Mike Masnick, *Acacia Buys Up More Smartphone Apps Patents: Watch The Patent Thicket Get Worse*, Techdirt, <http://www.techdirt.com/blog/wireless/articles/>

20110721/02264715188/acacia-buys-up-more-smartphone-apps-patents-watch-patent-thicket-get-worse.shtml (July 21, 2011) (depicting a graphic of twenty-eight firms involved in lawsuits concerning smartphone-related patents).

As a result, litigation costs associated with software and business-method patents skyrocketed, dwarfing the profits earned from those patents.

In 2008, software patents were more than twice as likely to be litigated as other patents. James Bessen & Michael J. Meurer, *Patent Failure* 22, 153 (2008). During the late 1990s, software patents alone accounted for 38 percent of the total cost of patent litigation to public firms. *Id.* at 22. Bessen and Meurer concluded that patents on business methods were nearly seven times more likely to be litigated than other patents. *Id.* at 22, 153. Patents related to financial products and services generally are litigated at a rate 27 to 39 times larger than patents in general. Josh Lerner, *The Litigation of Financial Innovations* 1 (2008), <http://www.people.hbs.edu/jlerner/FinPatLit.09222009.pdf>.

Participants in the software and financial industries thus face a significant risk attendant to their innovative endeavors—the potential cost of defending against patent lawsuits. In 1994, the senior vice president of Oracle Corporation, Jerry Baker, expressed the problem concisely. “Our engineers and patent counsel have advised me that it may be virtually impossible to develop a complicated software product today without infringing numerous broad existing patents.” U.S. PTO Hearings on Software Patents, San Jose, CA (Jan. 26, 1994) (statement of Jerry Baker, Senior Vice President of Oracle Corporation),

*available at* [http://www.uspto.gov/web/offices/com/hearings/software/sanjose/sj\\_baker.html](http://www.uspto.gov/web/offices/com/hearings/software/sanjose/sj_baker.html). The risk of litigation is all but unavoidable for participants in the software and financial industries. As a result, these companies must focus resources—which could otherwise be used on research and development—on defending their businesses against patent lawsuits.

Lerner observed that some financial institutions “engaged in strictly defensive patenting.” Lerner, *supra*, at 5. They patented innovations “to ensure that others did not patent them later” and “gathered patents with careful consideration of a possible counter-attack should any rival accuse them of patent infringement.” Lerner, *supra*, at 5.

Many software patentees also “obtain[] patents for purely defensive purposes, motivated by a fear of exclusion from markets at the hands of other patentees.” Merges & Duffy 4th ed., *supra*, at 198. For example, in 1995, Oracle announced that while it opposed software patents, it had “embarked on an aggressive program to secure patents for its software products—primarily to protect itself against potential infringement claims, in the face of a sharp increase in recent years in the number of software patents issued by the PTO.” Mark Walsh, *Bowing to Reality, Software Maker Begins Building a Patent Portfolio*, *The Recorder*, Aug. 17, 1995, at 1 (cited in Merges & Duffy 4th ed., *supra*, at 198).<sup>11</sup>

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<sup>11</sup> Since 1995, Oracle has also gone on the offensive, suing Google for violations of its patents. See Jessica Guynn, *Silicon Valley Titans Square Off; Oracle Sues Google over Java Technology Used in Android Mobile Devices*, *L.A. Times*, Aug. 14, 2010, at B2.

Similarly, Google recently acquired Motorola Mobility for \$12.5 billion, after Microsoft and Apple spent \$4.5 billion to purchase 6,000 patents from Nortel Networks, a Canadian telecommunications maker that filed for bankruptcy in 2009. See Evelyn N. Rusli & Claire Cain Miller, *Google to Buy Motorola Mobility for \$12.5 Billion*, N.Y. Times Dealbook Blog, <http://dealbook.nytimes.com/2011/08/15/google-to-buy-motorola-mobility/> (Aug. 15, 2011). Google's CEO Larry Page explained part of the motivation for the purchase. "[C]ompanies including Microsoft and Apple are banding together in anti-competitive patent attacks on [the smartphone platform] Android. . . . Our acquisition of Motorola will increase competition by strengthening Google's patent portfolio, which will enable us to better protect Android from anti-competitive threats from Microsoft, Apple and other companies." See Larry Page, *Supercharging Android: Google to Acquire Motorola Mobility*, Official Google Blog, <http://googleblog.blogspot.com/2011/08/supercharging-android-google-to-acquire.html> (Aug. 15, 2011). Microsoft had previously demanded that Samsung Electronics Co. Ltd. pay Microsoft fifteen dollars for each smartphone handset it makes based on Google Inc.'s Android operating system. See *Microsoft Wants Samsung to Pay Smartphone License: Report*, Reuters, <http://www.reuters.com/article/2011/07/06/us-samsung-microsoft-idUSTRE7651DB20110706> (July 6, 2011).

Companies such as Oracle, Google, and Microsoft are engaged in a patent "arms race," spending fortunes to obtain enough patents to deter competitors from suing them. Small firms that can't keep up may be run out of business, but these large firms will likely find themselves in a state of "mutually assured de-

struction,” in which no firm will dare to initiate patent litigation for fear of retaliation.

These firms will wind up in the same competitive position they would have been in had the patents never issued—free to compete against each other in the market without regard to patents—at a cost of billions of dollars. These billions would have been better used to improve products on the market, to bring new products to market, and to further research and development of new technology. In short, these firms are playing the prisoner’s dilemma game—and they are all defecting.

This patent arms race is not a necessary cost of encouraging innovation. Indeed, most innovations would be developed even if patent protection were unavailable. Between 90 and 98 percent of modern patent lawsuits are filed against independent inventors, not copiers. Mark A. Lemley, *The Myth of the Sole Inventor* 8 (2011), available at <http://ssrn.com/abstract=1856610> (citing Christopher A. Cotropia & Mark A. Lemley, *Copying in Patent Law*, 87 N.C. L. Rev. 1421 (2009)). Parties who infringe software and business method patents are overwhelmingly parties who have independently developed processes similar or identical to patented material, not those who have copied. The frequency of simultaneous, independent invention demonstrates that most software and business method advances would occur without patent protection, *see generally* Lemley, *Myth of the Sole Inventor*, *supra*, at 7-51, and that the costs of patenting borne by the software and financial industries are not associated with the benefit of developing new knowledge.

There is no evidence that the availability of software and business method patents create incentives for new innovations; these abstract process patents are simply not necessary to encourage new developments in the software and financial fields. The billions of dollars firms spend buying and litigating patents are truly wastes of resources, and as a result, consumers are likely to pay higher prices for less-advanced products.

**B. Enforcing the Patents at Issue Will Spread the Harms Caused by Abstract Process Patents to the Medical Profession and Healthcare Industries.**

Enforcing the patents at issue will spread the problems caused by abstract process patents to the healthcare industry in general and medical diagnoses in particular, placing researchers and institutions in “constant fear of litigation.” *Bilski*, 130 S.Ct. at 3256 (Stevens, J., concurring). “[M]any [diagnostic] decisions, no matter how small, could be *potential* patent violations.” *Id.* To avoid infringement, medical institutions and researchers would “need to undertake the costs of searching through patents” and then “decide whether their [diagnostic method] is one that remains in the public domain.” *Id.*

Perversely, as this case illustrates, searching through patents would be necessary to avoid inadvertent infringement, but also could perilously open the door to infringements of patents like Prometheus’s. For example, if in searching patent documents, a researcher read about the correlations in the ’623 or ’302 patents, her *previously un infringing* activity—looking at metabolite levels after administering a drug—would become infringing because she would be

unable to erase the information from Prometheus's patents from her memory. Moreover, by reading the patent, researchers and institutions could subject themselves to increased liability as willful infringers. See, e.g., Mark A. Lemley & Ragesh K. Tangri, *Ending Patent Law's Willfulness Game*, 18 Berkeley Tech. L.J. 1085, 1100-02 (2001) (noting that lawyers often advise engineers not to read competitor patents for fear of their becoming willful infringers); Doug Lichtman, *Substitutes for the Doctrine of Equivalents*, 93 Geo. L.J. 2013, 2023, 2023 n.42 (2005) (same).

Issuing patents on medical diagnostic techniques will result in economic harms in the healthcare industry similar to those that have been documented in the software and financial industries. Like many abstract process patents, medical diagnostic methods can often be performed and discovered by individuals or small groups. As a result, many parties may acquire patents, and even greater numbers of well-meaning parties may inadvertently infringe them, just as in the software and financial industries.

Permitting patenting of medical diagnostic methods may also "inhibit doctors from using their best medical judgment; . . . force doctors to spend unnecessary time and energy to enter into license agreements; . . . divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; [and] raise the cost of health care while inhibiting its effective delivery." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 138 (2006) (Breyer, J., dissenting).

Diverting resources to litigation and avoiding patent infringement in the healthcare and medical research industries will have not only a significant eco-

conomic cost, but a human cost as well. The Court should not allow the vast harms from broad and abstract process patents to persist and spread, particularly when human health is at stake.

### **III. The Patents At Issue Impermissibly Remove Existent Knowledge From The Public Domain And Restrict Public Domain Activity**

This Court stated in *Graham v. John Deere Co. of Kansas City* that “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.” 383 U.S. 1, 6 (1966). But that is precisely what the patents at issue here accomplish.

Because medical diagnostic patents such as those at issue here and in *Lab Corp* are infringed when a party *recognizes* a correlation or situation, they have the potential to swallow huge swaths of otherwise public domain medical activity and research, even that which has little to do with the subject of the patent. Dr. Rokea el-Azhary’s situation is simply one example of how upholding the patents at issue here would prevent unrelated research and treatment.

A patent on another recent discovery could have had even broader effects. It was recently discovered that gum disease is a risk factor that can be used to predict cardiovascular disease. An ordinary dentist who looks in a patient’s mouth and notices the presence of gum disease can “correlate” in his mind the presence of gum disease with a patient’s increased risk of heart attack. See Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 Wis. L. Rev. 759, 760 (2007) (citing Robert Genco et al., *Periodon-*

*tal Disease and Cardiovascular Disease: Epidemiology and Possible Mechanisms*, 133 J. Am. Dental Ass'n, June 2002, at 14S). If this diagnostic method had been patented, much common dental work and research could have become infringing for those who knew the correlation.<sup>12</sup>

Patents whose final step is entirely mental have the effect of transforming non-infringing, public domain activity into infringing activity for those who are aware of the thought that triggers infringement. This effect discourages the dissemination of knowledge, because access to patented knowledge places individuals in situations where they must elect to cease doing what was previously a public domain activity—such as reading the results of medical tests—or inadvertently infringe a patent.

Disclosure of new technologies is “the ultimate goal of the patent system,” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989), but medical diagnostic patents frustrate that purpose by necessitating that the content of the patent be kept secret from those who might need to perform the

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<sup>12</sup> Whether the Federal Circuit would continue to find this discovery to be patentable subject matter is not certain after *Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 2011 WL 3211513, at \*22 (Fed. Cir. July 29, 2011). As discussed by petitioners, the Federal Circuit's attempt to distinguish between the patentability of the patents at issue here and the patents in *Molecular Pathology* is strained and inconsistent with this Court's precedents. See Pet. Br. at 39-40. Regardless, the correlation between gum and cardiovascular disease suggests that many simple correlations between natural phenomena may yet be discovered and patented if the Court does not invalidate the patents here.

non-mental steps of the patent for other, public-domain purposes.

Upholding the patents at issue here would “confer power to block off whole areas of scientific development,” creating a kind of “monopoly of knowledge” that was not the intent of Congress. *Brenner v. Manson*, 383 U.S. 519, 534 (1966). Patents must not be allowed to fence off public domain activity because of what individuals may inadvertently think about after doing those acts.

#### **IV. Enforcing The Patents At Issue Here Would Violate The First Amendment Freedom Of Thought**

##### **A. The First Amendment Protects the Freedom of Thought.**

The government cannot regulate mere thought. *See Paris Adult Theatre I v. Slaton*, 413 U.S. 49, 67-68 (1973). The Court has repeatedly recognized that the First Amendment protects freedom of thought as well as freedom of speech. *See Stanley v. Georgia*, 394 U.S. 557, 565-66 (1969) (“[T]he right to control the moral content of a person’s thoughts . . . is wholly inconsistent with the philosophy of the First Amendment. . . . [The government] cannot constitutionally premise legislation on the desirability of controlling a person’s private thoughts.”); *United States v. Ballard*, 322 U.S. 78, 86 (1944) (“Freedom of thought . . . is basic in a society of free men.”); *see also Wallace v. Jaffee*, 472 U.S. 38, 51 (1985) (acknowledging that freedom of thought is protected by the First Amendment); *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (same). Recently, the Court, in *Ashcroft v. Free Speech Coalition*, explained, “First Amendment freedoms are most in danger when the government seeks

to control thought or to justify its laws for that impermissible end. The right to think is the beginning of freedom . . . .” 535 U.S. 234, 253 (2002).

Enforcing the patents at issue here would violate individuals, such as Dr. el-Azhary’s, freedom of thought. Before learning of the correlations described in the claimed patents here, Dr. el-Azhary was able to administer drugs and determine the amount of metabolites in patients without risk of patent infringement.<sup>13</sup> Only upon learning the correlations—and presumably thinking about them when she sees the metabolite levels of her patients—did she put her and Mayo’s interests at risk. By forcing Mayo, or any party not covered by 35 U.S.C. § 287(c), to pay damages for infringing the patents at issue here, the government engages in punishment for mere thought.

**B. Patents Granted under the Progress Clause Are Subject to First Amendment Scrutiny.**

Enforcing the patents at issue here constitutes a content-based regulation of thought. Even in light of the limited role of the First Amendment in the context of copyright, as articulated in *Eldred v. Ashcroft*, 537 U.S. 186 (2003), the patents at issue here should

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<sup>13</sup> Dr. el-Azhary conducted a study on patients suffering from autoimmune diseases of the skin. She prescribed thiopurine and collected data on patients’ metabolite levels to establish a therapeutic range for dermatological disorders. See 1JA 17-18. Dr. el-Azhary testified that Prometheus’s gastrointestinal-related metabolite levels were “irrelevant to [her] study” because “there [wa]s no reason to extrapolate [their findings] to dermatology.” 1JA 19. Nonetheless, once she learned Prometheus’s correlations, she could not help but infringe the patent while conducting what would have otherwise been non-infringing research.

be invalidated as an unprecedented content-based regulation of thought that ventures far beyond the traditional contours of patent protection.

The *Eldred* court articulated a limited role for the First Amendment in copyright law. “The [Progress] Clause and First Amendment were adopted close in time. This proximity indicates that, in the Framers’ view, copyright’s limited monopolies are compatible with free speech principles. . . . [C]opyright’s build-in free speech safeguards [such as fair use and the idea/expression distinction] are generally adequate to address [First Amendment concerns].” *Id.* at 219, 221.

Nonetheless, copyright law could still run afoul of the First Amendment. The Court noted that copyrights were not “categorically immune from challenges under the First Amendment.” *Id.* at 221 (internal quotations omitted). Where Congress “alter[s] the traditional contours of copyright protection,” First Amendment scrutiny may be necessary. *Id.*

Speech plays a very different role in patents and copyrights. Copyright law inherently restricts the dissemination of copyrighted materials that would otherwise constitute protected First Amendment activity. The *Eldred* majority’s observation that the Framers must have viewed “copyright’s limited monopolies” as “compatible with free speech principles” is understandable.

In contrast, patents generally do not raise First Amendment issues. Patent applicants must disclose their inventions to be awarded a patent, and those disclosures are made public and may be widely disseminated. Patent law has not developed the “free speech safeguards” of copyright law because patent

law does not usually exist in tension with First Amendment freedoms.

Because patent law lacks the “free speech safeguards” of copyright law, the patents at issue here should be subject to strict scrutiny because enforcing them places individuals who think particular thoughts, after doing otherwise non-infringing activity, at risk of punishment.

Even if patent law is subject to the limited First Amendment protections described in *Eldred*, these patents should be invalidated. *Eldred* specified that copyrights could require First Amendment scrutiny if “the traditional contours of copyright protection” were altered. *Id.* The patents at issue here represent an unprecedented departure from the traditional contours of patent protection. Patents have traditionally protected *objects* and *actions*.<sup>14</sup> Only recently have parties sought patent protection for claims which final element encompasses *pure thought*. The patents at issue here extend far beyond the traditional contours of patent protection and have frightening First Amendment implications. Even if they cover otherwise patentable subject matter, the claimed patents should be invalidated as unconscionable violations of the freedom of thought.

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<sup>14</sup> The objects may be animate or inanimate. *See, e.g., Chakrabarty*, 447 U.S. at 310.

## CONCLUSION

Thomas Jefferson, the author of the Patent Act of 1793, was one of the key framers of this country's intellectual property jurisprudence. In 1966, the Supreme Court thus characterized his views on the subject:

[Jefferson believed] [t]he patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given.

*Graham*, 383 U.S. at 8-9.

Enforcing the patents at issue here will not “bring forth new knowledge.” *Id.* at 9. Instead, it would further an improvident and unconstitutional expansion of patentable subject matter which has primarily served to slow rather than to spur innovation.

Continuing on this path by permitting medical-diagnostic patents will only serve to further slow the economy, retard technological innovation, distort the free market, and place human health at risk.

The Federal Circuit's judgment should be reversed.

Respectfully submitted,

CHRISTINA MULLIGAN  
Information Society Project  
Yale Law School  
127 Wall St.  
New Haven, CT 06511  
(617) 797-8605

ILYA SHAPIRO  
*Counsel of Record*  
JAMES W. HARPER  
Cato Institute  
1000 Mass. Ave., N.W.  
Washington, DC 20001  
(202) 842-0200  
ishapiro@cato.org

MANUEL S. KLAUSNER  
Law Offices of Manuel S.  
Klausner, P.C.  
One Bunker Hill Building  
601 W. Fifth St., Suite 800  
(213) 617-0414

SAM KAZMAN  
Comp. Enterprise Institute  
1899 L St., N.W., 12<sup>th</sup> Floor  
Washington, DC 20036  
(202) 331-2265

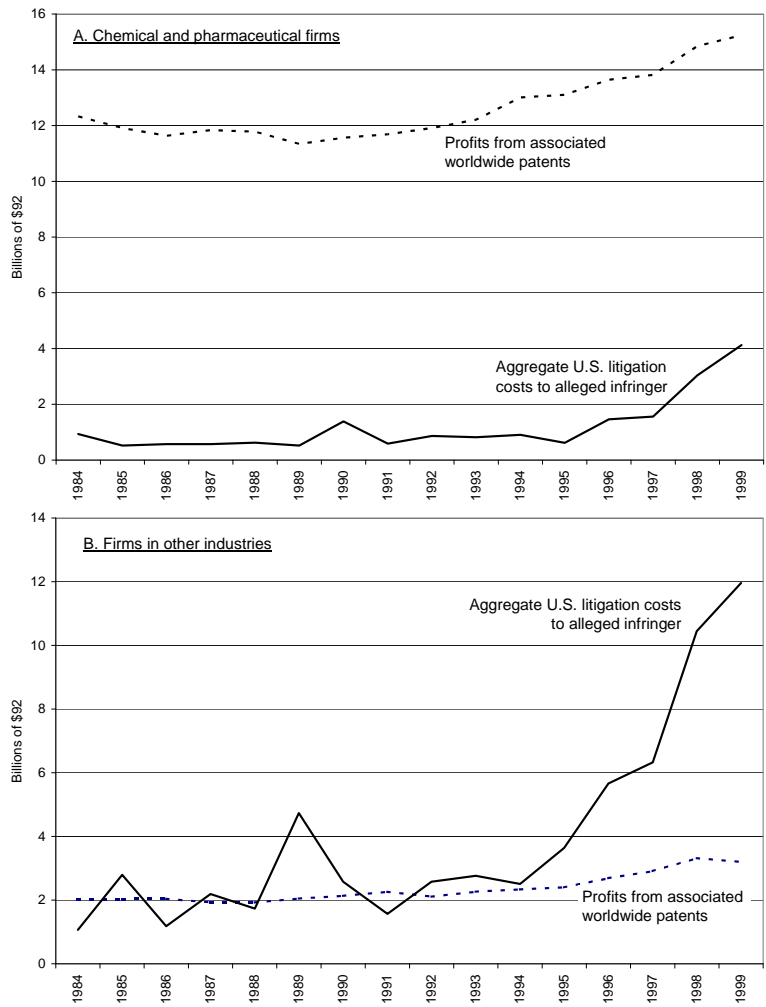
*Counsel for Amici Curiae*

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**APPENDIX A**

**Patents, Profits, and Costs**

Aggregate profits from patents and aggregate litigation costs for U.S. public firms.



James Bessen & Michael J. Meurer, *Of Patents and Property*, Regulation Mag. 18, 25 (Winter 2008/2009).