No. 00-1543

In The

Supreme Court of the United States

FESTO CORPORATION,

Petitioner,

v.

SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD., A/K/A SMC CORPORATION and SMC PNEUMATICS, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF AMICI CURIAE CHIRON CORPORATION, GUILFORD PHARMACEUTICALS, INC., AND XOMA IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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May 9, 2001

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STATEMENT OF INTEREST

Chiron Corporation, Guilford Pharmaceuticals, Inc., and XOMA are biotechnology and biopharmaceutical companies.[1] They depend on strong patent protection to obtain a reasonable return for their research and development costs to bring new drugs and medical products to market and to encourage stockholder investment. These companies rely on a vigorous doctrine of equivalents to ensure adequate protection for their inventions.[2]

SUMMARY OF ARGUMENT

The biotechnology and biopharmaceutical industry and the consumers of the industry's medical innovations benefit from a vigorous doctrine of equivalents. Patent protection for biotechnological inventions attracts investment capital to the industry, making possible the research necessary to discover and develop life-saving and life-improving medical treatments, which routinely require over ten years for research, development, and regulatory approval. The doctrine of equivalents has been crucial to the adequate protection of biotechnology inventions. Without benefit of the doctrine of equivalents, biotechnology patents will suffer a significant diminution in value, the industry will find it more difficult to attract investment and could not continue the research necessary to develop new treatments and save lives.

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[1] Written consent to the filing of this brief has been obtained from the parties and is lodged herewith. Counsel for a party did not author this brief in whole or in part. No person or entity other than the *amici curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

[2] The Appendix to this brief provides a more detailed description of Chiron Corporation, Guilford Pharmaceuticals, Inc., and XOMA.

The Court should grant *certiorari* to determine whether the *Festo* decision conflicts with the policy underlying patent law. Biotechnology inventions illustrate the need for the doctrine of equivalents to protect patentees' property rights against loss from alterations found to be equivalent after a patent is filed. First, many possible modifications to a biotechnology invention that could defeat literal infringement have no substantive impact on the invention. *Festo* provides a roadmap for a would-be copyist to avoid infringement by, for example, substituting a known interchangeable amino acid at one position of a claimed protein. This sort of substitution would be obvious to one of ordinary skill in the art, and increases the incentive to imitate while lessening the incentive to innovate. Second, there are after-developed improvements that build upon an invention, adding additional features or properties. The improvement itself may be patentable. That fact, however, should not limit the rights of the inventor whose basic invention is being exploited.

The Court should also grant *certiorari* to consider whether, if a complete bar is necessary to prevent ambiguity in the application of the doctrine of equivalents, the holding of *Festo* should only be applied prospectively – *i.e.*, to patents issuing from applications filed after *Festo*. The long-established availability of the doctrine of equivalents has profoundly influenced how inventors draft and prosecute their patent applications, especially in the biotechnology field. Applicants typically submitted broad claims for an invention and narrowed the scope during examination. Very few applications sailed through prosecution without any amendment or argument to distinguish prior art. Prior to *Festo*, in accordance with the decisions of this Court and the Federal Circuit, applicants agreed to claim amendments without expecting to surrender all protection under the doctrine of equivalents. Under *Festo*, the vast majority of patents in force today

will suffer a significant loss in the property right that existed upon grant of the patent without due process for the owners of these patents. The retroactive application of *Festo* may be one of the most significant takings of existing property rights by the federal courts. Because *Festo* announces a new principle of law and upsets the settled expectations of the parties to the patent system, it should not be given retroactive effect.

ARGUMENT

I. THE BIOTECHNOLOGY INDUSTRY DEPENDS ON A STRONG DOCTRINE OF EQUIVALENTS

A. The Complete Bar Rule of *Festo* Represents a Drastic Change in Patent Law that Should Be Made, If at All, by Congress

By holding "that when a claim amendment creates prosecution history estoppel, no range of equivalents is available for the amended claim element," the *Festo* court has dramatically altered the landscape of patent law. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 564 (Fed. Cir. 2000) (*en banc*). This decision "unfairly tips the balance away from patentees and toward competitors by constraining the legitimate rights of patentees to their inventions, even where competitors can reasonably determine the reasons for any amendments and the scope of any subject matter surrendered." *Id.* at 620-621 (Linn, J., dissenting in part). Such a shift in policy may particularly harm an industry, like biotechnology, where a claimed invention immediately suggests a large number of equivalents. *See id.* at 617 (Michel, J., dissenting in part).

The doctrine of equivalents has been an integral part of the United States patent system for nearly 150 years, since *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1854). In subsequent years, this Court's decisions repeatedly affirmed the vitality of the doctrine and rejected efforts to

limit its scope. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09 (1950) (collecting cases). This Court has reiterated the importance of the doctrine, noting that a patent claim "functions to forbid not only exact copies of an invention, but products that go to 'the heart of an invention but avoids the literal language of the claim by making a noncritical change.' " *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 373-74 (1996) (quoting H. Schwartz, Patent Law and Practice 82 (2d ed. 1995)).

Potential infringers must consider the doctrine when evaluating whether to engage in conduct that may infringe a patent. The decision to practice a patented invention near the borders of its claims is a calculated risk, requiring no more care than in analogous areas of the law. Application of the "insubstantial difference" test for equivalency is no less certain, for example, than application of a "reasonableness" test found in ordinary tort law. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). Parties must make judgment calls, and patent attorneys, schooled in claim interpretation and familiar with the technology, are eminently able to make such determinations. That they may sometimes be wrong is no reason to eliminate or severely limit the doctrine. They are also sometimes wrong in opining on literal infringement. *See, e.g., Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1278-79 (Fed. Cir. 1995).

Festo will lead to a number of predictable consequences. First, patentees, unable to rely on the doctrine of equivalents, will claim a greater number of variants of their inventions to attempt to gain protection against insubstantial changes. Such additional disclosures could cause an explosion in the verbiage a patent contains. This change to current patent drafting practice could lead to an even greater reliance on the doctrine of equivalents because narrowly drafted claims allowed by the PTO without any amendment would still be entitled to a range

of equivalents. *See Festo*, 234 F.3d at 592 (Plager, J., concurring).

The Court of Customs and Patent Appeals noted that "[t]o require such a complete disclosure would apparently necessitate a patent application or applications with 'thousands' of examples . . . along with information as to whether each exhibits [the property of the invention]." *In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). Because the additional information disclosed would consist of insubstantial variations, there would be little corresponding public benefit from this disclosure. Instead of reasonable notice of the scope of claims (including equivalents), competitors would be buried in "an avalanche of trivial information – a result that is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976) (finding that excessive financial disclosure provides less useful information than concise summaries).

Festo also encourages patentees to blur the boundaries of their inventions with broadening terms and imprecise adjectives. *See, e.g., Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923) (using "substantial" and "high" to describe a patentable improvement to a papermaking machine); *see generally* 3 D. Chisum, Patents § 8.03[3][c] (2000) (discussing words of degree and relational terms). During examination, a patent examiner must evaluate whether each claim is definite, enabled by the specification, and supported by a written description. 35 U.S.C. § 112. In addition, the examiner must compare each claim to the prior art to determine whether the art anticipated or rendered obvious the claim. 35 U.S.C. §§ 102, 103. The additional work created by vastly greater numbers of claims per patent and the use of fuzzy terms would increase the time

from the filing of a patent application to issuance of a patent.[3]

If this Court affirms the complete bar rule, patents obtained pre-*Festo* in reliance on the doctrine of equivalents could become valueless. Very few patents are granted with claims as originally filed. *See Festo*, 234 F.3d at 638 (Newman, J., dissenting in part). Many patentees accepted claim language amendments suggested by the PTO to facilitate allowance of their patents without intending to surrender claim scope. *See id.* at 234 F.3d at 622 (Linn, J., dissenting in part). If any change in the law is appropriate, it should be made by Congress, which can adopt suitable grandfathering legislation.

Lastly, and contrary to the constitutional objective of encouraging public disclosure of useful inventions, *Festo* may cause companies to rely more heavily on trade-secret protection for their inventions. "The interest of the public is that the bargain of 17 years of exclusive use in return for disclosure be accepted." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489 (1974). Faced with uncertainty that their patents may be rendered valueless by only strict literal reading, inventors may choose to limit early disclosure of certain inventions, especially in unpredictable arts such as biotechnology. *See Angstadt*, 537 F.2d at 503. But, because competitors could reverse engineer biotechnology and biopharmaceutical products without great difficulty, trade secret protection is often impractical. Without the exclusivity offered by reasonable patent

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[3] Biotechnology patents, which now may take eight or ten years to issue could well take fifteen years instead, leaving the patentee with only a few years of protection. *See, e.g., Hitzeman v. Rutter*, 243 F.3d 1345, 1348 (Fed. Cir. 2001) (Federal Circuit decision granting priority over nineteen years after filing of priority application); *Chiron Corp. v. Abbott Lab., Inc.*, 902 F.Supp. 1103, 1108-1109 (N.D. Cal. 1995) (eight years from filing to issuance).

or trade secret protection, the biotechnology industry has less of an incentive to innovate, and, consequently, the public interest suffers.

B. The Public Interest in Biotechnology Innovation Would Be Impaired If the Doctrine Were Eliminated or Cut Back

"It would be difficult to underestimate the effect that biotechnology will have on health care delivery and, more to the point, on the health care status of the American public and our neighbors throughout the world." 146 Cong. Rec. S144 (daily ed. Jan. 31, 2000) (statement of Sen. Hatch). "Approximately 1,300 biotech companies in this country employ more than 150,000 people. . . . The industry spent nearly $10 billion on research and development in 1998 while revenues totaled $18.4 billion." *Id.* (statement of Sen. Mikulski). "The biotechnology industry relies heavily on patent protection in recouping the costs of bringing new drugs to the market. Furthermore, adequate patent protection is vital in persuading investors to provide the necessary capital to the industry." 141 Cong. Rec. S15221 (daily ed. Oct. 17, 1995) (statement of Sen. Hatch).[4]

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[4] Recently, Arthur Andersen reported, in a survey of 272 senior industry executives in the pharmaceutical, biotechnology, and health care industries, "the development and protection of intellectual property is seen [to be] the most critical area" that drives their organizations' business strategies. Ninety-four percent of the respondents indicated that protecting proprietary research was a critical challenge, and ninety percent identified patent infringement as a critical area. Arthur Andersen, *Patients or Patents? New Andersen Survey Reveals What Matters Most to the 21st Century Healthcare Community* <http://biz.yahoo.com/prnews/010424/cgtu031.html> (April 24, 2001).

Much of the explosive growth in the biotechnology industry has resulted from technological advances in the last twenty years. Not coincidentally, this Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), that a human-made, genetically-engineered, living organism is patentable subject matter, signaled the beginning of the biotechnology industry itself. The United States has since emerged as the world's leading producer of biotechnology inventions, being the priority country for 63% of the patent families filed worldwide in 1990-94. *See* Rausch, *International Patenting Trends in Biotechnology: Genetic Engineering*, National Science Foundation, Issue Brief NSF 99-351 <http://www.nsf.gov/sbe/srs/issuebrf/sib99351.htm> (June 18, 1999). *Festo* weakens that crucial patent protection – a result that negatively impacts the American biotechnology industry.

To understand the special importance of the doctrine of equivalents to biotechnology patents, a modicum of background in biology is helpful. All living organisms contain genetic material, usually made of DNA (deoxyribonucleic acid). Smaller molecules, called nucleotides, are arranged in a DNA molecule like beads on a string. Only four nucleotides, typically labeled A, T, C, and G, comprise DNA, but a single strand of DNA may have thousands or millions of nucleotides.[5]

DNA contains encoded information that living cells use to build proteins. Proteins are molecules that perform a wide variety of functions in living organisms, from digesting food to forming muscles to helping the immune system combat infections. Like DNA, proteins can be described as linear (chain-like) molecules. All protein chains are made from combinations of smaller molecules,

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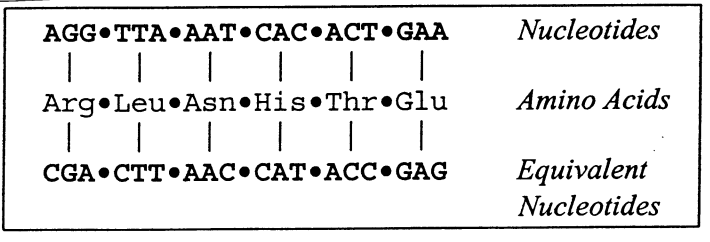
[5] For additional background, *see* K. Drlica, *Understanding DNA and Gene Cloning: A Guide for the Curious* 27-37 (2d ed. 1992).

called amino acids. There are twenty possible amino acids that can be classified based on their chemical characteristics. *See* Lodish *et al., Molecular Cell Biology* 55 (1995). The sequence of nucleotides in DNA "encodes" the sequence of amino acids in a protein. Each group of three nucleotides in a DNA sequence "codes" for one amino acid. In this way, a long molecule of DNA directs the production of a long protein molecule. Living cells have a complex machinery that "reads" a molecule of DNA, taking the sequence information from the DNA molecule and building the corresponding protein. A "gene" is simply a sequence of DNA that encodes for a particular protein.

The doctrine of equivalents is essential for biotechnology patents claiming particular genes or proteins. In biotechnology patent cases, the Federal Circuit has focused on specific disclosure of a gene's exact sequence. *See Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). Thus, under the policy that the PTO applies during biotechnology patent examinations, it is extremely difficult to obtain allowance of a claim for "a DNA sequence encoding protein X" unless the patent specification discloses the exact DNA sequence and the claims are correspondingly limited to it. Therein lies the rub. Because there are sixty-four combinations of three nucleotides (recall that three nucleotides encode one amino acid) and only twenty amino acids, several different combinations of nucleotides are known to encode for the same amino acid. For example, nucleotides AGG and CGA both code for the same amino acid. Thus, two very different strands of DNA can encode the same amino acid sequence:



Without a doctrine of equivalents, a gene patent would be valueless unless it claimed every equivalent sequence of nucleotides. Competitors could infringe simply by substituting nucleotides with others known to be interchangeable. A patentee would need to disclose and claim every variant to prevent such unscrupulous copying. Mathematics alone make describing every possible variant impractical. *See In re Bell,* 991 F.2d 781, 784 (Fed. Cir. 1993) (noting that 10^{36} nucleotide sequences could encode a protein called IGF). While no doubt a computer could be programmed to print out every analog, the resulting patent claims would be a stack of paper miles high, and would overwhelm the PTO, as well as those who track patents, with their sheer bulk.[6]

Protein patents present a similar problem. As the Federal Circuit noted in analyzing a patent claim to the protein erythropoietin, "over 3,600 different [protein] analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids." *Amgen, Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1213 (Fed. Cir. 1991). A substitution of one amino acid (*e.g.*, leucine) with another amino acid with similar chemical characteristics (*e.g.*, valine) often results in an insubstantially different protein. Even some additions or deletions of amino acids from the sequence of the protein will yield a functionally equivalent protein. Many analogs are functionally indistinguishable, and no purpose would be served by requiring their disclosure.

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[6] The difficulties of examining DNA and protein patents have forced the PTO to adopt special rules for the presentation of nucleotide or amino acid sequence disclosures. 37 C.F.R. §§ 1.821 et seq. (1999); U.S. Department of Commerce, Patent & Trademark Office, *Manual of Patent Examining Procedure* §§ 2420 et seq. (rev. ed. Feb. 2000).

One of the *Festo* majority wrote separately to express his opinion that the biotechnology industry's special need for the doctrine of equivalents was "largely theoretical." *Festo*, 234 F.3d at 597 (Lourie, J., concurring). This is not correct, and a recent decision demonstrates why the biotechnology industry needs a vital doctrine of equivalents.

Amgen obtained a series of patents relating to a recombinant DNA product similar to the natural protein erythropoietin (EPO) – a protein described as being made up of 166 amino acids.[7] *See Amgen, Inc. v. Hoechst Marion Roussel*, 126 F.Supp. 2d 69, 132-133 (D. Mass. 2001) ("*Hoechst*"). A competitor engineered cells to produce a variant that was 165 amino acids in length, missing only the last amino acid. *See id.* at 133. Thus, Amgen's claim was found not literally infringed. But, after applying the "function-way-result" test, the *Hoechst* court determined that the competitor's variant was equivalent to the claimed EPO. *Id.* at 134.

Hoechst demonstrates that skilled biotechnologists can readily recognize and create proteins (and DNA molecules) of equivalent function by making insubstantial changes to a claimed sequence. Amgen's inventors disclosed how to make a protein useful for treating many disease conditions, and their disclosure allowed competitors to readily create an equivalent protein through an insubstantial modification. Without a doctrine of equivalents, the value of Amgen's patent would have been lost, even though the deletion of the single amino acid created a molecule which is, for all known relevant biological purposes, the "same" protein. The concern of the

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[7] The patent at issue – like many based on an early disclosure of a biotechnology invention – described a protein (or DNA) sequence and contained broad functional language describing obvious variants.

biotechnology industry over the loss of the doctrine of equivalents is very real indeed.[8]

II. THE NEW RULES ANNOUNCED IN *FESTO* SHOULD NOT BE APPLIED RETROACTIVELY

Festo overturns the settled expectations of patent applicants based on precedent regarding the doctrine of equivalents. The *Festo* majority announced three new rules of law: (1) that a patentee who amends a claim for any reason relating to a statutory patentability requirement is subject to prosecution history estoppel, *Festo*, 234 F.3d at 566; (2) that voluntary amendments will create estoppel, *id.* at 568; and (3) that prosecution history estoppel creates a complete bar to application of the doctrine of equivalents, *id.* at 578. These rules "unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such [rules] would apply." *Warner-Jenkinson*, 520 U.S. at 41 (Ginsburg, J., concurring).[9] Because these new rules rescind the valuable property interests of patentees who prosecuted patents in justifiable reliance on obtaining a reasonable scope of equivalents, the holding of *Festo* should only be applied prospectively – to applications filed after *Festo*.

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[8] In 1999, Amgen had sales of $1.76 billion for its recombinant EPO product, Epogen(R). *Id.* at 77.

[9] On remand, the Federal Circuit acknowledged Justice Ginsburg's concerns and concluded that, when the record was silent as to the reason for an amendment, the patentee should have an "opportunity to establish the reason, if any, for a claim change." *Hilton Davis Chem. Co. v. Warner-Jenkinson, Inc.*, 114 F.3d 1161, 1163 (Fed. Cir. 1997) (*per curiam*).

A. Application of the *Chevron* Factors Demonstrates that *Festo* Should Only Be Applied Prospectively

Patentees who obtained their patents prior to *Festo* suffer a vital loss of property rights with the elimination of the doctrine of equivalents for a large class of claims and the delineation of a foolproof method to avoid infringement of such a claim. This Court has set forth three factors to consider in deciding whether a judicial decision would have a purely prospective effect: (1) whether the decision to be applied non-retroactively establishes a new principle of law, (2) whether retroactive application of the decision serves the purpose and effect of the decision, and (3) whether substantially inequitable results would occur if the decision is applied retroactively. *See Chevron Oil Co. v. Huson*, 404 U.S. 97, 106-107 (1971). *Festo* eliminates the doctrine of equivalents for a large proportion of the approximately 1.2 million patents in force today. If the dubious certainty of the complete bar is necessary, then *Festo* announced exactly the type of new rule that the Court has discretion to apply in a purely prospective manner.[10]

1. The Complete Bar Represents a New Principle of Law

Having found that the Supreme Court "has not fully addressed the [scope] of equivalents that is available once prosecution history estoppel applies," the *Festo* majority

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[10] In *Harper v. Virginia Dept. of Taxation*, 509 U.S. 86, 97 (1993), this Court held that when it "applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect. . . . " However, the issue here is whether the complete bar rule of *Festo* should have a purely prospective effect. Justice O'Connor noted that "the question of pure prospectivity [was] not implicated by [*Harper*]." *Id.* at 116 (O'Connor, J., dissenting).

concluded that it "must independently decide the issue." *Festo*, 234 F.3d at 571. After analyzing a long line of Federal Circuit decisions applying a "flexible bar" approach – that the range of equivalents is limited but not eliminated by prosecution history estoppel – the *en banc* majority overruled its prior decisions regarding the scope of prosecution history estoppel. *Id.* at 574. By overruling a long line of decisions upon which patentees relied, *Festo* completely changed the legal landscape for patentees and their competitors. *See id.* at 612-615 (Michel, J., dissenting in part) (collecting more than fifty Federal Circuit cases applying the flexible bar approach).

2. Retroactive Application of *Festo* Does Not Promote the Goals of Certainty and Promoting Innovation

If certainty in the scope of patent claims is the goal of the complete bar rule, that purpose is not advanced by applying the rule retroactively to patent applications filed before *Festo*. The premise underlying the new rule is that literal claim scope is readily ascertainable while the scope of the doctrine of equivalents is not. This is demonstrably wrong. The inherent limits in the ability of language to describe inventions create an inevitable amount of uncertainty at the borders of patent claims, whether the infringement asserted is literal or equivalent.

For example, in *Key Pharms. v. Hercon Lab. Corp.*, 161 F.3d 709, 716-17 (Fed. Cir. 1998), the Federal Circuit approved the use of extrinsic evidence to construe the phrase, "a pharmaceutically effective amount." The intrinsic record (the patent and prosecution history) contained no evidence on the point. *Id.* at 718. It can be no less certain to rely entirely on *extrinsic* evidence to determine the literal scope of a patent than to ascertain a scope of equivalents based on the *intrinsic* record.

Applying *Festo* retroactively also does not increase the certainty as to the scope of claims that have issued

after argument by the applicant. "Arguments made voluntarily during prosecution may give rise to prosecution history estoppel if they evidence a surrender of subject matter." *Festo*, 234 F.3d at 568. Accused infringers will now assert that arguments made during prosecution surrender subject matter, while patentees will argue the opposite. Courts will still have to make the difficult ultimate determination whether an argument made during prosecution surrenders claim scope. *See Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996) (noting that equivocal nature of argument during prosecution made it difficult to determine whether applicant surrendered subject matter).

Nor will any increased "certainty" in the scope of already-issued patents foster the purpose of promoting innovation. *See Festo*, 234 F.3d at 577. The "new rule hands the unscrupulous copyist a free ride on potentially valuable patented technology, as long as the copyist merely follows the prosecution history roadmap and makes a change, no matter how trivial or insubstantial, to an element otherwise covered by such a narrowed claim limitation." *Id.* at 627 (Linn, J., dissenting in part). Any rule that favors a copyist lessens the incentive to undertake the risks involved in invention. *See Graver Tank*, 339 U.S. at 607 (noting that limiting scope of claims to their literal language "would foster concealment rather than disclosure of inventions"); *see also Festo*, 234 F.3d at 639 (Newman, J., dissenting in part). Experience since *Winans* and *Graver Tank* demonstrates that a healthy range of equivalents promotes, rather than hinders, innovation.

3. *Festo* Retroactively Alters the Bargain Between the Patentee and the Government

Reliance on the flexible bar rule now leaves many patentees with worthless patents if *Festo* is applied retroactively. This Court acknowledged that the PTO also may

have relied on a flexible rule of estoppel when deciding whether to request an amendment to a claim. *See Warner-Jenkinson*, 520 U.S. at 32 n.6. If a complete bar applies, the typical patent prosecution practice would leave a patentee with claims that had no range of equivalents because the practice has been to claim broadly in the initial application and then arrive at an agreeable set of claims through negotiation with the examiner. *See Festo*, 234 F.3d at 592 (Plager, J., concurring). The complete bar rule thus reverses the rules of the game for most existing patents.

The patent process is a bargain between the inventor and the Government. The inventor agrees to disclose an invention to the public in exchange for the Government's agreement to grant a patent on the invention for a term of years. *See Kewanee Oil*, 416 U.S. at 481. *Festo* retroactively takes away from patentees part of the consideration they received from the Government before allowing their patent to be published. Thus, *Festo* destroys the reliance interest of patentees and instead benefits copyists who add nothing of value to the technology.

The injustice is clearer still in a rapidly-advancing industry like biotechnology. A consistent justification for the doctrine of equivalents is to accommodate "after-arising technology." *See Warner-Jenkinson*, 520 U.S. at 37. "Because after-arising technology was not in existence during the patent application process, the applicant could not have known of it, let alone surrendered it." *Festo*, 234 F.3d at 620 (Rader, J., dissenting in part). Restricting patentees to the literal language of the patent claim and allowing competitors to use after-developed equivalents with impunity would also render the vast majority of current biotechnology patents "hollow and useless." *Graver Tank*, 339 U.S. at 607.

The only way for an applicant to avoid estoppel under *Festo* is to show from the record that an amendment was not made for reasons of patentability. *Festo*, 234

F.3d at 586. However, "a patentee would have had little incentive to insist that the reasons for all modifications be memorialized in the file wrapper as they were made." *Warner-Jenkinson*, 520 U.S. at 41 (Ginsburg, J., concurring). And patentees have no way now to go back in time and supplement the record to comply with the new rule. Thus, *Festo* renders the "rebuttable presumption" of *Warner-Jenkinson* an absolute presumption. *See Festo*, 234 F.3d at 632 (Newman, J., dissenting in part).

During the prosecution process, patentees were entitled to rely on the existing law regarding the doctrine of equivalents in deciding whether to accept the bargain offered by the Government. As stated by Justice Frankfurter, "We should not indulge in the fiction that the law now announced has always been the law and, therefore, that those who did not avail themselves of it waived their rights." *Griffin v. Illinois*, 351 U.S. 12, 26 (1956) (Frankfurter, J., concurring). This is not a case where a court interpreted a statute for the first time. Rather, prosecution history estoppel is a judicially-created doctrine that has been changed, more akin to Congress amending a law. When Congress does amend a law affecting property rights, it takes into account the preexisting rights and the need to grandfather such rights. By imposing *Festo* retroactively this Court would punish patentees for behaving rationally under existing law.

B. Retroactive Application of *Festo* Deprives Patentees of Their Property Rights Without Due Process

In giving its new rules retroactive effect, the Federal Circuit has caused a significant diminution in value in a large percentage of the patents in force today. An inventor has a natural right to his or her discoveries. *See Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). "[The inventor] may keep his invention secret and reap its fruits indefinitely." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,

489 U.S. 141, 150 (1989). Or the inventor can disclose the invention and enjoy a time-limited period of exclusivity from the Government, including, exclusion of those who practice an insubstantial change to the invention. *Festo* eliminates a substantial portion of that exclusivity and significantly diminishes the value of most existing patents.

A patent provides a right to exclude others from practicing the claimed invention for a limited period of time. *See* 35 U.S.C. § 154 (2000). If Congress shortened the patent term retroactively, then the owner of an existing patent would likely be able to seek just compensation under the Takings Clause of the Fifth Amendment.[11] The *Festo* decision similarly takes a portion of the patentee's property by severely limiting the right to exclude. Retroactive application of *Festo* represents an uncompensated judicial taking of existing property rights. *See Hughes v. Washington*, 389 U.S. 290, 298 (1967) (Powell, J., concurring) (reasoning that the Takings Clause applies to courts as well as legislatures).

Expressed another way, *Festo* represents the taking of a valuable trade secret by inducing its disclosure in exchange for certain compensation, and then later taking back a portion of that compensation. In *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), Monsanto argued that forced disclosure of its trade secrets pursuant to administrative regulations would constitute a taking requiring just compensation. In response, this Court held that a trade secret was a property interest protected by the Takings Clause. *Id.* at 1003-1004. Because the Court found that the economic value to Monsanto was its competitive

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[11] *Cf., e.g., In re Berg*, 140 F.3d 1428, 1435 n.9 (Fed. Cir. 1998) (patents originally filed before June 8, 1995 were entitled to the *longer* of seventeen years from the date of issue or twenty years from the date of filing pursuant to amendment to 35 U.S.C. § 154 enacted by Pub. L. 103-465 § 532(a)(1) (1994)).

advantage by virtue of exclusive access to its trade secrets, it held that the EPA's use or disclosure of Monsanto's trade secrets was a taking for public use. *Id.* at 1016.

In the patent context, an inventor predicates the disclosure of an invention, which until such disclosure is held as a trade secret, in exchange for exclusivity for the disclosed invention and a reasonable scope of equivalents. "A State cannot be permitted to defeat the constitutional prohibitions against taking property without due process of law by the simple device of asserting retroactively that the property it has taken never existed at all." *Stevens v. City of Cannon Beach*, 510 U.S. 1207, 114 S.Ct. 1332, 1334 (1994) (Scalia, J., dissenting as to denial of writ of *certiorari*). By announcing the complete bar rule, the Federal Circuit has similarly extinguished existing property rights in patents by holding such rights never existed.

Patentees now subject to the complete bar rule have not had an opportunity to be heard "at a meaningful time and in a meaningful manner" as required by the Due Process Clause of the Fifth Amendment. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); *cf. Brinkerhoff-Faris Trust & Sav. v. Hill*, 281 U.S. 673, 679-680 (1930) (holding that deprivation of property rights by state judiciary without notice and opportunity to be heard violates Due Process Clause of Fourteenth Amendment). A patentee does not now have the option of retreating from the bargain and treating an invention previously disclosed in a patent as a trade secret. *See Kewanee Oil*, 416 U.S. at 490 (inventor could choose to treat invention as trade secret). Because the rules have been changed for owners of existing patents without an opportunity to be heard, the Court should consider whether the Due Process Clause prevents the retroactive application of *Festo*.

CONCLUSION

Patent protection and the doctrine of equivalents have played a particularly important role in promoting the advancement of the biotechnology and biopharmaceutical industry. *Festo* substantially changes the rules of the game for already issued patents and decreases the incentive to apply for patents in the future. For the foregoing reasons, the petition should be granted.

Respectfully submitted,

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CHIRON CORPORATION

Founded in 1981 by scientists at the University of California, Chiron Corporation ("Chiron"), with more than three thousand employees, is one of the world's largest biotechnology companies. Chiron applies biotechnology and other techniques of modern biology, including the rapidly expanding field of genomics, to develop products intended to lower the overall cost of healthcare and improve the quality of life by diagnosing, preventing, and treating disease. To carry out this mission, Chiron invests heavily in biological research – nearly $1.2 billion in the last four years. In return for its investment in research and development over the past twenty years, Chiron's inventions include drugs to treat cancer, multiple sclerosis, and cystic fibrosis; vaccines for hepatitis B, meningococcal C, and whooping cough; and blood tests used worldwide to screen donated blood for HIV and hepatitis C virus.

As do other biotechnology companies, Chiron depends on patent protection to achieve adequate returns on its research outlay to encourage stockholder investment. Chiron now owns over three thousand United States and foreign patents. Chiron has taken a lead role in litigating issues related to biotechnology patent protection, including both infringement actions against companies that seek to use its patented technologies without a license and appeals from Patent and Trademark Office ("PTO") decisions related to issues of patentability. *See, e.g., Genentech, Inc. v. Chiron Corp.*, 220 F.3d 1345 (Fed. Cir. 2000); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). Chiron also appeared as *amicus curiae* in *Warner-Jenkinson Co., Inc. v.*

Hilton Davis Chem. Co., 520 U.S. 17 (1997). From its vantage point on the cutting edge of biotechnology, science, and law, Chiron has a unique perspective on the necessity of the doctrine of equivalents to ensure adequate protection for biotechnology inventions.

GUILFORD PHARMACEUTICALS, INC.

Guilford Pharmaceuticals Inc. is a small biopharmaceutical company located in Baltimore, Maryland. Guilford Pharmaceuticals was incorporated in 1993 and presently employs more than 300 people. The company focuses its research and development on nervous system disorders, such as Parkinson's Disease, and biocompatible polymeric drug delivery systems for use in, *e.g.*, treating cancer. It is also developing delivery systems for analgesics. Guilford has one commercial product on the market – GLIADEL® Wafers.

Guilford holds more than 100 U.S. patents and has approximately 130 pending U.S. applications. It also has foreign counterparts to its U.S. cases.

Although Guilford is not a biotechnology company, like biotechnology companies, Guilford relies very heavily on patent protection in recouping its costs of bringing new drugs to the market and in persuading investors to provide necessary capital to support its research and development. Guilford Pharmaceuticals has no interest in either of the parties to this litigation or in the outcome of this case, other than its interest in seeking correct and consistent interpretation of the law relating to the doctrine of equivalents and in ensuring that valuable patents are not easily and unfairly circumscribed.

XOMA

XOMA develops and manufactures innovative biopharmaceuticals for disease targets that include cancer, immunological and inflammatory disorders and infectious diseases. Late-stage product collaborations include: 1) Genentech, Inc. to develop the Xanelim™ anti-CD11a monoclonal antibody product, in Phase III for psoriasis and in Phase I/II for kidney transplant rejection; 2) Baxter Healthcare Corporation to develop NEUPREX® (a systemic formulation of rBPI21) for meningococcemia (Phase III) and Crohn's disease (Phase II) and other indications; and 3) Onyx Pharmaceuticals, Inc. to develop and manufacture its CI-1042 product for cancer (Phase II and III). Earlier-stage programs include: ING-1, a Human Engineered™ antibody in Phase I studies in cancer patients; Genimune™, a Human Engineered™ antibody-based gelonin fusion product to treat autoimmune diseases and immunological cancers; Mycoprex™ for treatment of fungal infections; and BPI-derived anti-angiogenic compounds for retinal disorders. XOMA also has several proprietary enabling technologies, including the targeted gelonin fusion technology, bacterial cell expression systems for the manufacture of recombinant antibodies and other proteins, and the Human Engineering™ method for reducing the immunogenicity of antibodies.