No. 11-796

IN THE

Supreme Court of the United States

VERNON HUGH BOWMAN

Petitioner,

v.

MONSANTO CO. ET. AL.

Respondents,

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

Knowledge Ecology International ("KEI") is an international non-profit, non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. In particular, KEI is focused on the management of these resources in the context of social justice. KEI is drawn to areas where current business models and practices by businesses, governments or other actors fail to adequately address social needs or where there are opportunities for substantial improvements. Among other areas, KEI has expertise in access to medical technologies and access to knowledge issues.

KEI is concerned about the implications of the Federal Circuit decision in the present case because limits on the patent exhaustion doctrine will impact market competition, not only with respect to genetically modified seeds, but for all self-replicating technology. If the Federal Circuit decision is permitted to stand, such limits may have profound effects—potentially of unknown consequence—on other biotechnology industries that may use self-replicating technologies, including those involving cell lines, DNA or RNA sequences, virus strains, and microorganisms.

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[1] The parties have consented to the filing of this brief. Both Petitioner's consent to the filing of this brief as well as Respondent's consent have been filed with the Clerk of Court. No counsel representing any party to the case authored this brief, in whole or in part, and no counsel or party made any monetary contribution to the preparation or submission of the brief.

SUMMARY OF THE ARGUMENT

The patent exhaustion doctrine is a common law tradition that has existed in the United States for over 150 years. This doctrine, analogous to the statutorily codified "first sale" doctrine of Copyright Law, limits the patent owner's control to the first sale of the technology. Once the first authorized sale occurs, the patent owner's right to the invention are considered exhausted. This Court has not favored categorical exceptions to the patent exhaustion doctrine and has instead robustly applied these principles.

The present case turns on the application of patent exhaustion to the relatively new field of self-replicating technologies. This case involves Monsanto's patented genetically modified seeds, known as Roundup Ready® seeds. These seeds are self-replicating in the sense that, once planted, new, second-generation seeds result. As replication is a natural function of seeds, such self-replication is capable of taking place, even absent any human intervention.

Monsanto, through contractual agreements, elicited promises from licensed growers not to save second-generations of these seeds for future planting, among other clauses. The Petitioner, Bowman, fulfilled his contractual obligations for seeds purchased from licensed Monsanto distributors. However, he purchased risky commodity seeds from a grain elevator for a second-planting and, upon learning that some of these seeds exhibited the same traits as Monsanto's genetically modified seeds,

saved the future generations of the commodity seeds for future plantings.

It is apparently undisputed that the sales of second-generation seeds to grain elevators did not violate Monsanto's contractual agreement. No contractual privity exists between Monsanto and Bowman with respect to the seeds purchased from the grain elevator and Monsanto therefore turns to its theory that it possesses inexhaustible patent rights over all second, third, and *n*th generation seeds. Monsanto argues that all subsequent generations of self-replicating technologies (seeds, in the present case) are newly infringing items and its patent rights in future generations will therefore *never* be exhausted.

The Federal Circuit agreed with Monsanto's theory, thereby creating a judicial exception to patent exhaustion for self-replicating technology that is not based on this Court's precedent. The lower court's decision asserts that every new generation of seed that develops from the planting of genetically modified seed results in "the grower . . . creat[ing] a newly infringing article." *Monsanto Co. v. Bowman*, 637 F.3d 1341, 1348 (Fed. Cir. 2011). Such a holding results in a patent right that runs forever with future generations and ignores this Court's precedent requiring courts to look at whether a use is "substantially embodied" in the patent.

A judicially created exception for self-replicating technologies from patent exhaustion is an inappropriate solution. Such an exception, creating inexhaustible patent rights, will harm downstream

users who may have no notice that they are using patented technology. This exception may also have unknown consequences for other forms of self-replicating technologies, adding to the transaction costs or inhibiting research and development in other fields that use such technologies, including on organisms, viruses, DNA, or other nanotechnologies.

Rather than create judicial exceptions to patent exhaustion, this Court should rely on its precedent and uphold its longstanding history of applying a strong patent exhaustion doctrine. A patented invention that is sold and used for the purpose it was intended, or "substantially embodied" by the patent, such as the case of self-replicating technology, should exhaust the patent rights of the patent holder. Eliminating the Federal Circuit's judicial exception would create greater clarity and stability for users of patented self-replicating technology.

Applying patent exhaustion to self-replicating technology would not overly-burden the inventor who can still protect his investment through contractual agreements governing post-sale uses, provided that such contracts are not voided for antitrust violations or unconscionable terms. Contract law, by refusing to immunize anticompetitive behavior and providing appropriate safeguards to the public, therefore represents a more appropriate vehicle for enforcing post-sale restrictions on patented technology.

Additionally, while patent owners often assert the need for strong patent protection, lowered patentability criteria or, in this case, an exception to

patent exhaustion in order to induce investment, a plethora of alternative mechanisms to patent regimes exist to reward research and development. *Sui generis* systems of rewards or cash innovation inducement prizes are viable alternatives to the patent system. Such alternatives may represent more appropriate rewards for self-replicating technologies than an inexhaustible patent over all future generations of such technology.

ARGUMENT

I. CREATION OF AN INEXHAUSTIBLE MONOPOLY RIGHT OVER SELF-REPLICATING TECHNOLOGY HARMS THE PUBLIC

Although a patent owner possesses a bundle of rights over its patented technologies, limits on these rights exist. Such limits recognize that the purpose of the patent system is to promote progress and that a patent is not an absolute right. Patent exhaustion is one restriction on patent rights and enjoys a rich history in this Court's precedent. Patent exhaustion has been applied in the United States for over 150 years, and this Court has continually applied and enforced this limitation without creating categorical exceptions.

A. History of This Court's Precedent Supports Strong Patent Exhaustion Principles

The patent exhaustion doctrine provides that once an authorized sale of the patented invention is

made, the patent holder's rights terminate and the user can use, destroy, or sell the technology without seeking the permission of the patent holder. This doctrine protects the public and increases market competition because it limits the patent holder's control to the first authorized sale, thereby guarding against "double dipping." Patent exhaustion promotes downstream, secondary markets for patented technology and creates clarity for downstream users who need not fear being sued for patent infringement after the first authorized sale.

An examination of this Court's precedent reveals a long history of applying strong patent exhaustion principles, limiting the exclusive rights of a patent to the first authorized sale, which goes back over 150 years. In 1853, this Court stated that purchases of patented items could be used "in the ordinary pursuits of life" without permission from the patent owner. *Bloomer v. McQuewan*, 14 How. 539, 549 (1853). Once a lawful sale of a patented technology "passes to the hands of the purchaser, it is no longer within the limits of the monopoly. It passes outside of it, and is no longer under the protection" of patent law. *Id.* Twenty years later, this Court affirmed that "the purchase carrie[s] with it the right to the use of the machine so long as it [is] capable of use." *Adams v. Burke*, 17 Wall. 453, 455 (1873). Once the sale is made, the patent owner "parts with the right to restrict that use." *Id.* at 456. Without this doctrine, the "inconvenience and annoyance to the public [of not applying patent exhaustion] are too obvious to require illustration." *Keeler v. Standard Folding Bed Co.*, 147 U.S. 659, 667 (1895).

This Court has continually applied the doctrine of patent exhaustion, articulating a clear and bright-line rule that post-sale restrictions are not permitted under patent laws once the owner authorizes a sale and thus exhausts his rights. *Quanta Computer Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 631 (2008); *United States v. Univis Lens Co.*, 316 U.S. 241 (1942); *Motion Picture Patents Co. v. Universal Film Mfg.*, 243 U.S. 502, 516 (1917); *Keeler v. Standard Folding Bed Co.*, 147 U.S. 659 (1895). In applying patent exhaustion, this Court has evaluated whether the features of the patented invention "substantially embodies" the use. In *Univis*, to determine whether patent exhaustion applied to the facts of the case, this Court specifically looked to whether the use of the patented invention was "embodied in that particular article." *Univis* at 250-51. This approach was affirmed most recently in this Court's decision in *Quanta Computer, Inc. et. al. v. LG Electronics, Inc.* 533 U.S. 617 (2008).

In *Quanta*, this Court noted concerns that eliminating exhaustion would allow patent holders to control any downstream purchases and concluded that "the traditional bar on patent restrictions following the sale of an item applies when the item sufficiently embodies the patent—even if it does not completely practice the patent—such that its only and intended use is to be finished under the terms of the patent." *Quanta at* 625. Thus, the doctrine of patent exhaustion which "provides that the initial authorized sale of a patented item terminates all patent rights to that item," applies to uses and applications that are "substantially embodied" by the

patent and "prevents the patent holder from invoking patent law to control postsale use of the article." *Id*. at 622, 638.

Continually, this Court has reminded that the patent rights are not designed to "creat[e] the private fortunes for the owners of patents." *Motion Picture Patents Co. v. Universal Film Mfg. Co*., 243 U.S. 502, 511 (1916). Instead, patent rights must be carefully balanced and the exhaustion doctrine should be strictly applied in order to benefit society. *See United States v. Masonite Corp*., 316 U.S. 265 (1942) (finding that patent rights "must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute"); *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 329 (1858) (noting that "Whilst the remuneration of genius and useful ingenuity is a duty incumbent upon the public, the rights and welfare of the community must be fairly dealt with and effectually guarded.").

In the present case, second, third and *n*th generation progeny are certainly "substantially embodied" in the first generation authorized seed. These future generations of seeds are both literally and figuratively "substantially embodied" in the first generation seed. Certainly, the "only and intended use" of Monsanto's Roundup Ready® seeds are for planting, and the next generation of seeds that result from such plantings must be considered to be substantially embodied in the initial seeds. This court should strictly apply the patent exhaustion doctrine to the facts of the case.

Although Monsanto may argue that the seeds may be used for other purposes, such as for feed, the question before the court is the application of these principles to the *patent* in the seed, and not the seed's natural and non-patented features or values. Certainly, a seed may be used for feed, but the entire value and purpose of Monsanto's patented seed is its resistance to herbicide for purposes of planting. As use in feed, the patent—its herbicide resistant properties—has no value or purpose. In other words, the genetic trait of the seed has no benefit for any purpose other than planting. Thus, the only and intended use of the *patent* contained in the seed is for use in planting and the future generation seeds that result from the planting are substantially embodied within the patent. The Federal Circuit thus erred in creating a judicial exception to the patent exhaustion doctrine for self-replicating technology.

B. A Judicially Created Exception from Patent Exhaustion for Self-Replicating Technology Represents an Inappropriate Solution and Fails to Guard Against Unintended Consequences

A bright-line rule applying patent exhaustion to all forms of technology would provide clarity to purchasers, in particular for downstream users. Instead, the Federal Circuit opinion in the present case results in a judicially created exception for self-replicating technology from the doctrine of patent exhaustion. In essence, the Federal Circuit rule results in an *inexhaustible* right to control self-replicating technology and all subsequent

generations of the technology. *See* Yee Wah Chin, *Licensing: Patent Exhaustion, and Self-Replicating Technologies: A Case Study*, 32 THE LICENSING JOURNAL 7 (2012).

Exhaustion will never apply to seeds or other self-replicating technology if the Federal Circuit decision is permitted to stand. Thus, patent infringement will always be applicable to any use of second (or future) generations of self-replicating technology, creating great difficulties for downstream users.

The problem with creating an exception to patent exhaustion for self-replicating technology, such as the seeds in the present case, is that subsequent generations of the technology are not marked as patented items and downstream users may have no notice or knowledge of any infringement. Farmers who purchase commodity seeds from grain elevators rather than directly from an authorized Monsanto purchaser, for example, have no way of knowing whether those seeds include genetically modified, patented seeds. Similarly, farmers who do not purchase Monsanto's seeds, but purchase non-genetically modified seeds and save those for future plantings may nonetheless find themselves in possession of Roundup Ready® seeds and thus infringing Monsanto's patents—without any way of knowing that such infringement is occurring—due to cross-pollination. Even plants exhibiting the genetically modified trait found in the wild as a result of cross-pollination, would fall under the patent rights of the patent holder since his rights

would forever flow with the subsequent generations and he could prohibit the use or sale of such items.

Unknowing, downstream users may therefore be infringers under the Federal Circuit theory of exceptions for self-replicating technologies which could result in a burdensome requirement that a farmer who purchases seed from grain elevators or saves his non-genetically modified seed for future plantings must have this seed tested before using it. While damages may be not be available without notice to the alleged infringer, injunctions may still be applicable and result in unfair losses to farmers who have no way of determining whether seeds not purchased from Monsanto or its distributors contain the patented genetically modified trait.

Reducing application of the patent exhaustion doctrine for self-replicating technology would serve to eliminate certainty and clarity in the marketplace. *See* Yee Wah Chin, *Inexhaustible: Patents on Self-replicating Technologies*, Vol. 3, No. 5 LANDSLIDE (2011) (*quoting* Thomas G. Hungar, *Observations regarding the Supreme Court's Decision in* Quanta Computer Inc. v. LG Electronics, Inc., 49 IDEA 517, 530-31 (2009)). The reduction of stability and predictability with regard to markets for patented technology would have significant impacts on downstream purchasers and businesses that rely such inventions. Transaction costs would increase as downstream users would be forced to conduct patent searches and seek permission from patent owners in order to use the technology.

The Federal Circuit's *sui generis* exception from patent exhaustion would apply not only in the case of seeds, but also to other forms of self-replicating technology. As the Solicitor General noted in his brief, the outcome of the case applies to other self-replicating technologies including "for man-made cell lines, DNA molecules nanotechnologies, organic computers, and other technologies that involve self-replicating features." United States Amicus Br. On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fed. Cir., 19-20. In recommending against the granting of the petition, the Solicitor General suggested that case law further develop so that due consideration can be given to "unforeseen consequences for other present and future self-replicating technology." *Id.* Certainly, a categorical exclusion of self-replicating technologies from the application of patent exhaustion could have negative impacts on the wide and growing range of self-replicating technologies. Any decision to eviscerate the patent exhaustion doctrine will have consequences that cannot be adequately predicted in the field of rapidly evolving self-replicating technology and it would be imprudent to create categorical exceptions that will have unknown breadth and consequences for all downstream users.

This Court has previously rejected categorical exclusions from the doctrine of patent exhaustion, such as in the case of method claims. *Quanta Computer Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008) ("We therefore reject LGE's argument that method claims, as a category, are never exhaustible."). Categorical exclusions from patent

exhaustion are inappropriate and judicially created exceptions for self-replicating technology should not be granted, particularly given the unknown effects such an exception will have on other industries and the future of self-replicating technologies. This Court should continue to reject such categorical exclusions, recognizing the alternative mechanisms that can be used to protect and induce investments into research and development for self-replicating technology.

II. CONTRACT LAW PROVIDES THE MORE APPROPRIATE MECHANISM TO PROTECT INVESTMENTS IN SELF-REPLICATING TECHNOLOGY WHILE ALSO SAFEGUARDING USER RIGHTS

Rather than prevent usage of second and future generations of self-replicating technology through inexhaustible patent rights, contracts can provide a more appropriate mechanism to restrict usage.[2] A robust patent exhaustion doctrine plays an important role in promoting stability and clarity

[2] We note, also, that apart from an exception from patent exhaustion or contractual agreements, Monsanto has other potential avenues to prevent the use of future generations of its genetically modified seed. For example if exhaustion applies and contractual provisions are found to violate antitrust laws or contain unconscionable clauses, Monsanto could stack its genetically modified seed with a "terminator" gene that renders subsequent generations of seed sterile. Elizabeth I. Winston, *A Patent Misperception*, 16 LEWIS & CLARK L. REV. 289,335 (2012) (discussing U.S. Patent No. 5,723,765 granted to Delta which includes a genetic code rendering a seed fertile for only one planting while future generations are sterile.).

in the purchase, sale and use of patented technologies, including for use in further research and development. However, a strong patent exhaustion doctrine does not affect the use of contract law, rather than patent law, to enforce post-sale restrictions. Where patent owners are concerned that the initial sale of patented technology does not adequately protect their investments and wish to restrict usage of subsequent generations of self-replicating technology, they are generally free to rely on the use of contracts to limit post-sale uses.

In fact, Monsanto did just that in the present case, restricting farmers that purchased the genetically modified seed directly from authorized distributors from saving seed and planting future generations. Monsanto required farmers to sign a contractual technology agreement "1) to use the seed containing Monsanto gene technologies for planting a commercial crop only in a single season; 2) to not supply any of this seed to any other person or entity for planting; 3) to not save any crop produced from this seed for replanting or supply saved seed to anyone for planting; and 4) to not use this seed or provide it to anyone for crop breeding, research, generation of herbicide registration data or seed production." *Monsanto v. Bowman* at 1344-45 (*citing* Monsanto's Standard Form Technology Agreements, 1998-2007, J.A. 284-315). Monsanto is clearly capable of drafting contractual agreements that limit post-sale usage of its genetically modified seed, such as to restrict usage of future generation seed. Monsanto is therefore not without a cause of action against users who use second and future generation seed if these users violate their contracts.

The reason the question before the Court presents issues of patent exhaustion rather than a question of contract law because Monsanto did not have contractual privity with the petitioner, Bowman, with regard to the seed planted and saved from the purchase of commodity seed from the grain elevator. Had Bowman planted and saved the seed he purchased from the licensed distributor, Bowman would have violated the technology agreement. However, Monsanto acknowledged that a grower can sell its crop to grain elevators without securing any promise not to sell the seeds for planting without violating the contractual agreement. *Monsanto v. Bowman* at 1345 (*quoting* Oral Arg. at 19:34-20:14, *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/all/bowman.html). The sale of second-generation genetically modified seed to the grain elevator was, therefore, a legal sale that did not violate any contractual agreements. Purchasers of the seed from the grain elevator did so without restriction and Monsanto had no contractual agreement over such purchases. Monsanto therefore attempts to rely on a judicially created exception to the patent exhaustion doctrine.

In previous cases applying the patent exhaustion doctrine, this Court recognized that patent owners may seek to enforce post-sale restrictions through contract law even if their patent rights have been exhausted. In *Quanta*, for example, this Court "note[d] that the authorized nature of the sale to Quanta does not necessarily limit LGE's other contract rights. LGE's complaint does not include a breach-of-contract claim, and we express no opinion

on whether contract damages might be available even though exhaustion operates to eliminate patent damages." *Quanta* at n.7 (*citing Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895)). This Court has a long history of applying a robust patent exhaustion doctrine while recognizing that contract law may be used where patent law does not apply in order to enforce post-sale limitations. *Keeler v. Standard Folding Bed Co.*, 147 U.S. 659 (1895) ("Upon the doctrine of these cases, we think it follows that one who buys patented articles of manufacture from one authorized to sell them becomes possessed of an absolute property in such articles, unrestricted in time or place. Whether a patentee may protect himself and his assignees by special contracts brought home to the purchasers is not a question before us and upon which we express no opinion. It is, however, obvious that such a question would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws.").

Reliance on contract law, rather than reducing the patent exhaustion doctrine, is a better solution with regard to enforcing post-sale limitations because it can permit the inventor of self-replicating technology to implement such restrictions while still protecting the public and users of such technologies. While under patent law, inventors may be immunized from scrutiny for anti-competitive behavior or violations of antitrust law, contract law provides protection for users. *See* Mark R. Patterson, *Contractual Expansion of the Scope of Patent Infringement Through Field-of-Use Licensing*, 49 WM. & MARY L. REV. 157, 169-71 (2007). For example, contracts may be reviewed for antitrust

violations and can also be voided where the terms are unconscionable or otherwise against public policy. Contract law therefore provides a better alternative to restricting use of future generations of self-replicating technology than patent exhaustion because it can protect the interest of the inventor while simultaneously safeguarding users.

III. NON-PATENT MECHANISMS CAN AND SHOULD ENCOURAGE PROGRESS WHERE PATENTS ARE AN INAPPROPRIATE, UNNECESSARY, INSUFFICIENT, OR BURDENSOME REWARD

Alternative mechanisms outside of the patent system can, and should, encourage progress where patents are an inappropriate, unnecessary or burdensome reward. As noted above, in the case of self-replicating technology, patents may be an inappropriate reward because of problems in providing notice to the user in cases of second (or later) generations of the technology, hampering further research and development, and eliminating the availability of competition through secondary markets. Although in the present case contract law may provide a more appropriate solution with respect to self-replicating technology, some patent holders will still advocate for the inexhaustible right to own all future generations of the technology claiming the need to induce research and development in this area.

Proponents of liberal standards on patentability assert that patents are necessary to induce, protect

and reward investments in new technology. However, patents as incentives have known deficiencies and a wide range of non-patent mechanisms to stimulate research and development exist. It is therefore clear that patents are not the only method for inducing investment into the creation of new technology and great flexibility exists to design these alternative forms of incentive[3] and we urge this Court to keep in mind that if additional research and development in the area of self-replicating technology is, in fact, necessary such alternatives can be implemented to address shortcomings.

For example, trade secret protection, which is not without its own shortcomings in terms of limiting access to knowledge, can be used to promote investments in new medical products such as diagnostic or biotechnology drugs. Iraj Daizadeh, et. al., *A General Approach for Determining When to Patent, Publish, or Protect Information as a Trade Secret,* 20 NAT. BIOTECH at 1053-54 (2002).

In addition to trade secret protection, a wide range of new *sui generis* forms of intellectual property are used in parallel to the patent system, often when patent protection is unavailable. One type of common *sui generis* protection is the

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[3] Although several alternative incentive mechanisms are discussed herein, KEI does not necessarily endorse these alternatives, particularly with respect to the manner in which they have been implemented. The discussion of alternatives mechanisms discussed in this brief serve solely as examples of the range of incentives that currently exist outside the patent system, or those that have been proposed.

application of a limited time exclusive right to rely on test data used to register new drugs or vaccines. Food, Drug and Cosmetics Act, New Drugs, 21 U.S.C. §355. These rights include five years of test data protection for new chemical entity pharmaceutical products, and twelve years of test data protection for new biologic drugs. *Id*. More relevant to the present case, under the Federal insecticide, Fungicide, and Rodenticide Act (FIFRA), a *sui generis* regime for test data for agricultural products exists, granting an initial period of ten years of exclusive rights followed by four year of remuneration rights for the right to rely upon data used to establish the safety and efficacy of covered agricultural products. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Registration of Pesticides, 7 U.S.C. §136a.

Like trade secrets, exclusive rights over test data have their own shortcomings, including ethical concerns, such as redundant testing of humans and animals for product safety, but presently serve as a mechanism to promote investments in clinical test data. These mechanisms include cases in the United States and Europe where the monopoly can be set aside and replaced with a system of remuneration to the originators of the data.

Another existing non-patent right is the marketing exclusivity granted for development of new "orphan" drug indications and receipt of a fifty-percent tax credit for companies investing in the clinical trials. Internal Revenue Code, Clinical testing expenses for certain drugs for rare diseases or conditions, 26 U.S.C. §45C. The recently passed Generating Antibiotic Incentives Now (GAIN) Act

similarly seeks to encourage research on antibiotic resistance by granting an additional five years of market exclusivity. S.3187, Generating Antibiotic Incentives Now, Food & Drug Administration Safety and Innovation Act, 112th Cong., 2d Sess. (2012).

Congress has also created a "Priority Review Voucher" to stimulate research and development in treatments for rare tropical diseases. This voucher provides for a transferable right to an accelerated consideration of new drug approvals as a reward for registering drugs for rare diseases such as cholera or leprosy. Food, Drug and Cosmetic Act, Priority Review to Encourage Treatments for Tropical Diseases, 21 U.S.C. §360n.

In addition to these existing mechanisms, a class to reward investments in research and development, involving a system of cash prizes, is currently under consideration, both domestically and internationally. Cash innovation inducement prizes can stimulate investments in public health as well as other areas of public and private interest. *See, e.g.*, L. Brunt, et. al., INDUCEMENT PRIZES AND INNOVATION (2008); Bruce G. Charlton, *Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation*, 68 MEDICAL HYPOTHESES 1-3 (2007); K. Davidian, PRIZES, PRIZE CULTURE AND NASA'S CENTENNIAL CHALLENGES (2004); T. Kalil, *Hamilton Project and Brookings Intuition, Prizes for Technological Innovation* (2006); James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519, 1521-24 (2007); James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and*

Vaccines, 18 ANNALS HEALTH L. 155 (2009); James Love, *The role of Prizes in Developing Low-Cost, Point of Care Rapid Diagnostic Tests and Better Drugs for Tuberculosis*, KNOWLEDGE ECOLOGY INTERNATIONAL (2008), *available at* http://www.keionline.org/misc-docs/Prizes/prize_tb_msf_expert_meeting.pdf; Ron Marchant, *Managing Prize Systems*, 2 KNOWLEDGE ECOLOGY STUDIES (2008); W. A. Masters, *Prizes for Innovation in African Agriculture* (2004), *available at* http://www.eart.columbia.edu/cgsd/prizes; J. G. Morgan, *Inducing Innovation Through Prizes*, 3 INNOVATIONS: TECHNOLOGY, GOVERNANCE, GLOBALIZATION 105 (2008); Julien Penin, *Patents Versus Ex Post Rewards*, 34 RESEARCH POL'Y 641 (2005); Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations*, 333 BRITISH MEDICAL JOURNAL 129 (2006); Burton Weisbrod, *Solving the Drug Dilemma*, WASH. POST at A21 (Aug. 22, 2003); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes and Research Contracts*, 73 AM. ECON. REV. 691 (1983).

Domestically, for example, Senator Sanders (I-VT) has proposed the use of prize funds as an alternative reward mechanism for pharmaceutical drugs, rather than the exclusive right to a patent monopoly. In the 112th Congress, Senator Sanders introduced two bills proposing large cash prizes. The first bill, S.1137, would apply to all prescription drugs. Medical Innovation Prize Fund Act, S.1137, 112th Cong. (2011). The second bill, S.1138, would limit application to HIV/AIDS drugs. Prize Fund for HIV/AIDS Act, S.1138, 112th Cong. (2011).

On May 15, 2012, the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing on S.1138. Nobel Prize winner, Joseph Stiglitz, noted in testimony at the hearing that the patent system may "have adverse effects on innovation, because the most important input into any research is prior ideas . . . there is a simple way to 'square the circle,' which entails de-linking research and development incentives from drug price . . . It does this through a simple mechanism—prizes." Joseph E. Stiglitz, Testimony to the U.S. Senate HELP Committee, Subcommittee on Primary Health and Aging, Hearing on the High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative, *available at* http://www.help.senate.gov/imo/media/doc/Stiglitz.pdf.

Internationally, the concept of prizes has been introduced to address de-linkage of the costs of research and developments and the price of health products for particular conditions, or to address diseases disproportionately affecting developing countries. Global strategy and plan of action on public health, innovation and intellectual property. World Health Assembly 61.21 (2008). Such de-linkage includes the awards of prizes. *Id*. at Annex, element 5.3(a). An independent group of experts again endorsed this concept in an April 2012 report. World Health Organization, *Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination: R&D to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*,

http://www.who.int/phi/CEWG_Report_5_April_2012.pdf.

Prizes may be particularly relevant where products are not patent eligible or where it would be inefficient or harmful to permit enforcement of exclusive rights. Where unrestricted access to basic information or discoveries is critical to progress, patents act as a barrier and do more harm than good. *See* John Sulston, et. al., THE COMMON THREAD (2003); Aaron S. Kesselhein, et. al., *University Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850 (2005).

Although the above examples highlight current efforts to enact prize systems for pharmaceutical development, the use of cash innovation inducement prizes is not new. In fact, and particularly applicable to the facts of the present case, the agricultural and food industry has a long history of using such incentive mechanisms successfully.

As far back as the 1700s, prizes have been used in a variety of countries to reward specific advances in agriculture. Knowledge Ecology International, *Selected Innovation Prizes and Reward Programs,* 1 KEI RESEARCH NOTE 1, 5-9 (2008). For example, to address the famine of 1769 in France, a prize was announced to reward a vegetable that could be used during a famine; the prize was awarded in 1773 for the discovery of the nutritional value of the potato in France. *Id.* at 6. Similarly, in 1747, after a Berlin professor found a way to extract sugar from a beet, the Dutch Society for the Encouragement of

Agriculture offered a prize to stimulate research into extraction of sugar from native plants. *Id.* at 7. In 1826, the Royal Horticultural Society of Paris offered a prize to improve the fruits from apple and pear trees with the prize to be awarded in 1847. *Id.* at 8. In 1852, the Royal Agricultural Society of England created a prize for manure that had fertilizing capabilities equal to Peruvian Guano, provided that it was available in unlimited supply to English farmers at a low price. *Id.* at 8. These are just a few examples of historical uses of prizes in the field of agriculture. Many other exists, both in terms of agriculture and food, as well as a wide range of other areas including automotive, animal control, aviation and space, climate, environment, energy, power, design and architecture, governance and social innovation, mathematics, medical, mining, nanotechnology and robotics, sea and inland navigation, software, computer and information technology, and textile machines, among others.

In the present case, alternative reward systems, such as prizes, may provide a more appropriate incentive mechanism to induce research and development on self-replicating technology rather than granting inexhaustible rights to all future generations or self-replications. Should Congress find such incentives necessary due to exhaustion of patent rights in future generations, it can create such prize funds or other *sui generis* protections.

Congress has clearly shown that it is capable of remedying market failures or promoting alternative reward mechanisms to the patent system and, therefore, this Court should not create judicial

exceptions to its longstanding doctrine of patent exhaustion out of fear that research and development of self-replicating will be impeded if it continues to apply robust exhaustion principles. In fact, failure to apply patent exhaustion to self-replicating technology may increase transaction costs and impede research in areas that rely on such technologies. Inexhaustible patent rights on self-replicating technology are burdensome and can create uncertainties for market and unknown consequences, particularly in light of rapidly evolving technologies. A strong patent exhaustion doctrine can remedy such burdens and alternative mechanisms, such as those discussed *supra*, to inexhaustible monopoly rights may be more viable and appropriate solutions.

CONCLUSION

For the reasons stated above, this Court should reverse the opinion of the Federal Circuit.

Respectfully submitted,

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