No. 08-964

In The Supreme Court of the United States

BERNARD L. BILSKI AND RAND A. WARSAW,

Petitioners,

v.

JOHN J. DOLL, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF GEORGIA BIOMEDICAL PARTNERSHIP, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST OF THE *AMICUS CURIAE*

Georgia Biomedical Partnership, Inc. d/b/a Georgia Bio ("GaBio") is a non-profit, membership-based organization that promotes the interests and growth of the life sciences industry in Georgia. Members include companies, universities, research institutions, government groups and other industry associations involved in the discovery and application of life sciences products and related services that improve the health and well-being of people throughout the world. GaBio is the Georgia state affiliate of the Washington, D.C.-based Biotechnology Industry Organization (BIO).[1]

GaBio has an interest in this matter. GaBio submits that the Federal Circuit's decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), will reduce the value of patents held by members of GaBio, as well as others in the biotechnology industry. GaBio further states that a broad reading of "patent-eligible subject matter" benefits the biotechnology industry because the limited monopoly provided by patent protection is often necessary to compensate for the large investment needed to bring

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[1] Petitioners have consented to the filing of all *amicus curiae* briefs in support of either or neither party. Respondent has consented to the filing of this *amicus curiae* brief on behalf of GaBio. Pursuant to Rule 37.6, the *amicus* states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

biotechnology inventions to the public. Without the incentive of patent protection, many biotechnology inventions would not be developed for public use.

SUMMARY OF THE ARGUMENT

GaBio submits this *amicus* brief in support of Petitioners because this case is of special importance to the biotechnology and pharmaceutical industries. As Petitioners note, this case involves the most basic question in patent law: what is patentable? The Patent Code and this Court's decisions on this question support a broad view of what is patent eligible, with only limited exceptions. The Federal Circuit's decision in this case cuts off significant technologies from patent protection.

Although Petitioners' invention is a method of hedging financial risk (a so-called "business method patent"), the test adopted by the Federal Circuit to determine what is patent eligible can be, and already has been, applied to strike down a broad class of biotechnology and medical inventions, as pointed out by Petitioners. These types of biotechnology and medical inventions have long been patented, have been specifically considered by Congress and affirmatively included in the Patent Code, have considerable value to the public, and require patent protection to ensure their development. Without the limited monopoly provided by patent protection, the biotechnology and pharmaceutical industries cannot and will not make the large investments needed to commercialize these inventions for the benefit of the public. For this reason, this case has significance far beyond Petitioners' invention or even Petitioners' industry.

The Patent Code defines what can be patented. Included within this defined patent-eligible subject matter are processes. At the core of this case is the determination of the meaning and scope of "process." As defined in the Patent Code, a process includes a new use of a known process, machine, manufacture, composition of matter, or material. 35 U.S.C. § 100(b). Although the scope of a "process" as defined by the Patent Code is broad, this Court has determined that some limited subject matter is not patent eligible. In particular, this Court has held that "laws of nature, natural phenomena, and abstract ideas" are not patent eligible. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). In a misguided attempt to provide a definitive rule for determining what is patent eligible, the Federal Circuit adopted a mandatory test (referred to as the "machine-or-transformation" test) that, while purporting to define this Court's limited exceptions to patent-eligible subject matter, actually excludes far more inventions than those amounting to laws of nature, natural phenomena, and abstract ideas.

GaBio joins Petitioners' arguments and further submits that: (1) the Federal Circuit's "machine-or-transformation" test conflicts with Supreme Court precedent declining to adopt a rigid test for determining patent-eligible subject matter; and (2) the "machine-or-transformation" test conflicts with the proper construction of federal law defining what is a patent-eligible process.

The Federal Circuit held that its test was the *only* applicable test and required that the U.S. Patent & Trademark Office and lower courts apply this test when determining what is patent eligible. *Bilski*, 545 F.3d at 954, 964. Such a requirement

clearly contradicts this Court's precedent, which has been careful not to establish a single test or formula for determining patent eligibility, recognizing that one size does not fit all inventions.

The Federal Circuit formulated its test as a "gateway" test for patent eligibility. An invention is patent eligible *only* if it meets the test. In other words, the Federal Circuit's test determines whether an invention *is* patent eligible. This too contradicts this Court's precedent, which consistently seeks to determine if the invention at hand is *not* patent eligible. This Court's jurisprudence aligns more closely with a "culling" test than a "gateway" test. This Court carefully "culls" subject matter that is not patent eligible rather than applying a one-size-fits-all test of patent-eligible subject matter.

In addition, the Federal Circuit's mandatory test excludes from the definition of "process" in one section of the Patent Code processes that are specifically contemplated as patent eligible in other sections of the Patent Code. This is contrary to the Patent Code and to the rules of statutory construction.

Accordingly, this Court should reverse the Federal Circuit's decision and correct the Federal Circuit's improper adoption of the inappropriately narrow and rigid "machine-or-transformation" test.

ARGUMENT

I. THE FEDERAL CIRCUIT'S "MACHINE-OR-TRANSFORMATION" TEST CONFLICTS WITH SUPREME COURT PRECEDENT DECLINING TO ADOPT A RIGID TEST FOR DETERMINING PATENT-ELIGIBLE SUBJECT MATTER

The Framers of the United States Constitution recognized the importance of patents when they empowered the U.S. Congress "[t]o promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8, cl. 8. Based on this authority, Congress established a patent system early in our country's history. Congress codified this broad and open-ended power to promote the progress of science and the useful arts in what is now Title 35 of the United States Code. Section 101 of Title 35 defines what qualifies for patent protection:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101.

A. The Federal Circuit's "Machine-Or-Transformation" Test Is Too Rigid And Categorical

In *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc), the Federal Circuit adopted a single test, the so-called "machine-or-transformation" test, as the exclusive and mandatory test for determining patent-eligible subject matter. In doing so, it incorrectly characterized Supreme Court precedent as follows: "The Supreme Court … has enunciated a *definitive* test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than pre-empt the principle itself." *Id.* (emphasis added). The Federal Circuit went on to determine that the "machine-or-transformation" test was the exclusive test for patent-eligible subject matter:

> Neither the PTO nor the courts may pay short shrift to the "machine-or-transformation" test by using purported equivalents or shortcuts such as a "technological arts" requirement. Rather, the "machine-or-transformation" test *is the only applicable test and must be applied*, in light of the guidance provided by the Supreme Court and this court, when evaluating the patent-eligibility of process claims.

Id. at 964 (emphasis added).

With the Federal Circuit's mandate in *Bilski* that the "machine-or-transformation" test is the *only*

test for determining patent-eligible subject matter, the Federal Circuit contradicts this Court's precedent applying § 101 of the Patent Code, as well as this Court's avoidance of rigid and categorical rules for determining fact dependent inquiries in the complex area of patent law. For at least this reason, this Court should reverse.

B. Supreme Court Precedent On Patent Eligibility Is Flexible And Permissive

In adopting the "machine-or-transformation" test as the exclusive test for determining patent-eligible subject matter, the Federal Circuit cited *Diamond v. Diehr*, 450 U.S. 175 (1981), *Gottschalk v. Benson*, 409 U.S. 63 (1972), and *Parker v. Flook*, 437 U.S. 584 (1978). However, *Diehr*, *Benson*, and *Flook* do not mandate any exclusive, rigid test for determining patent-eligible subject matter, much less the "machine-or-transformation" test. Indeed, this Court has found that no collection of tests is even sufficient to define patent-eligible subject matter.

In *Benson*, this Court held that a particular algorithm for converting numerals in binary coded decimal form to numerals in binary form was not patent-eligible subject matter under § 101. 409 U.S. at 71-72. After reviewing the Court's prior cases on patent-eligible subject matter, the Court specifically declined to hold that "a process patent must either be tied to a particular machine or apparatus or must operate to change articles to a 'different state or thing.'" *Id.* In fact, the Court went further, stating that "[w]e do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents," *id.* at 71, thus signaling that

no prior holding or combination of holdings on patent eligibility affirmatively defines the limits of patent-eligible subject matter. Hence, the Court rejected a single, categorical test—or even a combination of tests—for patent-eligible subject matter.

In *Flook*, this Court solidified *Benson's* rejection of the notion that any of the Court's previous tests could be dispositive, stating: "[a]s in *Benson*, we assume that a valid process patent may issue even if it does not meet one of these qualifications of our earlier precedents." 437 U.S. at 588 n.9. This language was selectively quoted in *Bilski*, but was editorially changed. Specifically, the Federal Circuit replaced "one of these qualifications of our earlier precedents" with "[the machine-or-transformation test]," thus obscuring *Flook's* conclusion that even the totality of this Court's precedents cannot be applied as a litmus test. *Id.*; *Bilski*, 545 F.3d at 956.

Diehr merely identified the "machine-or-transformation" test as one way of determining patentability. The *Diehr* Court held that a process for curing synthetic rubber that included the use of a mathematical formula was patent-eligible subject matter under § 101. 450 U.S. at 192-93. In analyzing the claimed process, the Court noted that "a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patent-eligible subject matter. That respondents' claims *involve the transformation of an article*, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed." *Id.* at 184 (emphasis added).

Thus, *Diehr* involved a process in which a transformation of an article took place. Because the "machine-or-transformation" test is permissive, as indicated in the prior cases of this Court, and because the process in *Diehr* involved a transformation, this Court appropriately applied it there. However, that such a process fell within the subset of the Court's cases involving the transformation and reduction of an article to a different state or thing does not establish that such was the *only* test intended by this Court, or the only basis on which a process can qualify as patent-eligible subject matter under § 101. Rather, the Federal Circuit misinterpreted this Court's precedent, which is merely consistent with the inclusion of the "machine-or-transformation" test as one way of determining patent eligibility, as mandating the "machine-or-transformation" test.

C. The Federal Circuit's "Machine-Or-Transformation" Test Conflicts With The Supreme Court's Approach To Patent Eligibility

As set forth above, GaBio agrees with Petitioners that the rigid application of the "machine-or-transformation" test conflicts with this Court's previous patent-eligible subject matter holdings. In addition, the very manner in which the Federal Circuit framed the question of what is patent-eligible subject matter as a rigid exclusionary test flatly contradicts prior direction from this Court on this issue. The Federal Circuit seeks to take many tests and many ways of determining how to identify what is patent eligible from its own jurisprudence and condense them to a single test. However, prior jurisprudence from this Court

indicates that each test, and each way of determining patent-eligible subject matter, is permissive and that they are to be used as tools to verify that a claimed process is not disqualified as "a 'process' within the meaning of the Patent Act." *Benson*, 409 U.S. at 64; *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (product not patent eligible because the qualities of the product are manifestations of laws of nature); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) (product created by applying a scientific truth is patent eligible); *Waxham v. Smith*, 294 U.S. 20, 21-22 (1935) (method that achieves a function is not unpatentable as an attempt to patent the function performed or a natural law); *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 385-86 (1909) (method involving mechanical operations but not chemical transformation is patent eligible); *Dolbear v. American Bell Tel. Co.*, 126 U.S. 1, 534-35 (1888) (method using altered electrical current to transmit speech is patent eligible); *Tilghman v. Proctor*, 102 U.S. 707, 729 (1880) (process of chemical transformation not limited to a particular means or apparatus is patent eligible); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876) (process to achieve a result is patent eligible regardless of what instrument or machine is used to effect that result); *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874) (device embodying and applying an idea is patent eligible); *Corning v. Burden*, 56 U.S. 252, 268 (1853) (use of a machine to continuously process iron is not a patent-eligible method because it represents the function of the machine); *O'Reilly v. Morse*, 56 U.S. 62, 112-13 (1853) (method of using electromagnetism is not patent eligible as an attempt to protect a power of

nature); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (process applying a principle is patent eligible).

This Court has consistently held that there are many ways to define patent-eligible subject matter and that the use of precedents should be *inclusive* rather than *exclusive*. This comports with the broad notion of patent-eligible subject matter starting with the U.S. Constitution and continuing through each iteration of the Patent Code, especially the broad definition of patent-eligible subject matter in § 101. It is much more logical and sensible to determine whether a particular process before an examiner or a court is *not* patent eligible than to try to define—for all time, in all circumstances, and in one test—what *is* patent eligible. Determining what is not patent eligible is precisely how this Court has consistently handled the question. A condensation of *Diehr*, *Benson*, and *Flook*, as well as other prior cases, reveals that this Court has chosen to provide relatively clear direction as to what is *not* patent eligible (indicating that laws of nature, natural phenomena, and abstract ideas cannot be patented per se), as opposed to what *is* patent eligible.

Indeed, *Diehr*, far from validating *Bilski's* "machine-or-transformation" test, confirms and distinguishes the application of different principles for determining patent-eligible subject matter. *Diehr* actually recites with favor a more general test of patent-eligible subject matter: "It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." 450 U.S. at 188 (emphasis in original). The broad test set forth in *Diehr* in effect limits the exclusion of subject matter from patent eligibility. Even though

Diehr involved a process that transformed an article, the holding in *Diehr* was not based on the "machine-or-transformation" dichotomy of *Bilski*:

> On the other hand, when a claim containing a mathematical formula *implements or applies* that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.

Id. at 192 (emphasis added). Thus, contrary to the reasoning in *Bilski*, *Diehr* does not establish or support the "machine-or-transformation" test as the only test for determining patent-eligible subject matter. Instead, the rigid "machine-or-transformation" test of *Bilski* conflicts with this Court's precedent.

D. The Federal Circuit's "Machine-Or-Transformation" Test Conflicts With The Supreme Court's Interpretation Of The Patent Statute

The Federal Circuit in *Bilski* also failed to give sufficient weight to the constitutional and statutory source of patent-eligible subject matter. The Constitution grants Congress broad power to promote the progress of science and the useful arts. Under this broad power, Congress has enacted a broad definition of patent-eligible subject matter. As this Court has repeatedly noted, the definition and

scope of patent-eligible subject matter provided in § 101 is broad and without specific limits. *See Diehr*, 450 U.S. at 188; *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980) (statutory subject matter intended to include "anything under the sun that is made by man") (citations omitted); *Flook*, 437 U.S. at 588 n.9 ("As in *Benson*, we assume that a valid process patent may issue even if it does not meet one of these qualifications of our earlier precedents"); *Benson*, 409 U.S. at 71 ("We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents").

It is in this context that this Court has found careful, *limited* exceptions to the statutory mandate of broad patent-eligible subject matter. The Patent Code does not provide any exceptions and so, appropriately, this Court has made them of the most limited scope. The exceptions are rooted in the principle that only "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67. The Federal Circuit apparently lost sight of this limited basis for exceptions and misread Supreme Court precedent to produce an unwarranted and unsupported extension and expansion of this Court's limited exceptions to patent-eligible subject matter. Neither the Patent Code nor the exception for laws of nature, natural phenomena, and abstract ideas support the *effect* of the Federal Circuit's "machine-or-transformation" test, which is to exclude from patent protection inventions that meet the requirements of the Constitution and the Patent Code.

This Court's framework of finding limited exceptions to patent eligibility is akin to a "culling" of subject matter that is not patent eligible. In contrast, the Federal Circuit's categorical "machine-or-transformation" test is more like a "gateway," through which no invention can pass unless it has the particular attributes of patent-eligible subject matter set forth in *Bilski*. Many sound inventions that should never be culled will be blocked at the Federal Circuit's "machine-or-transformation" gate.

II. THE FEDERAL CIRCUIT'S "MACHINE-OR-TRANSFORMATION" TEST CONFLICTS WITH THE PROPER CONTRUCTION OF FEDERAL LAW

At issue in *Bilski* was the meaning of "process," as used in § 101 of the Patent Code. The § 101 definition of "process" established in *Bilski* contradicts the construction and clear meaning of "process" in other parts of the Patent Code. Because such a conflict between different sections of the same statute cannot stand under clear Supreme Court precedent, *Bilski's* § 101 definition of "process," and the "machine-or-transformation" test that depends on this definition, are inconsistent with federal law. For this reason as well, this Court should reverse.

The area of conflict between the *Bilski* decision and the statute discussed here by GaBio is different from the statutory conflict identified by Petitioners. In this discussion, GaBio demonstrates a broader Congressional intent not to limit patent-eligible subject matter and shows that the Patent Code contemplates and authorizes patent protection for biomedical and biotechnological inventions that

would be excluded from patent eligibility by *Bilski's* "machine-or-transformation" test.

A. Supreme Court Principles Of Statutory Construction Require Harmony Between Different Sections Of The Same Statute

It is a fundamental principle of statutory construction that provisions in the same act are to be construed in harmony. *See Peck v. Jenness*, 48 U.S. 612, 623 (1849). Moreover, an act is to be read as a whole, with an eye to its underlying context, object, and policy. *Richards v. U.S.*, 369 U.S. 1, 11 (1962). "[E]very section, provision, and clause of a statute shall be expounded by a reference to every other; and if possible, every clause and provision shall avail, and have the effect contemplated by the legislature." *Peck*, 48 U.S. at 623. In effecting Congressional intent, courts must "give full effect to all the provisions of the act." *Id.* at 623; *see also Richards*, 369 U.S. at 11 (adopting the construction that is most "consistent with the Act considered as a whole"); *Mastro Plastics Corp. v. National Labor Relations Bd.*, 350 U.S. 270, 286-87 (1956) (rejecting proposed construction of statute because of incongruous effect that would undermine the underlying purpose of the act).

Thus, statutes should be construed with due regard for their counterparts. No interpretation should undermine a neighboring provision without express direction from Congress. *Cf. Peck*, 48 U.S. at 623. In *Bilski*, the Federal Circuit interpreted "process" under § 101 so as to exclude some patent-eligible "uses of compositions" and "biotechnology processes" contemplated under § 287(c) of the Patent

Code, even though the express statutory language does not support or provide for that limitation. Furthermore, the *Bilski* definition of "process" conflicts with the clear meaning of "a new use of a known process" in § 100(b) of the Patent Code. The *Bilski* decision therefore creates disharmony between different sections of the Patent Code (§§ 100(b), 101, and 287(c)) where none need exist and, indeed, where principles of statutory construction provide that it shall not exist. It is possible to interpret "process" so as to give full effect to all patent-eligible processes contemplated by the express terms of §§ 100(b) and 287(c). Section 101's reach should comport with the purposes and expansive intent behind the Patent Code, considering that provision not in isolation, but in harmony with the remainder of the Code.

B. Section 287(c) Of The Patent Code Contemplates As Patent Eligible Biomedical Inventions That Are At Risk Of Exclusion By *Bilski's* "Machine-Or-Transformation" Test

Section 287(c) of the Patent Code contemplates patent protection for biomedical and biotechnological processes excluded by *Bilski's* "machine-or-transformation" test. Because, as set forth above, statutes in the same act are to be construed in harmony and statutes should be construed with due regard to their counterparts, the processes contemplated by § 287(c) must fall within the definition of "process" in § 101 of the Patent Code. Nevertheless, the *Bilski* test impermissibly excludes at least some of the processes contemplated by § 287(c).

Section 287(c) of the Patent Code exempts medical practitioners from patent infringement liability when their performance of a "medical activity" infringes a patent. 35 U.S.C. § 287(c)(1). This exemption is itself limited by the exclusion of three enumerated activities from the definition of "medical activity." *Id.* at § 287(c)(2)(A). Specifically, § 287(c) does not exempt medical practitioners from infringement liability if the activity they perform is "(i) the use of a patented machine, manufacture, or composition of matter in violation of [the] patent, (ii) the practice of a patented use of a composition of matter in violation of [the] patent, or (iii) the practice of a process in violation of a biotechnology patent." *Id.*

As explained below, "use of a composition of matter" and "a process in violation of a biotechnology patent" encompass more processes than just those that transform an article or use a particular machine, as required by the *Bilski* test.[2] 35 U.S.C. § 287(c)(2)(A). Thus, *Bilski's* "machine-or-transformation" test excludes from patent eligibility some processes clearly considered patent eligible in another section of the same statute.

The legislative history of § 287(c) makes the scope of processes contemplated in that section especially clear and highlights the discord between the processes contemplated there and the limited scope of patent-eligible subject matter allowed under *Bilski*. The amendment that became § 287(c) initially proposed barring patents on medical

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[2] GaBio notes that the Patent Code defines a "process" as including "use of a composition of matter." 35 U.S.C. § 100(b).

activities. 142 Cong. Rec. H8275-79 (daily ed. July 24, 1996). Over strenuous objection to the breadth of the amendment—but not to the intent of insulating doctors from certain types of infringement—the Senate version was altered to exempt doctors from infringement liability, but *not* to bar the patenting of medical activities. *Id.* In a discussion of the definition ultimately adopted in § 287(c), the Committee stated:

> 'Uses of compositions of matter' include, without limitation, novel uses of drugs, novel uses of chemical or biological reagents for diagnostic purposes, novel methods for scheduling or timing administration of drugs, novel methods for combining drug therapies, and novel methods for providing genetic or other biological materials to a patient (including gene therapies.) [sic] A particular example would be a claim that recites only the novel use of a drug for the treatment of diabetes that involves the administration of a drug at a particular time of day and/or at a specified dose and/or with a specified concomitant medicinal therapy could not be construed as a 'medical activity.'

H.R. Rep. No. 104-863, at 854 (1996) (Conf. Rep.).

Thus, Congress intended to exclude "uses of chemical or biological reagents for diagnostic

purposes" and "methods for scheduling or timing administration of drugs" from § 287(c)'s definition of "medical activity." *Id.* Congress contemplated these activities as the subject of patents and thus as patent-eligible subject matter. Yet, many such "uses of chemical or biological reagents for diagnostic purposes" and "methods for scheduling or timing administration of drugs," *id.*, may not involve the "transformation of an article" or the use of a "particular machine," as required in *Bilski's* "machine-or-transformation" test. *Bilski*, 545 F.3d at 954. An example of this is discussed below. Thus, the *Bilski* test excludes from patent eligibility some processes considered patent eligible in another section of the same statute.

GaBio sees special urgency for the present case to correct this conflict with § 287(c) of the Patent Code because the Federal Circuit has already used the *Bilski* test to invalidate a claim that both uses a "chemical or biological reagent[] for diagnostic purposes" and is a "method[] for scheduling or timing administration of drugs." H.R. Rep. No. 104-863, at 854 (1996) (Conf. Rep.). In *Classen Immunotherapies, Inc. v. Biogen Idec*, 304 Fed. Appx. 866, 2008 WL 5273107, at *1 (Fed. Cir. 2008), in a one paragraph opinion, the Federal Circuit held that a claim to a method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder failed the *Bilski* "machine-or-transformation" test. Thus, although the *Classen* claim arguably fell within the meaning of § 287(c)(2)(A), the Federal

Circuit held that it fell outside the definition of a process in § 101.[3]

The claim at issue in *Classen* reads:

> A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more *immunogens*, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

U.S. Pat. No. 5,723,283, claim 1 (emphasis added); *see also Classen Immunotherapies, Inc. v. Biogen Idec*, Civil No. WDQ-04-2607, 2006 WL 6161856, at *5 (D. Md. Aug. 16, 2006), *aff'd*, 304 Fed. Appx. 866 (Fed. Cir. 2008).

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[3] Notably, 35 U.S.C. § 287(c) was not at issue in *Classen*. However, the claim in *Classen* is an example of the type of invention that § 287(c) may have contemplated as patent eligible, and the Federal Circuit's invalidation of that claim using *Bilski's* "machine-or-transformation" test is inconsistent with the scope of patent-eligible biomedical processes, as established in § 287(c) of the Patent Code.

Without commenting on whether the claim at issue in *Classen* should or should not fall within the § 287(c) exemption, one cannot doubt that Congress understood that § 101 encompassed the type of activity embodied by the *Classen* claim when it amended the Patent Code by adding § 287(c) precisely to address such activities by doctors. The *Bilski* "machine-or-transformation" test thus unduly restricts Congressional intent regarding what can be a patent-eligible process.

One can also analyze the *Classen* claim from the perspective of § 287(c)'s "process in violation of a biotechnology patent." 35 U.S.C. § 287(c)(2)(A). While the Patent Code itself does not define "biotechnology patent," during the legislative process, Congress stated that a biotechnology patent is "… a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level." H.R. Rep. No. 104-863, at 854 (1996) (Conf. Rep.). Congress went on to state:

> Biological materials which may be manipulated *ex vivo* at the cellular or molecular level include a variety of cellular, intracellular, extracellular, and acellular substances. Cellular substances include (but are not limited to) cultured microbial and mammalian cells. Intracellular substances include (but are not limited to) genetic materials, such as DNA and RNA that is obtained from within the cell. Extracellular

> substances include (but are not limited to) proteins and other molecules that are secreted or excreted by cells. Acellular substances include (but are not limited to) viruses and other vectors for transmitting genetic material. *Ex vivo* manipulation includes propagation, expansion, selection, purification, pharmaceutical treatment, or alteration of the biological characteristics of these substances outside of a human body.

Id.

The "immunogen" of the *Classen* claim can be considered a "biological material" because immunogens commonly include "proteins and other molecules that are secreted or excreted by cells," which are mentioned in the Congressional Report. *Id.* Thus, the *Classen* claim can be considered a "biotechnology process." Because Congress, in enacting § 287(c), contemplated that such claims are patent eligible, and because *Bilski's* "machine-or-transformation" test excluded the *Classen* claim from patent eligibility, *Bilski* conflicts with the proper interpretation of the Patent Code as a whole.

C. Section 100(b) Of The Patent Code Defines As Patent Eligible Inventions That Are At Risk Of Exclusion By *Bilski's* "Machine-Or-Transformation" Test

The *Bilski* "machine-or-transformation" test also conflicts with § 100(b) of the Patent Code, which

provides definitions for the Patent Code, including § 101. Section 100(b) reads: "The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b). Thus, patent-eligible subject matter under § 101 includes a new use of, for example, a composition, such as a drug. Many uses of compositions are not tied to a particular machine and might be considered not to involve a transformation to a new state or thing. For example, a known chemical compound may be discovered to be useful to treat a particular disease. This would be a "new use of a known … composition of matter." *Id.* If the compound is administered using known and conventional techniques, this use arguably would not be tied to a "particular machine" and might be considered not to involve "a transformation to a new state or thing" as required under the *Bilski* "machine-or-transformation" test.[4] The result would be to exclude from patent eligibility an invention falling within the definition of "process" in § 100(b). Thus, it is clear that *Bilski's* rigid "machine-or-transformation" test excludes from patentability some processes plainly contemplated in § 100(b).

Indeed, the *Classen* claim could be considered a new use of a composition of matter. The immunogen in the *Classen* claim is a composition of

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[4] GaBio does not take a position for the purpose of this *amicus curiae* brief regarding whether a compound administered to a patient does or does not involve "a transformation to a new state or thing" so as to satisfy the *Bilski* "machine-or-transformation" test. Rather, GaBio points out the error and harm that result when no such transformation is found.

matter, and the claim includes a method of using the immunogen—"immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens." U.S. Pat. No. 5,723,283, claim 1. Thus, the *Classen* claim falls within the definition of a patent-eligible process in § 100(b). However, the Federal Circuit has already applied the *Bilski* test to the *Classen* claim and held it not to be patent eligible. Because such a result conflicts with § 100(b) of the Patent Code, the rigid *Bilski* "machine-or-transformation" test, which has the effect of pitting one section of the Patent Code against another, is contrary to established tenets of statutory construction.

In short, *Bilski's* definition of "process" will exclude from patent eligibility many claims that are patent eligible according to settled expectations, and at worst will carve out entire areas of subject matter from patent eligibility because they do not transform an article. *See, e.g., Classen*, 304 Fed. Appx. at 866. *Bilski's* "machine-or-transformation" test is so broad that it undermines clear Congressional intent and proper statutory construction as to what "processes" are patent eligible under § 101.

Although Washington and Jefferson could not have envisioned such a method as the one in *Classen* when the first U.S. patent for a "process" of making potash (U.S. Patent X000001) was issued, GaBio submits that the Framers would have intended, and Congress has so determined, that Article I, section 8 of the Constitution covers this modern day process and many others like it. The conflict between the test articulated in *Bilski* and other sections of the Patent Code, as well as the violation of this Court's statutory construction precedent by the *Bilski* court,

require that the Supreme Court reverse the Federal Circuit's decision in *Bilski* and its adoption of a mandatory "machine-or-transformation" test.

CONCLUSION

The Federal Circuit's "machine-or-transformation" test conflicts with this Court's precedent declining to adopt a rigid test for determining patent-eligible subject matter, as well as with the proper construction of federal law defining what is a patent-eligible process.

The Federal Circuit's test is formulated as a "gateway" test of what is patent eligible. This is contrary to this Court's precedent, which consistently seeks to determine if the invention at hand is *not* patent eligible, in keeping with this Court's limited exceptions to patent-eligible subject matter. Only if an invention is clearly not patent eligible under these limited exceptions has this Court excluded the invention from patent protection.

In addition, the Federal Circuit's mandatory test excludes from the definition of "process" in one section of the Patent Code—and thus excludes from patent protection—biotechnology and medical processes that are specifically contemplated as patent eligible in other sections of the Patent Code. This conflict between sections of the Patent Code is contrary to the rules of statutory construction.

Accordingly, the Court should reverse the Federal Circuit's improper adoption of the inappropriately narrow and rigid "machine-or-transformation" test.

Respectfully Submitted,

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