2010-1406

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant,

and

MYRIAD GENETICS, INC.,
Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE,
RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS,
THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG,
in their official capacity as Directors of the University of Utah Research Foundation,
Defendants-Appellants.

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

BRIEF OF *AMICUS CURIAE* ALNYLAM PHARMACEUTICALS, INC. IN SUPPORT OF DEFENDANTS-APPELLANTS, SUPPORTING REVERSAL

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STATEMENT OF INTEREST OF THE *AMICUS CURIAE*

I. IDENTIFICATION OF *AMICUS CURIAE* ALNYLAM PHARMACEUTICALS, INC.

Alnylam Pharmaceuticals, Inc. ("Alnylam") is a biopharmaceutical company based in Cambridge, Massachusetts. Alnylam is a leader in an emerging biotechnology therapeutic approach, based upon the principle of a mechanism to silence specific genes that blocks their production of abnormal proteins that are central to most human disease.

II. ALNYLAM'S INTEREST IN THIS ACTION

Alnylam's issues of interest in this action are:

1. Macroscopically, consistent with the international obligations of the United States under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), whether the open door to patent-eligibility under 35 U.S.C. § 101 should remain open for all "field[s] of technology" without prejudice to individual patentability determinations for novelty, nonobviousness, formal requirements and enforceability considerations (e.g., 35 U.S.C. §§ 102, 103(a), 112, & 282(1)); and

2. More specifically, whether the *Bergy* open door to patent-eligibility for any "composition of matter" under Section 101 should remain open where the properties of the composition of matter are based upon a phenomenon of nature – or whether the Court should judicially legislate an exclusion from patent-eligibility

for specific, concrete "compositions of matter," merely because their properties are based upon natural phenomena.

Alnylam has no interest in whether the particular patented invention at issue does or does not meet standards of novelty (35 U.S.C. § 102), nonobviousness (35 U.S.C. § 103) or written description and particularity (35 U.S.C. § 112). Nor is Alnylam concerned with issues of enforceability based upon the manner of enforcement of the patent rights at issue. Rather, Alnylam's sole concern as *amicus* is to support the traditional interpretation of "composition of matter" under Section 101 as embracing all forms of compositions – including compositions which are derived from natural products and which derive their beneficial effect from their interactions with natural phenomena. (Whether such patent-eligible subject matter is then patentable depends upon whether the statutory conditions of Sections 102, 103 and 112 are satisfied, and whether a thus-obtained patent is enforceable depends on, *inter alia*, equitable issues under Section 282(1)).

Critical to Alnylam's therapeutic approach is the discovery of "small interfering RNAs" (siRNAs) which bind to messenger RNAs (mRNAs) and silence the disease-causing gene. Patent protection for the synthetic siRNA molecules is absolutely vital to recoup development costs. (The field of RNAi which includes the research and development of synthetic siRNA molecules is explained in more detail on Alnylam's website. *See About RNAi*, ALNYLAM.COM,

http://www.alnylam.com/Leadership-in-RNAi/About-RNAi/ index.php (last visited Sept. 1, 2010).) Alnylam faces the classic challenges for any new, emerging technology, particularly biotechnology where there is a long backlog of cases in the United States Patent and Trademark Office (USPTO). The company has over fifty published patent applications, filed since 2003, that are now in the queue awaiting examination. Alnylam's broad RNAi portfolio contains additional licensed applications that are also in the queue. All of these applications are in the RNAi field and describe inventions that involve, in some manner, synthetic siRNA molecules. Alnylam thus has an interest in asking the Court to provide clear guidance on patent-eligibility to remove the unnecessary cloud cast by the decision below.

While Alnylam's business model depends upon the patent-eligibility of its synthetic molecules, Alnylam also acknowledges the responsibility it has to share its information with the public as well as its peers, as shown by its many publications in peer-reviewed scientific journals such as *Nature*, *Nature Medicine*, *Nature Biotechnology*, and *Cell*. In addition to furthering the public knowledge of the RNAi field and its potential to provide new therapies for patients, Alnylam has been at the forefront of this developing field not only through its own research, but also through the financial and scientific support of numerous collaborators, including some of the world's preeminent research laboratories and academic

institutions. Alnylam believes that its numerous publications, collaborations, and support of independent research are important measures of a scientific leader in the RNAi field. Alnylam's commitment to developing RNAi-based therapeutics for the public good is exemplified by its participation in the Pool for Open Innovation Against Neglected Tropical Diseases, a patent pool where Alnylam provides RNAi intellectual property, technology and know-how on a royalty-free, non-profit basis in the least developed countries. Alnylam's activities in the RNAi field demonstrate to leading academic scientists, clinicians, pharmaceutical executives and the public the potential of RNAi-based therapeutics and the impact these therapeutics would have on the treatment of patients. *See Leadership in RNAi*, ALNYLAM.COM, http://www.alnylam.com/Leadership-in-RNAi/index.php (last visited Sept. 1, 2010).

III. ALNYLAM'S AUTHORITY TO FILE

All parties have consented in writing to Alnylam's filing of this amicus brief. Consequently, in accordance with Federal Rule of Appellate Procedure 29(a) (amicus brief may be filed "if the brief states that all parties have consented to its filing"), no motion for leave to file has been submitted.

SUMMARY OF THE ARGUMENT

The modern field of biotechnology has been domestically keyed to the landmark opinion *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979) (Rich, J.), and the

imprimatur given *Bergy* through Supreme Court affirmance in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). These rulings kept the door of patent-eligibility wide open for any "composition of matter" under 35 U.S.C. § 101 – without prejudice as to whether an individual patent-eligible composition of matter was patentable based upon considerations of novelty, nonobviousness, formal matters or enforceability issues under 35 U.S.C. §§ 102, 103(a), 112, and 282(1). *Bergy* is on all fours with the issue of patent-eligibility. In *Chakrabarty*, the Supreme Court affirmed the *Bergy* holding of patent-eligibility for microorganisms, inventions that are the epitome of innovation keyed to principles which may be called "nature's secrets."

Furthermore, judicial exclusion of certain "compositions of matter" from patent-eligibility would take an unambiguous term and move the United States into an interpretation of law that is inconsistent with its international treaty obligations, contrary to the rule laid down by Chief Justice John Marshall more than 200 years ago in *Murray v. Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64 (1804). To spread the cost of development on a global basis and also provide the benefits of the positive approach of *Bergy* and other decisions supporting strong minimum protection concepts, the United States pioneered the adoption of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) that includes the promise of each World Trade Organization member state to provide "patents … and patent

rights enjoyable without discrimination as to … the field of technology[.]" TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

ARGUMENT

I. *BERGY*'S PATENT-ELIGIBLE MICROORGANISMS: EPITOME OF "NATURE'S SECRETS"

The consolidated appeal decision of Messrs. Malcolm E. Bergy *et al.* and Ananda M. Chakrabarty styled as *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), held that the specific microorganism inventions in each case were directed to patent-eligible subject matter under 35 U.S.C. § 101. *Bergy* was affirmed *sub nom Diamond v. Chakrabarty,* 447 U.S. 303 (1980), thus putting the imprimatur of the Supreme Court on the wisdom of Judge Rich in *Bergy.*[1] While numerous organic chemistry inventions are derived from various steroid, prostaglandin or other ring structures and thus have activity coupled to "nature's secrets," the epitome of an

[1] Certiorari was granted as to both *Bergy* and *Chakrabarty sub nom Diamond v. Bergy,* 444 U.S. 924 (1979). The *Chakrabarty* test case was seen as a better vehicle for Supreme Court consideration, as it dealt with microorganisms to "eat" oil in oil slicks as opposed to the pharmaceutical application of the *Bergy* microorganism. Subsequently, the claim in controversy in *Bergy* was cancelled, causing the *Bergy* appeal to be vacated as moot. *See Diamond v. Chakrabarty,* 444 U.S. 1028 (1980).

invention keyed to a secret of nature is a microorganism as in both the *Bergy* and *Chakrabarty* appeals.

A. A Microorganism is a Patent-Eligible "Composition of Matter"

Bergy held that a microorganism, *per se,* is patent-eligible subject matter under Section 101, whether in the form of a biologically pure culture (Bergy) or a man-modified version (Chakrabarty). The Court of Customs and Patent Appeals stated that "Bergy's and Chakrabarty's appealed claims define[d] subject matter that falls within the categories named in § 101 and are thus 'statutory subject matter.'" *Id.* at 973; *see id.* at 987 (holding that inventions "clearly fit[] into the plain terms . . . 'compositions of matter.').

The Court also ruled that "it is not necessary that Congress shall have *foreseen* a new field of technology or useful art to bring it within § 101. . . . Clearly, the language Congress chose to use in § 101 fairly brings the appealed claims within the statute. To insist on specific Congressional foresight in construing § 101 would be the very antithesis of the Constitutional and Congressional purpose of stimulating the creation of new technologies – by their nature unforeseeable – and their progressive development." *Id.* (citing *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1859)) (emphasis in original). The Court further opined:

> The present recital of categories in § 101, '*Any* new and useful process, machine, manufacture, or composition of matter, or *any* new

> and useful improvement thereof' (our emphasis), has been the same ever since the Patent Act of 1793, except for substituting 'process' for 'art' and defining it (§ 100(b)) to include art. For the nearly 200 years since, those words have been liberally construed to include the most diverse range imaginable of unforeseen developments in technology. The list is endless and beyond recitation. We merely suggest that the Founding Fathers and the Congresses of the past century could not have foreseen the technologies that have allowed man to walk on the moon, switch travel from the railroads to heavier-than-air craft, fill our houses with color TV, cure normally fatal diseases with antibiotics produced by cultures of molds (microorganisms), and give to schoolchildren at small cost pocket calculators with which they can produce square roots in microseconds through complex electronic circuitry on an 'IC' (integrated circuit) so small the circuits are not visible to the naked eye."

Id. at 973-74 (footnote omitted).

B. Debunking Myths of *Funk Bros. Seed Co. v. Kalo Inoculant Co.*

As discussed in more detail *infra* at paragraph I(C)(3), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) concerned a claim to a new mixture of individually old bacteria, analyzed under pre-1952 standards for nonobviousness, and is not relevant to today's standards for patent-eligibility under Section 101 in light of *Chakrabarty* and *Bergy*. If the discovery of the properties of Bond's synergistic mixture of bacteria in *Funk* flowed from "nature's secret," (333 U.S. at 132,) so too do vast areas of modern technology find their origins in "nature's secrets." As explained in *Bergy*, ". . . microbiological processes have long been used to make beer, wine, cheese, bread, pickles and sauerkraut, rett flax, age tobacco, bate leather, produce silage and digest sewage. . . . [T]hey have come to

be used to produce a vast variety of chemicals and drugs such as alcohols, ketones, fatty acids, amino acids, vitamins, antibiotics, steroids, and enzymes." 596 F.2d at 975. *Bergy* also notes the many "chemical reactions carried out by microorganisms . . . which include oxidation, reduction, condensation, esterification, amination, deamination, phosphorylation, hydrolysis, decarboxylation, methylation, dismutation, acrylation, and dehydration." *Id.*

The *Bergy* Court concluded,

> . . . In short, microorganisms have long been important tools in the chemical industry, especially its pharmaceutical branch, and when such a useful, industrial tool is invented which is new and unobvious, so that it complies with those conditions for patentability, we see no reason to deprive it or its creator or owner of the protection and advantages of the patent system by arbitrarily excluding it at the outset from the § 101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. The law has long and unhesitatingly granted patent protection to new, useful, and unobvious chemical compounds and compositions, in which category are to be found such important *products* of microbiological process as vitamin B-12 and adrenalin and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves, or to pure microorganism cultures, – the tools used by chemical manufacturers in the same way as they use chemical elements, compounds, and compositions – when they are new and unobvious. In fact, we see no *legally* significant difference between active chemicals which are classified as 'dead' and organisms used for their *chemical* reactions which take place because they are 'alive.' Life is largely chemistry. We think the purposes underlying the patent system require us to include microorganisms and cultures within the terms 'manufacture' and 'composition of matter' in § 101. Whether they *otherwise* qualify for patents under § 102 and § 103 is a question not before us. In short, we think the fact that microorganisms are alive is a distinction without legal

> significance and that they should be treated under § 101 no differently from chemical compounds.

596 F.2d at 975 (emphases in original) (internal citations and quotation marks omitted).

C. The Supreme Court Affirmed *Bergy* in *Diamond v. Chakrabarty*

The Supreme Court held in *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) that an engineered microorganism is patent-eligible under 35 U.S.C. § 101 − the antithesis of the view taken by the district court here. *Chakrabarty* was an affirmance of *Bergy*, the leading appellate opinion on patent-eligibility of such inventions authored by the late Judge Giles Sutherland Rich. *Chakrabarty* is still good law and its holding is binding on this issue, while other cited precedent represents dicta in cases having nothing to do with patent-eligibility.

1. *Bilski v. Kappos*: Post-*Chakrabarty* Supreme Court Dicta

The starting point to consider both pre- and post-*Chakrabarty* precedent is the recent Supreme Court decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). The holding of *Bilski* has absolutely nothing to do with the patent-eligibility of a "composition of matter" under Section 101. Rather, the holding is limited to the denial of patent-eligibility of an "abstract idea," the exact opposite of the discrete, identifiable and synthetically reproducible chemical composition of matter at issue in this case.

Considering the dicta in the post-*Chakrabarty* case law of the Supreme Court, the Supreme Court in *Bilski* identifies a "laws of nature" exclusion to patent-*eligibility* when in fact the cited pre-*Chakrabarty* precedent relates to *patentability* under what today would be considered nonobviousness under 35 U.S.C. § 103(a). The dicta in *Bilski* reads as follows:

> The Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.' *Chakrabarty*, [447 U.S.] at 309. While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be 'new and useful.' And, in any case, these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years. See *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174-175 (1853). The concepts covered by these exceptions are 'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.' *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The cases cited, *Le Roy* and *Funk,* came from the era before the codification of the "invention" standard of *Hotchkiss* v. *Greenwood*, 52 U.S. (11 How.) 248 (1851), that was replaced by what is today nonobviousness under Section 103(a). Consequently, the dicta addresses only patentability − a separate analysis required after the invention has passed through the door of patent-eligibility.

2. *Le Roy v. Tatham*: Patenting Lead Pipes

Le Roy v. Tatham claimed a classic article of manufacture within the meaning of Section 101, a lead pipe, which was old, while the patentee should have based his claim on his new method of making lead pipe:

> A patent for leaden pipes would not be [valid] . . . and would . . . prohibit all other persons from using the same article, however manufactured. Leaden pipes are the same, the metal being in no respect different. . . . The new property in the metal claimed to have been discovered by the patentees, belongs to the process of manufacture, and not to the thing made. . . . The question whether the newly developed property of lead, used in the formation of pipes, might have been patented, if [properly] claimed . . . was not in the case.

Le Roy, 55 U.S. (14 How.) at 176-77.

The holding in *Le Roy* adopted the opinion of Mr. Justice Story in a line of cases dealing with a new use of an old product:

> [The patentee] says that the same apparatus, stated in this last claim, has been long in use, and applied, if not to chairs, at least in other machines, to purposes of a similar nature. If this be so, then the invention is not new, but at most is an old invention, or apparatus, or machinery applied to a new purpose. Now I take it to be clear, that a machine, or apparatus, or other mechanical contrivance, in order to give the party a claim to a patent therefor, must in itself be substantially new. If it is old and well known, and applied only to a new purpose, that does not make it patentable.

Bean v. Smallwood, 2 F.Cas. 1142, 1143 (D. Mass. 1843) (Story, J.), *cited and quoted in Le Roy*, 55 U.S. (14 How.) at 176-77. *Bean sub silentio* followed *Howe v. Abbott,* 12 F.Cas. 656, 658 (D. Mass. 1842) (Story, J.) (holding that "[t]he application of an old process to manufacture an article, to which it had never before been applied, is not a patentable invention."). *See also Dunbar v. Myers*, 94 U.S. (4 Otto) 187, 199 (1876) (citing with approval *Howe* and *Bean*).

3. *Funk v. Kalo*: A Classic "Composition of Matter"

Funk involved a claim to a garden variety "composition of matter" – a new mixture of individually old bacteria – that had absolutely nothing to do with what is today patent-eligibility under Section 101, but everything to do with whether there was patentable "invention" in the sense of the pre-1952 *Hotchkiss* test under what is now Section 103(a) nonobviousness. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (discussing codification of *Hotchkiss v. Greenwood,* 52 U.S. (11 How.) 248 (1851)).

a. *Hotchkiss* "Invention" = § 103(a) "Nonobviousness"

The terminology used before the 1952 Patent Act speaks of "invention" to describe the necessary advance in the art beyond novelty to establish patentability. This was superseded four years later in the 1952 Patent Act by the statutory test of "nonobviousness" under what is today Section 103(a).

Prior to the 1952 Patent Act, an invention which was "obvious" was instead termed to lack patentable "invention." In *Funk v. Kalo*, the Court found a patent to a mixture of known bacteria lacked "invention" − in other words, that it was obvious. *Funk* has absolutely nothing whatsoever to do with patent-eligibility under 35 U.S.C. § 101.

The mistake made today is to read *Funk* from the vantage point of a post-1952 understanding of the term "invention" which was used in that case to describe

what today is nonobviousness. As Chisum has noted, "[*Funk*] is perhaps best viewed as an interpretation of the nonobviousness or 'invention' requirement, and not of the statutory classes of subject matter." 1-1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.02[7][b] (2010).

b. *Parker v. Flook*: Failure to Understand the 1952 Act

The same mistake was made in *Parker v. Flook,* 437 U.S. 584 (1978), as Judge Rich explained in *Bergy*:

> . . . [W]e find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in § 101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103. The confusion creeps in through such phrases as . . . 'patentable invention.' [That] term is perhaps one of the most difficult to deal with unless it is used *exclusively* with reference to an invention which complies with *every* condition of the patent statutes so that a valid patent may be issued on it.
>
> The problem of accurate, unambiguous expression is exacerbated by the fact that prior to the Patent Act of 1952 the words 'invention,' 'inventive,' and 'invent' had distinct legal implications related to the concept of patentability which they have not had [since the 1952 Patent Act]. Prior to 1952, … they were used by courts as imputing *patentability*. Statements in the older cases must be handled with care lest the terms used in their reasoning clash with the reformed terminology of the present statute; lack of meticulous care may lead to distorted legal conclusions.
>
> The transition made in 1952 was with respect to the old term 'invention,' imputing *patentability,* which term was replaced by a new statutory provision, § 103, requiring *nonobviousness,* as is well explained and approved in *Graham* v. *John Deere Co.,* [383 U.S. 1 (1966)]. . . .

> The Revised Statutes of 1874, which contained the primary patent statutes revised and codified in 1952, lumped most of the conditions for patentability in a single section, § 4886. . . . The 1952 Act divided that statute up into its logical components and *added* the nonobviousness requirement [of what is today 35 U.S.C. § 103(a)], which until then had been imposed only by court decisions.

Bergy, 596 F.2d at 959 (Rich, J.) (emphases in original). As discussed *supra*, the "court decisions" previously imposing the nonobviousness requirement dated from *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851).

c. Nature's Secrets as Patentable (Nonobvious) Invention

The patentable "invention" of the claimed mixture of bacteria in *Funk v. Kalo* was said to reside in a secret of nature, wherefore, the invention was obvious – or lacked "invention." It was in the sense of obviousness that the *Funk* court said that "[i]f there is to be [a nonobvious, patentable] invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Funk*, 333 U.S. at 130.

The claimed mixture of bacteria was established as having an advantage over the prior art application of individual strains of bacteria. The reason why the invention was deemed obvious – or lacked "patentable invention" in the terminology prior to the 1952 Patent Act – was because a nonobvious invention could not (per the majority opinion) be attributed to the biological benefits of the

combination, which were within the realm of the "ancient secrets of nature now disclosed" in the patent. *Funk*, 333 U.S. at 131-32.

More fully, the *Funk* court stated that:

> There is, of course, an advantage in the combination. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, as respondent says, the packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like. But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. *Cuno Eng'g Corp. v. Automatic Devices Corp*., [314 U.S. 84, 90, 91 (1941)], and cases cited; 35 U.S.C. § 31, 35 U.S.C.A. § 31, R.S. § 4886. The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. *But once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step*. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.

Id. (emphasis added).

As pointed out in a concurring opinion, "[i]t only confuses the issue . . . to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable

composite exemplifies in its properties 'the laws of nature.' . . . Nor can it be contended that there was no invention [in Bond's mixture] because the composite has no new properties other than its ingredients in isolation. Bond's mixture does in fact have the new property of multi-service applicability." *Funk*, 333 U.S. at 134-35 (Frankfurter, J., concurring), *quoted in* 1-1 CHISUM § 1.02[7][b].

D. In Sum, Chemical Compounds Are Patent-Eligible "Compositions of Matter"

Under the legal precedents discussed *supra*, chemical compounds (compositions of matter) are patent-eligible, even if they are analogous to those found in nature; even if they are keyed to or designed to operate via natural phenomena or processes; and even if they were discovered during research of those natural phenomena. The evolution of the statutory requirements of the Patent Act must be taken into account, particularly with respect to parsing the separate and distinct tests between patent-eligibility and patentability.

II. EXCLUDING CERTAIN "COMPOSITIONS OF MATTER" FROM PATENT-ELIGIBILITY WOULD VIOLATE THE UNITED STATES' TREATY OBLIGATIONS UNDER THE TRIPS AGREEMENT

There is absolutely zero ambiguity in the meaning of "composition of matter" as encompassing any chemical compound. To exclude certain chemical compounds from the scope of patent-eligible subject matter would constitute a violation of the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). In particular, it would violate

Article 27(1) of the TRIPS Agreement, in which the United States promised to grant "patent rights enjoyable without discrimination as to . . . the field of technology . . .."

A. *Charming Betsy* Requires Reading the Patent Statute Consistently With the TRIPS Agreement

The Court should be reluctant to judicially exclude compositions of matter from the scope of patent-eligible subject matter when to do so would be inconsistent with the country's international treaty obligations under TRIPS. Under *Murray v. Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64 (1804) [hereinafter "*Charming Betsy*"], "an act of Congress ought never to be construed to violate the law of nations if any other possible construction remains." *Id.* at 118, *cited and quoted in F. Hoffmann-La Roche Ltd v. Empagran S.A.,* 542 U.S. 155, 164 (2004).

As this Court has recently stated, "The rule of interpretation announced in *Murray v. Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64, 118 (1804), instructs that domestic law should be interpreted consistently with American international obligations to the degree possible." *Norsk Hydro Canada, Inc. v. United States*, 472 F.3d 1347, 1360 n.21 (Fed. Cir. 2006) (internal parallel citation omitted). *See also Litecubes, LLC v. Northern Light Prods., Inc.*, 523 F.3d 1353, 1364 n.11 (Fed. Cir. 2008) (recognizing *Charming Betsy* rule); *In re Rath*, 402 F.3d 1207, 1211

(Fed. Cir. 2005) (same); *Corus Staal BV v. U.S. Dep't of Commerce*, 395 F.3d 1343, 1347 (Fed. Cir. 2005) (same).

B. Excluding Certain Chemical Compounds Would Undermine Global Minimum Standards For Patent Protection

The United States scored a major victory for the globalization of a strong patent regime through the successful conclusion of the Marrakesh Treaty in 1994 that established the WTO and the TRIPS Agreement. Through TRIPS, global minimum standards for patent protection have been mandated for all countries of the WTO world.

The past generation has seen attempts by developing countries to chisel away at the broad scope of protection mandated by TRIPS, thus jeopardizing both the spreading of the benefits of strong patent protection and the spreading of product development costs on a global basis. To the extent that this Court does anything other than send a strong message of support for broad *Bergy*-based standards of patent-eligibility, the message would be transmitted around the world that the United States itself is not living up to the promise of TRIPS Article 27 to provide "patent rights enjoyable without discrimination as to . . . the field of technology[.]" TRIPS Agreement, art. 27(1). If the United States thus stands in violation of a broad interpretation of the minimum standards of Article 27, the perfect defense for a developing country being attacked in a mandatory WTO dispute settlement proceeding in Geneva would be to argue that the United States'

own interpretation of the TRIPS does not mandate broad protection. The developing country could then contend that all it is doing in the evisceration of American patent rights is following the U.S. interpretation of TRIPS, which hardly should be a violation of the treaty.

CONCLUSION

For all the foregoing reasons, this Court should reverse the holding of the district court.

Respectfully submitted,

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