St. Mary's Law Journal

Volume 33 | Number 3 Article 4

1-1-2002

Doctrine of Equivalents: Is Festo the Right Decision for the Biomedical Industry.

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COMMENTS

DOCTRINE OF EQUIVALENTS: IS *FESTO* THE RIGHT DECISION FOR THE BIOMEDICAL INDUSTRY?

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I. INTRODUCTION

Patents are the key to innovation, particularly in the biomedical industry.[1] Over 200 million people worldwide benefit from drugs and vaccines licensed by the Food and Drug Administration ("FDA").[2] An even greater number of people may benefit from the more than 350 products currently at the clinical trials stage of obtaining FDA licensure.[3] Typically, many patents precede FDA licensure, including patenting of raw materials, processes, and products. These patents ensure that the inventors and companies recapture significant initial investments and make profits.[4] Many products originate with patents by research universities, which eventually transfer the technology to commercial industry through licensing agreements.[5] These agreements provide royalties that open the door for future research into more innovative products.[6] Therefore, the continued viability of the biomedical industry holds undeniable importance to both world health and the world's economy.[7]

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1. *See* Brief of Amicus Curiae Chiron Corp. at 29, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 125109 (describing how patents are critical to promoting advancement in the biotechnology industry). Chiron noted that the doctrine of equivalents is needed to ensure sufficient protection for patents in the biotechnology industry. *Id.* at 2; *see also* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 639 (Fed. Cir. 2000) (Newman, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (commenting that the industry's economy is driven by innovation and that the primary function of patents is encouragement of innovation).

2. Biotechnology Industry Organization: Editors' & Reporters' Guide to Biotechnology, *Some Facts About Biotechnology*, www.bio.org/aboutbio/guide2000/facts.html (last visited Jan. 31, 2002).

3. *Id.*

4. *See* Brief of Amicus Curiae Chiron Corp. at 1, *Festo* (No. 00-1543) (describing the reliance on patent protection for return on research investments); *see also Festo*, 234 F.3d at 621 (Linn, J., concurring and dissenting) (recognizing that the Founding Fathers' intent for patents was to foster technological progress).

5. *See* Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 2, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 156915 (mentioning that the Bayh-Dole University and Small Business Procedures Act allows the transfer of patented technology to commercial enterprises to promote innovation and encourage economic development). Amici Curiae notes that technology transfer opportunities fuel unprecedented technological innovations benefiting the public. *Id.* at 17.

6. *See id.* at 18 (noting how royalties from licensing agreements are used to fund additional research).

7. *See* Brief of Amici Curiae Minnesota Mining & Manufacturing Co. et al. at 4-5, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025380 (stating that patents provide incentives for investment in research and development, which is required for future innovation); Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 2, *Festo* (No. 00-1543) (discussing how patents are beneficial to the economy).

Due to the importance of the biomedical industry, protection of biomedical patents is a necessity.[8] Accordingly, the doctrine of equivalents provides a valuable layer of protection to biomedical patents.[9] The doctrine was created over a century and a half ago to protect an original patent owner from another party seeking to copy the invention, narrowly avoiding literal infringement by varying the new copy slightly.[10] As a result, a patentee may still use this doctrine to assert infringement against an accused product when there is no literal infringement.[11] Literal infringement occurs when the accused device has exactly every element of a patent claim.[12]

The U.S. Supreme Court reaffirmed the existence of the doctrine of equivalents in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*[13] The Court held that the doctrine balanced the competing policies of public notice and patent protection.[14] Determination of equivalence is subject to judicial interpretation; however, courts should not evaluate equiva-

8. *See* Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 2, *Festo* (No. 00-1543) (indicating the importance of biotechnological patents).

9. *Cf.* Brief of Amicus Curiae Chiron Corp. at 2, *Festo* (No. 00-1543) (stressing that the doctrine of equivalents allows adequate patent protection for the biotechnology industry). Chiron also noted that without the doctrine of equivalents, biotechnology patents will suffer a diminution in value and biotechnology companies will be less likely to make the investments required for new products that can save lives. *Id.*

10. Jonathan M. Harris, Festo *Has Decimated the Doctrine of Equivalents*, TEX. B.J., Jan. 2002 at 58.

11. *See* Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (stating if there is no literal infringement of express claims, there may still be infringement by equivalence).

12. *See* Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991) (holding that no infringement occurred when the accused joined the links of a conveyor belt because it was not the appropriate means for the patented device); *see also Warner-Jenkinson*, 520 U.S. at 21 (stating literal infringement is a violation of a patent's express claims).

13. *See Warner-Jenkinson*, 520 U.S. at 40 (setting an "equivalence" guideline when an accused product is compared to "the claimed elements of the patented invention").

14. *See* Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 794 (1998) (explaining that patents need protection from copying, but others argue the more important purpose is public disclosure of the invention to ensure knowledge of what is available for public use); *see also Festo*, 234 F.3d at 638-39 (Newman, J., concurring and dissenting) (commenting that the majority is attempting to legislate a new balance between the inventor and copyist and noting that finding the optimum balance is crucial to the economy).

lence in a vacuum.[15] Use of the doctrine must allow consideration of a product's purpose, qualities, and functions.[16]

Although the doctrine of equivalents is a powerful tool, it has limitations. A significant limitation to the doctrine is prosecution history estoppel.[17] "Prosecution history" is the record of amendments and correspondence between an applicant and patent examiner.[18] The documented prosecution history may be used to invoke prosecution history estoppel, which limits the doctrine of equivalents.[19] This limitation prevents a patentee suing for patent infringement from regaining prior surrendered subject matter through patent claim amendments and

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15. *See* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950) (claiming that a patentee is not a prisoner of the formula in the patent and that equivalence is not absolute); William S. Galliani, *Patent Infringement Amidst Rapidly Evolving Technologies: New Equivalents, the Doctrine of Equivalents and the Reverse Doctrine of Equivalents*, 6 SANTA CLARA COMPUTER & HIGH TECH. L.J. 75, 88 (1990) (commenting that claim language is insufficient for determining the scope of protection, which requires the consideration of equivalents).

16. *See Graver Tank*, 339 U.S. at 609 (stating that one of the most important areas to analyze is whether a skilled person in the technical field would know whether a component is substitutable for the device named in the patent); *see also Festo*, 234 F.3d at 639 (Newman, J., concurring and dissenting) (asserting that patent systems should consider various factors). These factors include:

> nature of the technology, the rate of technologic change in the particular field, the maturity of the field, the cost of invention and development for various technologies, market risks and competitive structures, the ease and cost of imitation, and the choice between disclosure in patents and maintaining the technology in secrecy.

Id.

17. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 564 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001) (defining prosecution history estoppel as a tool preventing the doctrine of equivalents to vitiate claim notice requirements); Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1542 (Fed. Cir. 1995) (Plager, J., dissenting), *rev'd*, 520 U.S. 17 (1997) (arguing the Federal Circuit allowed an expansion of the application of the doctrine of equivalents that was "operationally unsatisfactory and jurisprudentially unjustified").

18. T. Whitley Chandler, Note, *Prosecution History Estoppel, the Doctrine of Equivalents, and the Scope of Patents*, 13 HARV. J.L. & TECH. 465, 466 (2000); *see also Festo*, 234 F.3d at 565 (describing that during patent prosecution, a record is created that notifies the public of surrendered matter).

19. *See* T. Whitley Chandler, *Prosecution History Estoppel, the Doctrine of Equivalents, and the Scope of Patents*, 13 HARV. J.L. & TECH. 465, 466 (2000) (noting that prosecution history estoppel is when prosecution history is used to the inventor's chagrin); Donald S. Chisum, *The Scope of Protection for Patents After the Supreme Court's* Warner-Jenkinson *Decision: The Fair Protection—Certainty Conundrum*, 14 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 23 (1998) (explaining that the use of prosecution history estoppel is allowed to stop patentees from obtaining protection on a claim surrendered earlier during prosecution); *see also Festo*, 234 F.3d at 564 (stating that actions, such as amendment and argument, may create prosecution history estoppel).

arguments to the patent examiner.[20] Most claim amendments are asserted to avoid prior art, but amendments are also made to meet other statutory patent requirements.[21] If prosecution history estoppel is extended as proposed by the Federal Circuit in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,[22] it would bar the use of the doctrine of equivalents in many, if not all, patents.[23]

Historically, there are two approaches the Federal Circuit uses to apply the doctrine of equivalents and the counter doctrine of prosecution history estoppel: (1) the flexible bar rule and (2) the complete bar rule.[24] The following illustrates these two rules:

> Imagine a claim that describes two members as being connected together, when the prior art discloses the members connected together by a nail. To avoid the prior art, the claim is amended to state that the members are glued together. Suppose further that there are two accused devices, one using paste to secure the connection and the other using a screw. Under a complete bar, the doctrine of equivalents would be unavailable as to both accused products. Under a 'flexible bar' regime, equivalence could not be asserted as to the screw, it being closely related to the prior art that the amendment was designed to avoid. But because paste is far more like glue than a screw or nail is, the patent could be enforced against the paste product if the patentee is able to prove at trial that glue and paste are equivalents.[25]

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20. *See Festo*, 234 F.3d at 619 (Rader, J., concurring and dissenting) (defining estoppel as preventing a litigant from denying a prior admission that another has subsequently relied upon); Petitioner's Brief at 5, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025738 (reiterating that traditional prosecution history estoppel prevented a patentee from obtaining equivalents previously surrendered during patent prosecution).

21. *See* Petitioner's Brief at 2, *Festo* (No. 00-1543) (noting that amendments are often created to redefine subject matter and sometimes to meet formal the requirements of a patent's description); Brief of Amici Curiae Minnesota Mining & Manufacturing Co. et al. at 3, *Festo* (No. 00-1543) (pointing out that almost all amendments made during patent prosecution are related to patentability).

22. 234 F.3d 558 (Fed. Cir. 2000).

23. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 33 (1997) (holding that prosecution history estoppel barred the use of the doctrine of equivalents because there was no reason for the amendment); *Festo*, 234 F.3d at 564 (stating that a patentee is precluded by prosecution history estoppel from coverage under the doctrine of equivalents of subject matter surrendered during prosecution).

24. *See Festo*, 234 F.3d at 573 (noting two lines of authority represented in *Hughes I* and *Kinzenbaw*, which lead to confusion in the patent system). Furthermore, one line of authority follows a strict approach and another follows a flexible approach. *Id.*

25. Petitioner's Brief at 32-33, *Festo* (No. 00-1543).

Recently, the Federal Circuit officially adopted the complete bar rule in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*[26] The *Festo* court held that during patent prosecution, there is no range of equivalents for an amended claim element or limitation regardless of the reason for the amendment.[27] Thus, courts will no longer consider the circumstances surrounding an amendment to determine if the applicant actually surrendered any subject matter.[28]

In effect, without full use of the doctrine of equivalents, patents are referred to as "a hollow and useless thing."[29] Without the doctrine, copyists could slightly modify inventions with insubstantial and inconsequential changes and avoid patent infringement.[30] Allowing these methods to avoid infringement takes away the patentee's protection she deserves.[31] Furthermore, the resulting injustice also promotes concealment of inventions, which defeats Congress's primary purpose for allowing patents.[32]

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26. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 574-75 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001) (holding predictability primarily makes the flexible bar approach unworkable).

27. *See id.* at 569 (ruling through an en banc decision that when a claim is narrowed by an amendment related to patentability, which creates prosecution history estoppel, there is no range of equivalents available for that amended claim limitation). *But see Warner-Jenkinson*, 520 U.S. at 32 (asserting there is no substantial reason to require a more rigid rule that invokes estoppel regardless of the amendment's reasons).

28. *See* Petitioner's Brief at 23, *Festo* (No. 00-1543) (stating that the *Festo* majority modified the rule of equity to a legal conclusion that does not consider the circumstances of amendments). Petitioner points out amendments that avoid prior art surrender overbroad claims, but amendments to clarify or improve a description do not automatically surrender subject matter. *See id.* at 26. In addition, Petitioner provides an example that illustrates this type of amendment. *See id.* at 23. Consider a patent applicant who accidentally omits a claim element that links two other claim elements. *Id.* The patent examiner rejects this claim under § 112 and the applicant amends to add the required linking element. *Id.* This amendment now creates prosecution history estoppel and completely bars the doctrine of equivalents even though there was no surrender of subject matter. Petitioner's Brief at 23, *Festo* (No. 00-1543).

29. Graver Tank & Mfg. Co. v. Linde, 339 U.S. 605, 607 (1950).

30. *See id.* at 607 (commenting that piracy must be prevented because it deprives inventors of the benefit of their invention and promotes concealment of inventions); *Festo*, 234 F.3d at 616 (Michel, J., concurring and dissenting) (suggesting how easy it will be for copyists to read prosecution history and identify amended claims). Judge Michel goes on to say that the copyist can copy all un-amended claims and make minor modifications to amended claims. *Id.* After this, the copyist has the same functional product but has not infringed upon the patent. *Id.*

31. *See Graver Tank*, 339 U.S. at 607 (stating this limitation allows copyists to make minor changes allowing the infringement to reach outside of the law); *Festo*, 234 F.3d at 621 (Linn, J., concurring and dissenting) (noting the exclusive rights granted by patents is valuable to inventors because it guarantees protection).

32. *See Graver Tank*, 339 U.S. at 607 (emphasizing that if piracy is allowed, form would prevail over substance).

Festo will likely affect the majority of the current 1.2 million unexpired patents that were probably amended during prosecution.[33] Moreover, *Festo* threatens to strip away 150 years of doctrine of equivalents precedence that applicants rely upon.[34] As a result, applicants must draft narrower claims and avoid any amendments by negotiating with the patent examiner.[35] These new guidelines will likely lead to more appeals.[36]

However, *Festo* must still face its greatest challenge. In June 2001, the Supreme Court granted certiorari on two issues.[37] The Court heard oral arguments in early January 2002 and will likely issue a decision before the end of 2002.[38] This Comment proposes a solution that may alleviate the potential devastation that *Festo* will inflict on the biomedical industry. The solution includes the adoption of a three-prong, modified, flexible bar approach which would allow courts to consider whether prosecution history estoppel should limit the use of the doctrine of equivalents. Part II provides background information regarding *Festo*, the patent prosecution system, and the history and development of the doctrine of equivalents and prosecution history estoppel. Furthermore, the back-

33. Petitioner's Brief at 43, *Festo* (No. 00-1543) (commenting that *Festo* "will do a gross injustice" to current patentees); Brief of Amici Curiae Minnesota Mining & Manufacturing Co. et al. at 1, *Festo* (No. 00-1543).

34. *Festo*, 234 F.3d at 598 (Michel, J., concurring and dissenting); *see also* Brief of Amicus Curiae Chiron Corp. at 8, *Festo* (No. 00-1543) (expressing that current patentees rely on precedent that the doctrine of equivalents can be asserted in an infringement action even if amendments unrelated to prior art are made).

35. *See* U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 36, *available at* http://www.uspto.gov/web/offices/com/advisory/notices (noting that applicants will probably come in with narrow claims and later broaden them with continuations after the patent's issuance); *see also* Noreen Krall & Celeste B. Filoia, *The Doctrine of Equivalents: An Analysis of the* Festo *Decision*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 373, 383 (2001) (warning that patent attorneys must be careful not to draft patent claims too narrowly, which can result in inadequate protection). *But see* Michael O. Sutton & Christopher G. Darrow, *Recent Developments in Patent Law*, 9 TEX. INTELL. PROP. L.J. 429, 444 (2001) (stating how practitioners may be able to avoid the effects of *Festo*).

36. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 618 (Fed. Cir. 2000) (Michel, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (noting that an already backlogged PTO Board of Patent Appeals and Interferences will receive more appeal filings); U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 37, *available at* http://www.uspto.gov/web/offices/com/advisory/notices (speculating that because more complex cases and double patent issues will arise, more appeals are likely, which will lead to increased PTO costs).

37. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 121 S. Ct. 2519, 2519 (2001); Petitioner's Brief at I, *Festo* (No. 00-1543).

38. Supreme Court Docket, 00-1543, http://www.supremecourtus.gov/docket/00-1543.htm (last visited Feb. 14, 2002); Jonathan M. Harris, Festo *Has Decimated the Doctrine of Equivalents,* 65 TEX. B. J. 58, 59 (Jan. 2002).

ground provides an overview of the biomedical industry and related patent prosecution. The third part introduces the *Festo*-induced problems with the doctrine of equivalents. Part IV specifically analyzes problems the biomedical industry faces with the new *Festo* patent protection. Finally, Part V offers a broad solution for addressing the doctrine of equivalents and prosecution history estoppel beyond the bounds of biomedical technology.

II. BACKGROUND

A. *Patent Prosecution*

The first United States patent was issued on July 31, 1790, by President George Washington to Samuel Hopkins for a fertilizer ingredient.[39] Since then, over six million patents have been issued.[40] A patent is essentially a contract between the patentee and the U.S. government, whereby the government grants the patentee the exclusive right to make, use, and sell the patented or claimed invention for a period of time.[41] In exchange, the patentee must fully disclose the invention so that after the exclusivity ends, those skilled in the field may use the invention for further development.[42] During the twenty-year exclusivity period, competitors may develop improvements; however, the patentee has the right to file an infringement claim to exclude others from using the claimed invention.[43]

The basic patent prosecution process begins when a patent-seeking inventor discloses her invention to a patent attorney.[44] The attorney then prepares and files a patent application with the Patent and Trademark

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39. Press Release, United States Patent and Trademark Office, First U.S. Patent Issued Today in 1790 (July 31, 2001), *at* http://www.uspto.gov/web/offices/com/speeches/01-33.htm (reporting that the first patent was issued for a system to make potash).

40. *Id.*

41. Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 785 (1998).

42. Anand Gupta, *Patent Law: The Supreme Court Reinforces the Validity of the Doctrine of Equivalents in* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 23 S. ILL. U. L.J. 123, 124-25 (1998); *see also* 35 U.S.C. § 112 (1984) (requiring enablement and mandating those skilled in the art to provide an enabling description); Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 4 (1997).

43. 35 U.S.C. § 281 (1984); 35 U.S.C. § 154(a)(2) (1984 & Supp. 2001); Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 4 (1997); *see also Festo*, 234 F.3d at 621 (Linn, J., concurring and dissenting) (noting that patents are valuable to the public because their disclosure stimulates building on human knowledge and creates advancements in technology).

44. Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 786 (1998); *see also* U.S. PATENT AND TRADEMARK OFFICE, Attorneys and Agents, *available at* http://

Office ("PTO") along with a declaration that the applicant is truly the first inventor.[45] The application's claims lend guidance upon where the boundaries of the inventor's protection will reach,[46] thus determining the "metes and bounds of the patentee's right to exclude."[47] After an application is filed, a PTO patent examiner evaluates and searches the invention and compares the claims to prior art.[48] The patent examiner often rejects the claims, triggering amendments to the claims that narrow or modify the patent, to gain approval.[49] All amendments submitted must include support from the contents of the original application.[50] Ulti-

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www.uspto.gov/web/offices/pac/doc/general/attorney.htm (last visited Oct. 28, 2001) (noting that patent attorneys or agents not recognized by the PTO cannot represent inventors).

45. *See* U.S. PATENT AND TRADEMARK OFFICE, Attorneys and Agents, *available at* http://www.uspto.gov/web/offices/pac/doc/general/attorney.htm (last visited Oct. 28, 2001) (stating that the patent attorney must include a general description of the invention along with specific claims); *see also* Anand Gupta, *Patent Law: The Supreme Court Reinforces the Validity of the Doctrine of Equivalents in* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 23 S. ILL. U. L.J. 123, 125 (1998) (noting that filing an application to the PTO is a requirement to obtain a patent).

46. *See* T. Whitley Chandler, *Prosecution History Estoppel, the Doctrine of Equivalents, and the Scope of Patents*, 13 HARV. J.L. & TECH. 465, 470 (2000) (reiterating that the claims are required to particularly and distinctly explain the subject matter of the invention); *see also* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1540 (Fed. Cir. 1995) (Plager, J., dissenting), *rev'd*, 520 U.S. 17 (1997) (commenting that claims define the legal rights of a patentee).

47. Graver Tank & Mfg. Co. v. Linde, 339 U.S. 605, 609 (1950).

48. *See* Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 787 (1998) (noting that patent examiners are experts in their technical field). Patent examiners review applications to ensure that the requirement for an "enabling" disclosure is met and that the invention is neither prior art nor already in the public domain. *Id.* Prior art is described as "prior patents and other technical literature." *Id.*; *see also* Petitioner's Brief at 4, *Festo* (No. 00-1543), 2001 WL 1025738 (noting that a patent examiner reviews an application to determine whether the claim scope is patentable and whether the claims are in proper statutory form).

49. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 618 (Fed. Cir. 2000) (Michel, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (commenting that the patent prosecution process is iterative as the applicants submit claims, the examiner provides rejections based on patentability, and the applicant amends claims to overcome rejections); Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 787 (1998) (explaining that narrowing amendments usually result from a claim rejection because it is not novel, it is obvious, or it does not distinctly point out the claim).

50. Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 787-88 (1998); *see also* Brief of Amicus Curiae United States at 16, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025650 (noting that amendments can clarify ambiguous terms or to state the same, or broader, claim in more precise terms).

mately, a patent is issued once the examiner is convinced the patent claims define over the prior art, all other statutory requirements are satisfied, and the fee is paid.[51] If a patent is not allowed by the examiner, the patentee has the right of appeal.[52] Correspondingly, the United States Court of Appeals for the Federal Circuit hears most patent appeals.[53]

The burden of proof for infringement is on the patentee.[54] Infringement analysis requires two steps: (1) a determination of the meaning of the claims and (2) a comparison of the accused device to patent claims.[55] Statutorily, infringement is defined as when anyone "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent."[56] The doctrine of equivalents is used by a patentee in an infringement action by comparing the accused product with the patent claims, and applies when the accused product has a slight modification from a claim, but the "heart of the invention is clearly copied."[57] The doctrine balances the goals of providing

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51. *See* T. Whitley Chandler, *Prosecution History Estoppel, the Doctrine of Equivalents, and the Scope of Patents*, 13 HARV. J.L. & TECH. 465, 471 (2000) (commenting that when a patent application meets all Patent Act requirements, the PTO must issue a patent); Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 788 (1998) (noting a patent is issued when the patent examiner is content with compliance of all regulatory and statutory requirements).

52. 35 U.S.C. § 134(a) (1984).

53. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164 § 1295(a)(4), 96 Stat. 25; *see also* 35 U.S.C. § 145 (1984) (allowing a party to seek a civil action remedy if dissatisfied with the 35 U.S.C. §134(a) appeal); *Festo*, 234 F.3d at 571 (recognizing that the Federal Circuit was specifically created to address patent law issues).

54. Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 685 (Fed. Cir. 1990); *see also* Jeffrey P. Kushan, Comment, *Protein Patents and the Doctrine of Equivalents: Limits on the Expansion of Patent Rights,* 6 HIGH TECH. L.J. 109, 147 (1991) (noting the burden of proof in protein infringement cases is particularly heavy if the patentee only claimed a specific sequence).

55. Frederick A. Spaeth, *"Equivalents Thereof" v. The Doctrine of Equivalents in the Interpretation of U.S. Patent Claims*, 20 QUINNIPIAC L. REV. 487, 487-88 (2001); *see also* Markman v. Westview Instruments, Inc., 517 U.S. 370, 374 (1996) (affirming judgment as a matter of law for the accused device and holding the construction of a patent lies exclusively with the court); Derick E. Allen, Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.: *Is It Time for the Supreme Court to Resolve How the Doctrine of Equivalents Should Be Applied?*, 15 ST. LOUIS U. PUB. L. REV. 157, 159 (1995) (explaining that patent infringement requires an interpretation of the scope and meaning of claims, and then the interpretation must be applied to the accused product).

56. 35 U.S.C. § 271(a) (1984 & Supp. 2001).

57. Werner H. Stemer, *The Doctrine of Equivalents After* Hilton Davis *and* Markman, *and a Proposal for Further Clarification*, 22 NOVA L. REV. 783, 793-94 (1998). The doctrine of equivalents provides the courts with a doctrine to stop copycats from designing around literal claims. *Id.*

full protection to a patentee and fair notice to the public regarding the scope of protection.[58]

B. *Doctrine of Equivalents*

The United States Constitution provides Congress with the power "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[59] Based on this clause, Congress enacted patent acts to provide inventors with protection. In 1790, the first patent act provided a review system to determine the invention's usefulness and importance.[60] The Act only required a specification that allowed enablement and distinguished the invention from currently known and used technologies.[61] Three years later, the 1793 Patent Act adopted a simplified review and issuance approach, which required a sufficient description with drawings and an oath that the inventor was the true inventor.[62] Because these two acts relied on the invention's description to define protection, patentees were shielded with broad coverage and competitors had difficulties developing products without infringing on existing patents.[63] Demonstrating the patent system's evolution, the 1836 Patent Act required a patentee to specifically point out the claims in the description, which determined the scope of an invention's protection.[64] However, the

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58. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 623 (Fed. Cir. 2000) (Linn J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (describing the doctrine of equivalents as standing at the intersection of justice for patentee protection and notice to the public of patentee's rights); London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991) (explaining that "designing or inventing around patents to make new inventions is encouraged, [however,] piracy is not").

59. U.S. CONST. art. I, § 8, cl. 8.

60. *See* Act of Apr. 10, 1790, ch. 7, §§ 1, 2, 1 STAT. 109, *microformed on* Vol. 1, Card 4 (Microcard Editions NCR) (approving a system for the Secretary of State, Secretary for the Department of War, and Attorney General to determine whether patent letters should be issued by the President).

61. *See id.* (requiring detailed specifications with a description distinguishing prior art). The Act also required enablement, which means that a person skilled in the area can make and use the invention after the patent expires. *Id.*

62. *See* Act of Feb. 21, 1793, ch. 11, §§ 1, 3, 1 STAT. 318, *microformed on* Vol. 1, Card 6 (Microcard Editions NCR) (allowing the Secretary of State to issue patents for the President and requiring full review along with exact, and clear terms in the specification).

63. *See* Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 6 (1997) (commenting that even though the claim requirement was codified, the infringement analysis remained focused on the "essence" of the invention, not the claims).

64. *See* Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, *microformed on* Vol. 5, Card 2 (Microcard Editions NCR) (requiring an applicant to specifically point out the claimed invention).

"spirit of the invention" was still the focus of infringement actions.[65] To facilitate patent-protection analysis, the 1836 Patent Act also established the Patent Office, which evaluated patent claims.[66] Subsequently, the 1870 Patent Act continued to refine the patent process by further defining the role of the Patent Office and detailing the patenting process.[67]

Winans v. Denmead[68] was the first case to address the concept of the doctrine of equivalents.[69] In *Winans*, the patented claim had a conical form while the accused device was designed with an octagonal form.[70] Despite the variation in form, the Supreme Court favored substance over form in its holding that an accused device infringes on an existing patent if the substance of the invention is copied in a varying form.[71] The *Winans* doctrine was further defined by the landmark case, *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*[72] This doctrine is based on the theory that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape."[73] These three factors have become known as the "function-way-result" test.[74] In *Graver Tank*,

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65. *See* Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 6 (1997) (noting that infringement was based on violation of the "spirit" of the invention, which is difficult for competitors to define).

66. Act of July 4, 1836, ch. 357, §§ 1-5, 5 Stat. 117, *microformed on* Vol. 5, Card 2 (Microcard Editions NCR).

67. *See* Act of July 8, 1870, ch. 230, §§ 1-33, 16 STAT. 198, *microformed on* Vol. 16, Card 3 (Microcard Editions NCR) (detailing the structure and responsibilities of the Patent Office and adding requirements for specifications, claims, drawings, models, oaths, and the patent review process); *see also* Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 6 (1997) (commenting that the doctrine of equivalents developed from this Act and that the Act requires a more elaborate definition and list of claims, which protects the patentee from the entire invention endeavor).

68. 56 U.S. 330 (1853).

69. Winans v. Denmead, 56 U.S. 330, 332 (1853).

70. *See id.* (describing the patented claim as a coal-carrying car that could hold more coal than previous cars and did not distort the shape; the accused device had the same functions but with an octagonal shape).

71. *See id.* at 343 (holding that since substance and form are separable, infringement is found even if the accused form is not claimed in the patent). *But see* McCormick v. Talcott, 61 U.S. 402, 408 (1857) (holding that change in form and combination is not patent infringement).

72. *See* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950) (explaining the purpose of the doctrine of equivalents is to prevent patent fraud).

73. *See id.* (quoting Union Paper-Bag Mach. Co. v. Murphy, 97 U.S. 120 (1877)). *But see Graver Tank*, 339 U.S. at 613-14 (Black, J., dissenting) (arguing that the majority ignored the Congressional statute requiring distinct claims and that what is not particularly disclosed is open for public use).

74. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1518 (Fed. Cir. 1995), *rev'd*, 520 U.S. 17 (1997); *see also Graver Tank*, 339 U.S. at 608 (stating a patentee

both parties claimed electric welding compositions.[75] The patented device claimed "a combination of alkaline earth metal silicate and calcium fluoride[,]" and uses calcium and magnesium to meet this claim.[76] The accused device contained silicates of calcium, but substituted magnesium for silicates of manganese, which is not an alkaline earth metal.[77] The Court found infringement because prior art demonstrated that manganese silicate was a useful welding material and therefore considered it an equivalent to the prior device.[78]

The half-century old Patent Act of 1952 is the latest legislation.[79] The Act makes a reference to equivalents, however it does not codify *Graver Tank*.[80] The Act's equivalents reference actually overrides *Halliburton Oil Well Cementing Co. v. Walker*,[81] which held that at the point of novelty, an applicant cannot claim by a functional "means."[82] The Patent Act of 1952, which is now partially included in 35 U.S.C. § 112, allows expression of any element as a "means."[83] The 1952 Patent Act requires the inventor to write an "enabling" disclosure and distinct claims.[84] The Act also established the novelty and the non-obvious requirements for obtaining a patent.[85]

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can use the doctrine of equivalents "if it performs substantially the same function in substantially the same way to obtain the same result").

75. *See Graver Tank*, 339 U.S. at 610 (comparing the patented Unionmelt Grade 20 with the accused Lincolnweld 660 device, both of which produce the same quality weld).

76. *Id.*

77. *Id.*

78. *See id.* at 612 (holding that the substitution resulted from imitation and not experimentation or invention). When changes to a patented invention are only "colorable," it is considered infringement, even though it is not literal. *See id.*

79. Act of July 19, 1952, Pub. L. No. 82-593, 66 Stat. 792.

80. *See* D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1575 (Fed. Cir. 1985) (noting the equivalents in the Patent Act of 1952 should not be confused with the doctrine of equivalents); *see also Warner-Jenkinson*, 520 U.S. at 28 (1997) (noting that Congress can pass legislation any time it chooses to eliminate the doctrine of equivalents); Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 23 (1997) (commenting that the drafters of the 1952 Patent Act noted the Act's purpose was to codify all existing patent laws).

81. 329 U.S. 1 (1946).

82. Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 8-9 (1946), *rev'd by* 35 U.S.C. § 112 (2001).

83. *Hilton Davis*, 62 F.3d at 1570 (stating that *Halliburton* was overruled by the Patent Act of 1952).

84. 35 U.S.C. § 112 (2001); *see also* T. Whitley Chandler, *Prosecution History Estoppel, the Doctrine of Equivalents, and the Scope of Patents*, 13 HARV. J.L. & TECH. 465, 469 (2000) (urging that the 1952 Patent Act was enacted to reverse cases requiring a hostile and subjective invention definition).

85. 35 U.S.C. §§ 102, 103 (2001).

The doctrine of equivalents was further refined by the newly established all-elements rule, set forth in *Pennwalt Corp. v. Durand-Wayland, Inc.*,[86] which held that the doctrine of equivalents is applied element by element.[87] Further modifications occurred in *Wilson Sporting Goods Co. v. David Geoffrey & Associates*,[88] where the court established the hypothetical claim test.[89] There, the issue in infringement cases became whether the PTO would have issued a patent on the hypothetical claim in consideration of prior art.[90] The *Wilson* court also noted that the doctrine of equivalents does not enlarge claims of a patent, but the scope of patent claims remain "as defined" while the doctrine "*expands the right to exclude*" equivalents of the claims.[91]

Since *Graver Tank*, the doctrine of equivalents had not received much attention until 1997.[92] The U.S. Supreme Court, in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*,[93] further defined the doctrine.[94] First, the Court affirmed that the *Graver Tank* decision survived the 1952 Patent Act and left it to Congress to legislate the doctrine as needed.[95] Second, the Court reiterated that the doctrine is applied in an element-by-element

86. 833 F.2d 931 (Fed. Cir. 1987) (en banc).

87. *See* Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935, 937 (Fed. Cir. 1987) (en banc) (finding that for equivalence, the patent element must have substantially the same function as an element in the accused device); Frederick A. Spaeth, *"Equivalents Thereof" v. The Doctrine of Equivalents in the Interpretation of U.S. Patent Claims*, 20 QUINNIPIAC L. REV. 487, 489 (2001) (defining the all elements rule as infringement under the doctrine of equivalents, where "each claim limitation or its equivalent must be found in the accused device").

88. 904 F.2d 677 (Fed. Cir. 1990).

89. *See* Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684 (Fed. Cir. 1990) (requiring courts to create a hypothetical broad claim that literally encompasses the accused device).

90. *See id.* at 684 (providing that if the hypothetical claim is rejected, the doctrine of equivalents is available for the patentee). *But see* Conroy v. Reebok Int'l, Ltd., 14 F.3d 1570, 1576 (Fed. Cir. 1994) (holding the hypothetical claim test not mandatory).

91. *See Wilson Sporting Goods*, 904 F.2d at 684 (stating that the doctrine merely examines what is described by the patent claims and determines whether the accused device is equivalent).

92. *Warner-Jenkinson*, 520 U.S. at 28-29; *see also* John F. Sweeney & James F. Bush, *The Doctrines of Equivalents and Prosecution History Estoppel: What Has* Warner-Jenkinson *Changed?*, 573 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 135, 143 (1999) (stating prior to the current Patent Act, the Supreme Court's last ruling on the doctrine of equivalents was in *Graver Tank*).

93. 520 U.S. 17 (1997).

94. *See Warner-Jenkinson*, 520 U.S. at 21-24 (regarding a dispute over an amendment modifying the range of pH for the invention and whether the lower pH was infringed because there was no reason established for the lower pH modification).

95. *See id.* at 28 (holding that the precedent of historical cases stands, especially the refusal of the Court in *Graver Tank*, to hold that the Patent Act conflicts with the doctrine of equivalents).

manner and not by a comparison of the inventions and accused devices as a whole.[96] Third, the Court held that the burden of establishing a reason for an amendment is on the patentee, and required the lower court to decide if the reason was sufficient to "overcome prosecution history estoppel," which bars the use of the doctrine of equivalents.[97] The Court also established a presumption that if no reason is established for an amendment, a reason related to patentability for the amendment is presumed.[98] In addition, the Court disposed of the argument that the doctrine of equivalents is an equitable doctrine and bad intent is required for its use.[99] Lastly, the Court left it to the Federal Circuit to further refine a test for equivalence as it examines each case.[100]

C. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.

Festo's importance and likely repercussions cannot be ignored due to its harshness, diversion from U.S. Supreme Court precedent, and many potential consequences.[101] In 1995, the Federal Circuit affirmed a Massachusetts District Court ruling of infringement on the Festo patent.[102] The Federal Circuit originally affirmed the trial court and held that even though Festo established no reason for the amendments at issue, estoppel did not bar use of the doctrine of equivalents.[103] In 1997, the Supreme

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96. *See id.* at 29 (emphasizing that claims of a patent cannot be expanded with the doctrine and the invention cannot be protected beyond its claims).

97. *See id.* at 33 (remanding to the Federal Circuit for a determination of whether there was a reason for the amendment lowering the pH).

98. *See id.* at 33 (commenting the presumption also bars the use of the doctrine of equivalents but prevents any conflicts with the current Patent Act). *But see* Brief of Amicus Curiae Chiron Corp. at 26, *Festo* (No. 00-1543) (noting the presumption has become absolute since *Festo*).

99. *See Warner-Jenkinson*, 520 U.S. at 36 (commenting that the *Graver Tank* decision left room for using intent-based elements, but the Court refused to require intent).

100. *See id.* at 40 (stating the Court did not want to micro-manage the Federal Circuit).

101. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 630 (Fed. Cir. 2000) (Newman, J., concurring and dissenting), *cert. granted*, 121 S. C. 2519 (2001) (noting the severe consequences and effect *Festo* will have on the country's technology industry was not considered by the majority). Judge Newman also noted that "[t]he interdependent policy aspects of technologic innovation, industrial growth, and competition were not briefed, and do not inhere in this court's 'special expertise' in adjudication of patent disputes." *Id.*; *see also* Frederick A. Spaeth, *"Equivalents Thereof" v. The Doctrine of Equivalents in the Interpretation of U.S. Patent Claims*, 20 QUINNIPIAC L. REV. 487, 492 (2001) (describing the court's adoption of the complete bar rule over the flexible bar rule).

102. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 72 F.3d 857, 860 (Fed. Cir. 1995) (describing that Festo's patent and the accused device related to magnetically-coupled, rodless cylinders).

103. *See id.* at 864 (noting that Festo could attempt to prove equivalency between its magnetizable sleeve claim and the accused device's aluminum alloy sleeve).

Court granted certiorari, vacated the judgment, and remanded the case for reconsideration based on its recent *Warner-Jenkinson* decision.[104]

The Federal Circuit analyzed the patents separately, which included the Carroll patent and the Stoll patent.[105] The Carroll and Stoll patents are for "magnetically coupled rodless cylinders" used to move articles short distances such as in assembly lines.[106] The prosecution history of the Carroll patent revealed a voluntary amendment that added sealing rings, but the court held that this did not establish prosecution history estoppel; therefore, Festo could claim the doctrine of equivalents.[107] However, for the Stoll patent, the prosecution history regarding the sealing rings was potentially applicable to create estoppel.[108] Thus, the Federal Circuit remanded the case to the district court to determine if estoppel applied.[109]

In 1999, petitions for rehearing were filed and a rehearing of the appeal en banc was granted.[110] The Federal Circuit addressed five questions on appeal.[111] The first question was whether "a substantial reason related to patentability"[112] is limited to amendments related to 35 U.S.C. §§ 102 & 103 to overcome prior art.[113] The Federal Circuit responded that amendments creating prosecution history estoppel include more than those to overcome prior art—they include any reason related to patent statutory requirements.[114] The second question addressed whether a voluntary amendment to a claim created prosecution history estoppel.[115] The Federal Circuit reasoned that voluntary claim amendments are no different

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104. Shoketsu Kinzoku Kogyo Kabushiki Co. v. Festo Corp., 520 U.S. 1111, 1111 (1997).

105. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 172 F.3d 1361, 1374 (Fed. Cir. 1999).

106. *Id.* at 1364.

107. *See id.* at 1374 (affirming summary judgment of infringement on the Carroll patent based on equivalency).

108. *Id.* at 1380-81.

109. *See id.* (stating that the record is "insufficient for appellate determination *ab initio*").

110. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 187 F.3d 1381, 1381-82 (Fed. Cir. 1999).

111. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 563-78 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001).

112. *See id.* at 566 (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 33 (1997)).

113. *Id.*

114. *See id.* at 566-67 (expanding the limits of prosecution history estoppel to include 35 U.S.C. §§ 101, 112).

115. *Id.* at 568.

than any other amendment; therefore, prosecution history estoppel should apply for that particular claim element.[116]

The most contentious issue is most likely the third question, which asked what range of equivalents is available, according to *Warner-Jenkinson*, for claim amendments creating prosecution history estoppel.[117] The Federal Circuit boldly stated "there is no range of equivalents available for the amended claim element."[118] The fourth question asked whether the range of equivalents is available when no reason for a claim amendment is given, thus invoking the *Warner-Jenkinson* presumption of prosecution history estoppel.[119] Again, the Federal Circuit held that "no range of equivalents is available for the claim element so amended."[120] The court effectively avoided the fifth question which asked whether an infringement judgment, in light of *Warner-Jenkinson*, constituted a violation of the "all-elements" rule.[121]

Based on these holdings, the court found the Carroll patent amendment, which added a pair of sealing rings, created prosecution history estoppel, and eliminated any range of equivalents available to Festo.[122] The Stoll patent issue revolved around the amendment's addition of a cylindrical sleeve made with magnetizable substances and sealing rings.[123] Festo failed to prove its voluntary amendment was unrelated to patentability because the sleeve was added in a new claim, instead of an amendment to the old claim.[124] The court held that no range of equivalents was available to Festo for the sleeve amendment.[125] The court found that the sealing rings amendment narrowed the scope of the claim to overcome

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116. *See Festo*, 234 F.3d at 568 (asserting the voluntary amendment must be one that narrows the claim scope for reasons related to patent statutory requirements).

117. *Id.* at 569.

118. *Id.*

119. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 578 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001)

120. *See id.* (holding *Warner-Jenkinson* answered this question when the Court stated that prosecution history estoppel barred the use of the doctrine of equivalents for the amended claim element).

121. *Id.* at 578.

122. *See id.* at 590-91 (stating the amendment allowed prosecution history estoppel since Festo failed to establish an explanation for the amendment unrelated to patentability).

123. *Id.* at 587.

124. *See Festo*, 234 F.3d at 587-88 (holding "that voluntary amendments are treated the same as other amendments"). The court rejected Festo's argument that the voluntary nature of the amendment prevented prosecution history estoppel. *Id.* at 588.

125. *See id.* at 587-88 (holding that Festo did not escape the *Warner-Jenkinson* presumption requiring proof that the amendment was unrelated to patentability). Therefore, the sleeve amendment enabled prosecution history estoppel and completely barred the use of the doctrine of equivalents. *Id.*

prior art, which, according to the new *Festo* holdings, creates prosecution history estoppel and completely bars the use of the doctrine of equivalents.[126] Therefore, the Federal Circuit overruled the infringement holdings of both patents and reversed the lower court.[127]

On June 18, 2001, the U.S. Supreme Court granted certiorari for *Festo*.[128] The Federal Circuit continues to address difficult patent issues and will soon consider en banc another issue of whether a patentee can use the doctrine of equivalents for subject matter described in the specification, but not mentioned in the claims.[129] One patentee urged a district court to delay its ruling until the U.S. Supreme Court resolved *Festo*, but the district court declined.[130]

D. *Biomedical Industry and Patent Law*

Many products licensed by the FDA demonstrate the benefits of the biomedical industry.[131] In 2000, the FDA approved twelve biologicals, thirty-four medical devices, and sixty-seven drugs.[132] The 2000 approvals alone illustrate the benefits of patents issued that lead to the develop-

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126. *See id.* at 588-89 (holding that because the claim amendment replaced means-plus-function words with words stating the corresponding structure, it constituted a narrowing amendment).

127. *See Festo*, 234 F.3d at 591 (concluding that the patents were infringed pursuant to the doctrine of equivalents).

128. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 121 S. Ct. 2519 (2001).

129. *See* Johnson & Johnston Assoc. v. R.E. Serv. Co., 238 F.3d 1347, 1347 (Fed. Cir. 2001) (ordering an en banc appeal).

130. *See* Jackson v. Casio PhoneMate, Inc., No. 98 C 6250, 2001 WL 395182, at *3 (N.D. Ill. Apr. 17, 2001) (holding that *Festo* is binding precedent).

131. *See* FDA Product Approvals and Related Actions, *available at* http://www.fda.gov/opacom/7approvl.html (last visited Sept. 14, 2001) (describing how the FDA must ensure product safety and efficacy prior to approval and evaluate whether the benefits to people outweigh the product's risks).

132. *See* 2000 Biological License Application Approvals, *available at* http://www.fda.gov/cber/appr2000/2000lic.htm (last visited Sept. 14, 2001) (including in part plasma and platelets for transfusions, TNKase, which reduces mortality of acute myocardial infarcation, Prevnar vaccination for infants to prevent invasive pneumococcal disease, and MYOBLOC (Botulinum Toxin type B) to treat cervical dystonia); Medical Device Approvals—Recently Approved Devices, *available at* http:// www.fda.gov/cdrh/mda/index.html (last visited Sept. 14, 2001) (including in part endoscopy, bone sonometers, glaucoma devices, stomach band, heart valve, hip prostheses, skin, temporomandibular joint, biopsy devices, shock wave therapy, stents, defibrillators, and lasers); FDA Drug Approvals List, *available at* http://www.fda.gov/cder (last visited Oct. 21, 2001) (including in part EVOXAC for dry mouth, ALLEGRA for allergies, LOTRONEX for irritable bowel syndrome, VIADUR for prostate cancer, MALARONE for malaria, RAPAMUNE for organ rejection, KALETRA for HIV-1 infection, LUNELLE for birth control, and TAMIFLU for influenza).

ment of new, improved, and innovative products.[133] The courts have also encouraged innovation by providing patent protection to creative advances.[134] For example, in 1980, the U.S. Supreme Court affirmed that a living, genetically-engineered bacterium is patentable.[135] This holding gave promise to the biotechnology industry, as the Supreme Court recognized there is unique patentable material of great public importance.[136]

In addition, the PTO opened the door to biomedical advances when it patented the first transgenic mouse which was highly susceptible to breast cancer.[137] As a result, living organisms are statutorily patentable based on 35 U.S.C. § 101.[138] The biomedical industry uses these and other organisms to develop valuable medical products and processes.[139] Research on these organisms has led to patents such as recombinant DNA, monoclonal antibodies, expression vectors, cell lines, gene sequencing techniques, diagnostics, pharmaceutical drugs, biologics, and many others.[140]

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133. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 639 (Fed. Cir. 2000) (Newman J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (stating the primary function of patents is to encourage investment into innovative ideas and has "the national purpose of development of new industries, improved productivity, increased employment, and overall economic growth as well as technologic advance").

134. Diamond v. Chakrabarty, 447 U.S. 303, 321-22 (1980) (Brennan, J., dissenting).

135. *Id.*

136. *See id.* at 322 (noting that a living organism is unique and "implicates matters of public concern"); *see also* Jeffrey P. Kushan, Comment, *Protein Patents and the Doctrine of Equivalents: Limits on the Expansion of Patent Rights,* 6 HIGH TECH. L.J. 109, 110 (1991) (noting that since *Diamond*, there have been massive biotechnology patent filings, indicating the importance of patent protection in the biotechnology industry).

137. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988), *available at* www.uspto.gov.

138. *See* 35 U.S.C. § 101 (1984) (stating that "anything under the sun that is made by man" is patentable).

139. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 407 (2000) (stating that disciplines such as genetic engineering, biology, biochemistry, virology, immunology, and others are involved in the biotechnology arena); *see also* Shaoyi Alex Liao, *Resolving the Dilemmas Between the Patent Law and Biotechnology: An Analysis of Three Recent Biotechnology Patent Cases*, 11 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 231 (1995) (noting patents using recombinant DNA technology have been issued in the health care area).

140. Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 407 (2000); *see also* Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 746-47 (1998) (noting that biotechnology patents include engineering and naturally occurring DNA molecules and proteins, genetically engineered organisms, antibodies, animals, and raw materials for research).

The PTO also granted patents for human gene sequences that furthered the development of biomedical technologies.[141] Much of the biomedical industry's purpose is to "seek[ ] to address human suffering."[142] The research into human genes is leading to biological advances, which result in improved drugs.[143] A major desire of biomedical companies is to seek patent protection of proteins and to build upon the protected proteins to make improved proteins.[144] Proteins are considered the "building blocks" of living organisms.[145] Protein engineers take naturally existing proteins and re-engineer them into new and useful proteins that harness amazing potential for the biomedical industry.[146] An example of protein re-engineering is Genentech's tissue plasminogen activator, which is developed through recombinant DNA technology and helps dissolve blood clots.[147]

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141. *See, e.g.*, U.S. Patent No. 5,169,941 (issued Dec. 8, 1992), *available at* www.uspto.gov (patenting DNA sequence used to diagnose multiple sclerosis); U.S. Patent No. 5,220,013 (issued June 15, 1993), *available at* www.uspto.gov (patenting DNA sequence used for detecting Alzheimer's disease).

142. James A. Geraghty, *Cloning-Challenges for Public Policy*, Congressional Testimony by Federal Document Clearing House, Mar. 12, 1997, *available at* 1997 WL 119712 (stating the industry offers the potential to provide many treatments for diseases that are not currently curable).

143. *See* Elyse Tanouye et al., *Genetic Giant: Glaxo and SmithKline Give Stock Markets Shock Treatment*, WALL ST. J. EUR., Feb. 3, 1998 at 1 (proclaiming an explosion of breakthroughs in the scientific arena mainly from human genes research, which lead to improved drug actions by finding biological targets).

144. *See* Jeffrey P. Kushan, Comment, *Protein Patents and the Doctrine of Equivalents: Limits on the Expansion of Patent Rights*, 6 HIGH TECH. L.J. 109, 115 (1991) (explaining the legal question involved when making protein products); *see also Festo*, 234 F.3d at 639 (commenting on how innovations began to include complexities of sequential improvements on inventions publically disclosed).

145. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 416 (2000) (explaining that proteins contain amino acids in string sequences and build organisms ranging from viruses to humans). Sequences of amino acids are encoded by genes, which identify amino acid order. *Id.* Genes are composed of DNA or RNA. *Id.*

146. *See* Jeffrey P. Kushan, Comment, *Protein Patents and the Doctrine of Equivalents: Limits on the Expansion of Patent Rights*, 6 HIGH TECH. L.J. 109, 115 (1991) (explaining that newly discovered proteins become the building blocks for new entities); *see also* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 417 (2000) (noting that manipulations to protein sequences provide new and purified proteins, hormones, antibodies, and enzymes).

147. *See* Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1557-58 (Fed. Cir. 1994) (discussing the role of a protein tissue plasminogen activator); *see also* Shaoyi Alex Liao, *Resolving the Dilemmas Between the Patent Law and Biotechnology: An Analysis of Three Recent Biotechnology Patent Cases*, 11 SANTA CLARA COMPUTER & HIGH TECH.

However, the 35 U.S.C. § 102 novelty requirement indicates that biomedical patents are required to illustrate the difference between the original protein and their modified protein, thereby creating a difficult obstacle.[148] There is also difficulty in counteracting prior art according to 35 U.S.C. § 103.[149] These concerns were briefly addressed in the Biotechnology Patent Protection Act of 1993.[150] The Act amended 35 U.S.C. § 103 to add biotechnological processes and materials as non-obvious claims.[151] Uncertainty exists in the requirements of 35 U.S.C. § 112 for biotechnology inventions.[152] There is a special requirement for biotechnology inventors to meet an eight-factor test before the court or PTO allows a claim for all similar proteins and fragments to a specific protein or fragment.[153] Biotechnology inventors are also required to disclose the

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L.J. 229, 233-34 (1995) (explaining recombinant DNA process and providing an example of a human protein used for blood clotting, which was produced inside a baby hamster's kidney cells). Recombinant DNA technology is used to isolate genes and reconnect DNA to a DNA vector that can self-replicate in the host cells. *Id.*

148. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 421-22 (2000) (stating that native proteins made by rDNA technology may be denied patentability because novelty is non-existing); Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 151, 155 (1995) (noting that the novelty requirement is difficult to meet in the biotechnology industry because it is rapidly evolving and it is hard to evaluate the invention through the eyes of those skilled in the field).

149. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 424-25 (2000) (explaining the criteria considered when comparing prior art). The industry is struggling with what is obvious in DNA technology. *Id.* at 431.

150. *See* H.R. 760, 103d Cong. § 101 (1993) (passing the Act amending 35 U.S.C. regarding patenting certain processes); *see also* S. 298, 103d Cong. § 101 (1993).

151. *See* H.R. 760, 103d Cong. § 101 (1993) (amending 35 U.S.C. § 103 regarding non-obviousness of biotechnological processes and materials). Biotechnological process is defined as "any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products." *Id.* This term includes "recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material." *Id.* Biotechnological material is defined as "any material (including a host cell, DNA sequence, or vector) that is used in a biotechnological process as defined under section 103(d)." *Id.* at § 201; *see also* S. 298, 103d Cong. §§ 101, 201 (1993) (transcribing H.R. 760 definitions).

152. Brief of Amicus Curiae Chiron Corp. at 16, *Festo* (No. 00-1543).

153. *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (listing factors for consideration). The factors include:

> (1) the quality of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims).

Id.

gene sequence in order to claim that gene, which makes the doctrine of equivalents critical to biotechnology patents.[154]

III. THE PROBLEM

A. *Two Harsh* Festo *Rulings Granted Certiorari*

One of the problems with *Festo* is that 1.2 million patents were prosecuted with the understanding that the doctrine of equivalents would be available for infringement actions.[155] In her *Warner-Jenkinson* dissent, Justice Ginsburg noted that retroactivity weakened the previous patent protection of the doctrine of equivalents.[156] A massive group of patentees are anxiously awaiting the Supreme Court's review of two harsh rulings by the Federal Circuit.[157]

First, the Court will address "[w]hether every claim narrowing amendment designed to comply with any requirement of the Patent Act—including those not related to prior art—automatically creates prosecution history estoppel."[158] Second, the Court will address "whether every finding of prosecution history estoppel completely bars every application of the doctrine of equivalents."[159] The Federal Circuit chose form over substance because only the fact of amending a claim (form) is considered and not the nature of the amendment (substance).[160] One commentator calls *Festo* a "death sentence to claim scope."[161]

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154. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997) (holding that a recombinant DNA invention requires a precise definition, including chemical names, a structure, formula, and physical properties of the DNA itself); Brief of Amicus Curiae Chiron Corp. at 12-13, *Festo* (No. 00-1543) (stating that patents for genes would need to claim all variants and their sequences if the doctrine of equivalents was not available).

155. *See* Stephan Herrera, *Biotech Patents Fester After* Festo, RED HERRING COMMUNICATIONS, May 25, 2001, *available at* http://www.herring.com/index (discussing the detrimental effects of *Festo* as it eliminated the use of the doctrine of equivalents as a weapon against infringement); *see also* Noreen Krall & Celeste B. Filoia, *The Doctrine of Equivalents: An Analysis of the* Festo *Decision*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 373, 384 (2001) (commenting that business relationships are affected and now patent holders must prove literal infringement for claims whose scope was modified by *Festo*).

156. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 41 (1997) (Ginsburg, J., dissenting) (noting that years later patentees will have difficulty acquiring evidence to avoid prosecution history estoppel).

157. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 121 S. Ct. 2519 (2001).

158. Petitioner's Brief at i, *Festo* (No. 00-1543).

159. *Id.*

160. *See* Winans v. Denmead, 56 U.S. 330, 343 (1853) (holding substance over form).

161. *See* Harold C. Wegner, *Biotechnology Patent Litigation: Dealing with* Festo, Johnson and Johnston *and Beyond*, 666 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 175, 183 (2001) (arguing

1. Initial District Court Interpretation of *Festo*

District courts have interpreted *Festo* to include a four-part test.[162] First, the court must decide what claim limitations are asserted as having equivalents.[163] Second, the court must determine whether those claim limitations were amended during patent prosecution.[164] Third, the court must decide if the amended claim limitations narrowed the claim's scope.[165] Fourth, if the amendment narrowed the claim's scope, the patentee must establish that the patent was amended for a reason unrelated to patentability.[166] If a viable reason is not demonstrated by the patentee, the *Festo* holdings applies, which results in prosecution history estoppel and no range of equivalents in an infringement suit.[167]

District courts are mandated to follow the *Festo* analysis and its holdings unless its application is barred by procedure or res judicata.[168] A California district court applied the four-part *Festo* test in *Pickholtz v. Rainbow Technologies, Inc.*[169] First, the court identified the claim limitation as a computer software security device "located in the computer."[170] Second, the court determined the applicant added the limitation in an amendment during patent prosecution, since the PTO examiner rejected the original claims because they were obviously based on an existing patent.[171] Third, the court found that the amendments of the original six claims narrowed the claim when it indicated the device was "located in

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that leaving no room for expansion of protection by equivalents is the harshest ruling made in *Festo*).

162. *See* Molten Metal Equip. Innovations, Inc. v. Metaullics Sys. Co., L.P., 130 F. Supp. 2d 917, 921 (N.D. Ohio 2001) (applying the *Festo* four-part test); Pickholtz v. Rainbow Techs., Inc., 125 F. Supp. 2d 1156, 1161 (N.D. Cal. 2000) (stating the *Festo* four-part test for whether an amendment bars use of the doctrine of equivalents).

163. *Pickholtz*, 125 F. Supp. 2d at 1161.

164. *Id.* (indicating that if the limitations were not amended, the doctrine of equivalents may be asserted).

165. *Id.* (asserting that if the amendment did not narrow the claim scope, the doctrine of equivalents may be asserted).

166. *Id.* (stating that if the amendment reason is not related to patentability, the doctrine of equivalents may be asserted).

167. *See id.* (stating the results of step four depend on whether the patentee met his burden of proving reasons unrelated to patentability); *see also* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 566-78 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001) (answering questions one and three en banc).

168. *See* Insituform Tech., Inc. v. CAT Contracting, Inc., 58 U.S.P.Q. 2d 1392, 1397 (Fed. Cir. 2001), 2001 WL 294164, *6 (declaring that the mandate is based on Supreme Court decisions).

169. *See Pickholtz*, 125 F. Supp. 2d at 1162 (applying the *Festo* test to a patent for pseudorandom number ("PRN") generator device).

170. *Id.*

171. *Id.*

the computer."[172] Fourth, the patentee could not meet its burden to establish that the amendment did not relate to patentability, because he responded to the claim rejection by amendment adding the location and arguing that prior art does not state the location.[173] Therefore, the amendment created prosecution history estoppel, which completely barred the patentee from using the doctrine of equivalents to prove infringement.[174] The patentee attempted to refute this holding by presenting extrinsic evidence that the amendment merely clarified the claim and is meaningless; however, *Festo* does not allow a patentee to meet its burden with extrinsic evidence.[175] Furthermore, the patent specification and its amendments made are also not included in prosecution history so copyists cannot use them to establish estoppel.[176]

In *Control Resources, Inc. v. Delta Electronics, Inc.*,[177] a Massachusetts district court provided an additional early analysis of *Festo*.[178] The court initially wanted to modify *Festo* by adding a fifth part to the *Festo* test, but failed to do so.[179] The court's *Festo* analysis lead to the conclusion that the doctrine of equivalents was completely barred, but if the court was allowed to resolve the issue in a less mechanical way and delve into the true meaning of the amendment, the case would reach a different conclu-

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172. *Id.*

173. *See id.* (finding the amendment was made to avoid the obviousness created by prior art).

174. *See Pickholtz*, 125 F. Supp. 2d at 1163 (holding a complete bar to the use of the doctrine of equivalents); *see also Molten Metal*, 130 F. Supp. 2d at 921-22 (following the *Festo* test for a molten metal pump patent). Here, the court applied the *Festo* test and found that adding the term "non-volute" in front of "pump chamber" in an amendment to avoid obviousness based on prior art created prosecution history estoppel and completely barred the patentee's use of the doctrine of equivalents. *Molten Metal*, 130 F. Supp. 2d at 921-22.

175. *See Pickholtz*, 125 F. Supp. 2d at 1162-63 (stating that the attorney's declarations were inadmissible, and even if they were, they clearly establish that the reason for the amendments was related to patentability). Also, even if the amendment was meaningless, and the prosecution did not state the reason for the amendment, *Festo* would still require the court to hold that the reason was related to patentability. *See id.* at 1163.

176. *See* Gart v. Logitech, Inc., 254 F.3d 1334, 1344 n.2 (Fed. Cir. 2001), *cert. denied*, No. 01-710, 2002 WL 75704 (S. Ct. Jan. 22, 2002) (noting that remarks made related to the specification are irrelevant to the prosecution history estoppel analysis established by *Festo*); *see also* SRAM Corp. v. AD-II Eng'g, Inc., 155 F. Supp. 2d 826, 837-38 (N.D. Ill. 2001) (holding the amendment made to the specification to address a 35 U.S.C. § 112 rejection did not create estoppel because the claims were not amended).

177. 133 F. Supp. 2d 121 (D. Mass. 2001).

178. *See* Control Res., Inc. v. Delta Elecs., Inc., 133 F. Supp. 2d 121, 137 (D. Mass. 2001) (holding that since the amendment was related to patentability, there was a complete bar from using the doctrine of equivalents).

179. *See id.* (seeking to add a thorough prosecution history review to the *Festo* test).

sion.[180] In *Control Resources*, the applicant amended a patent by narrowly describing a computer fan speed as "one-half maximum speed" from the original claim that set the speed at a "preselected minimum."[181] After reviewing the prosecution history, the court inferred that the patentee intended to abandon the minimum speeds that are below the half maximum.[182] However, the analysis of equivalence of speeds above the half maximum, which is not part of the prior art nor within the claim scope, is not allowed according to *Festo*, because the analysis ends with the purpose of the amendment and not the actual meaning of the amendment.[183]

B. *Quick and Easy Establishment of Prosecution History Estoppel*

Festo expanded the definition of a "substantial reason related to patentability" to include amendments related to 35 U.S.C. §§ 101, 102, 103, & 112, which require non-obviousness, definiteness, patentable subject matter, utility, written description, enablement, best mode, and no anticipation.[184] The court further expanded the powers of estoppel to volun-

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180. *See id.* at 136 (stating that *Warner-Jenkinson* suggested the estoppel analysis is not mechanical).

181. *See id.* (finding the original claim of "preselected minimum" was an amendment to overcome prior art).

182. *See id.* at 137 (finding that it is obvious to a competitor that a fan with a speed below the half maximum would not infringe this patent).

183. *See Control Res.*, 133 F. Supp. 2d at 137 (intimating that allowing this analysis may be useful to Control Resources, Inc., because twenty-four of the twenty-five accused devices are above the half maximum).

184. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 566-67 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001) (holding that an amendment related to any of these statutory requirements was related to patentability and therefore created prosecution history estoppel); *see also* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1381 (Fed. Cir. 1999) (holding patent claims invalid because they were not enabled based on the 35 U.S.C. § 112(1) requirements); Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1350 (Fed. Cir. 1999) (holding invalid proposed patent claims as anticipated under 35 U.S.C. § 102); Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1359 (Fed. Cir. 1999), *cert. denied*, 529 U.S. 1037 (2000) (holding that inoperative claims failed to meet the utility requirement in 35 U.S.C. § 101 or the enabling requirement of 35 U.S.C. § 112(1)); Mitsubishi Elec. Corp. v. Ampex Corp., 190 F.3d 1300, 1313-14 (Fed. Cir. 1999), *cert. denied*, 529 U.S. 1054 (2000) (ruling invalid proposed patent claims as obvious under 35 U.S.C. § 103); State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1377 (Fed. Cir. 1998) (analyzing 35 U.S.C. § 101 requirements for a patentable subject matter); Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480-81 (Fed. Cir. 1998) (holding patent claims invalid for failure to meet the requirement for a written description in 35 U.S.C. § 112(1)); United States Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1216 (Fed. Cir. 1996) (holding patent claims invalid for failure to meet the best mode requirement in 35 U.S.C. § 112(1)); Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1470

tary and unexplained amendments.[185] However, according to the *Festo* test, these amendments related to patentability must narrow the claim scope.[186] Judge Linn points out in a *Festo* dissenting opinion, that the majority fails to define "narrowing."[187] As one commentator stated, one should only infer from an amendment that the applicant intended to have the patent issued.[188] Judge Linn indicated that claims are often amended for clarification or foreign translation without the intent to modify the scope of the claim.[189]

The Federal Circuit applied this new and broad definition of prosecution history estoppel in its decisions following *Festo*. In one case, the court held that a patentee, who amended a claim to add the words "if and only if" to overcome an anticipation and obviousness rejection, created estoppel, therefore completely barring the use of the doctrine of equivalents.[190] In another case, the court used *Festo* to determine an amendment that modified the phrase "ion beam source" to a more specific "Kaufman-type ion beam source" narrowed the amendment under 35 U.S.C. § 112(2) and created estoppel.[191] Finally, another patentee created estoppel by amending a claim to identify a specific number of vacu-

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(Fed. Cir. 1993) (announcing patent claims invalid because of the failure to meet the definiteness requirement in 35 U.S.C. § 112(2)).

185. *Festo*, 234 F.3d at 578 (answering question four en banc). The *Festo* holding does not apply to the structural equivalent analysis under 35 U.S.C. § 112(6). *See* TM Patents, LLP v. Int'l Bus. Machs. Corp., 136 F. Supp. 2d 209, 213 (S.D.N.Y. 2001). Here, the court held there can be literal infringement of "means-plus-function patent" if the structure is not identical to the embodiment disclosed in the patent. *Id.* The Federal Circuit ruled the range of equivalence under 35 U.S.C. § 112(6) can be limited by prosecution history estoppel, but the *Festo* decision did not address whether the complete bar rule applies to these means-plus-function claims. *See* Frederick A. Spaeth, *"Equivalents Thereof" v. The Doctrine of Equivalents in the Interpretation of U.S. Patent Claims*, 20 QUINNIPIAC L. REV. 487, 521 (2001) (stating that *Festo* may need modification).

186. *Pickholtz*, 125 F. Supp. 2d at 1161.

187. *See Festo*, 234 F.3d at 622 (Linn, J., concurring and dissenting) (pointing out that the majority clarified the complete bar rule, but failed to provide a clear definition of a narrowing amendment).

188. *See* Glenn K. Beaton, *File Wrapper Estoppel and the Federal Circuit*, 68 DENV. U. L. REV. 283, 286 (1991) (stating that a patent applicant anticipates that his reward for advancing technology is great and the limits of his award are small).

189. *See Festo*, 234 F.3d at 622 (Linn, J., concurring and dissenting) (arguing that merely replacing one word with a synonymous word does not change the scope, and that all claim amendments should not imply the applicant was giving up all matter beyond the literal language of the claim).

190. *See* Jackson v. Casio PhoneMate, Inc., No. 98 C 6250, 2001 WL 395182, at *2-3 (N.D. Ill. Apr. 17, 2001) (holding the amendments to a patent for a device that controls appliances by remote control were related to patentability under 35 U.S.C. §§ 102(b), 103).

191. *See* Litton Sys., Inc. v. Honeywell, Inc., 238 F.3d 1376, 1380 (Fed. Cir. 2001) (holding a complete bar to the use of the doctrine of equivalents).

ums used for a process to repair damaged pipelines in response to lack of specificity and obviousness rejections.[192] These three examples illustrate the effects of *Festo* when changes to claim language are made in amendments that are all related to patentability.

Interestingly, the Federal Circuit left an issue open regarding the extent of the complete bar rule to amended claims.[193] In *ACLARA BioSciences, Inc. v. Caliper Technologies Corp.*,[194] the applicant amended a claim, but only to a limitation in the claim that was not at issue in the infringement case.[195] Even though the amendment narrowed the scope of the claim for a reason related to patentability, the court made a distinction between an element and a limitation.[196] Because an element may contain a series of limitations, as in the instant case, the court only applied the *Festo* test to the amended limitation.[197]

C. Notice to the Public v. Fairness to the Patentee—Policies Behind the Doctrine of Equivalents

One policy behind patents is protection of the patentee's scope of claims.[198] The patentee needs broad protection against copyists making

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192. *See* Insituform Tech., Inc. v. CAT Contracting, Inc., 58 U.S.P.Q. 2d 1392, 1399 (Fed. Cir. 2001), 2001 WL 294164, *8 (unpublished opinion) (holding that patentee could not use the doctrine of equivalents for an accused device claiming use of multiple vacuums because the amendment narrowed the claims based on 35 U.S.C. §§ 112, 103); *see also* TM Patents, LLP v. Int'l Bus. Machs. Corp., 136 F. Supp. 2d 209, 215-16 (S.D.N.Y. 2001) (holding that an amendment deleting "across a plurality of memory units" to a claim for generation of correction bits to correct computer errors created estoppel because it narrowed the claim and was related to patentability under 35 U.S.C. §§ 112, 103 and the amendment responded to the indefinite and obviousness rejections).

193. *See* ACLARA BioSciences, Inc. v. Caliper Techs. Corp., 125 F. Supp. 2d 391, 403 (N.D. Cal. 2000) (declining to apply *Festo* to an amended claim as a whole, but applied it only to the amended claim limitation).

194. 125 F. Supp. 2d 391 (N.D. Cal. 2000).

195. *See* ACLARA BioSciences, Inc. v. Caliper Techs. Corp., 125 F. Supp. 2d 391, 401 (N.D. Cal. 2000) (analyzing an amendment to a claim changing the scope in terms of insulation, but not changing the scope as to electrode placement).

196. *See id.* at 402 (describing an element as a structural part of a device and a limitation as words or phrases used to individually describe the invention).

197. *See id.* at 402-03 (holding the three limitations of the element clause included a number of electrodes, electrode configuration, and no insulation; only the insulation limitation was amended and only the electrode configuration limitation was at issue for the infringement case). The court ruled that estoppel was not created by the amendment. *Id.*

198. *See* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1530 (Fed. Cir. 1995) (Newman, J., concurring), *rev'd*, 520 U.S. 17 (1997) (stating how the doctrine of equivalents is derived from the principle that an inventor's rights should be protected by patents).

only minor changes to design around the literal patent claims.[199] Proponents for the doctrine of equivalents argue that this is the primary policy.[200] On the other hand, opponents of the doctrine of equivalents indicate that patents are important to the progression of science because they provide public notice of what is available for public use when designing around the patent.[201] The doctrine of equivalents balances these two competing policies.[202]

Some commentators argue that the prosecution history estoppel limitation encourages patentees to disclose a complete and specific public notice of the invention, which should protect competitors from designing equivalents covered by the patent.[203] The *Festo* majority argues that the complete bar rule eliminates any public speculation about surrendered subject matter during a narrowing amendment.[204] Judge Newman argues in her *Festo* dissent that the majority eliminated the balance between inventor and copier and replaced it with "paramount" notice to the competitor.[205]

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199. *See id.* (mentioning Justice Story's comment that inventors should have superior rights against merely colorable alterations).

200. *See id.* at 1531 (arguing a lack of reliance on trade secrets, increased analytical capability to create imitations, harsh competition, and technological advancement incentives are all factors supporting a non-literal reading of claims).

201. *See id.* at 1540 (Plager, J., dissenting) (stating that competitors should be able to rely on claims when determining a patent's scope); *see also id.* at 1530 (Newman, J., concurring) (stating the public notice function provides a strong argument for a literal reading of claims); Matthew C. Phillips, *Taking a Step Beyond* Maxwell *to Tame the Doctrine of Equivalents,* 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 155, 159-60 (2000) (stating an important reason for 35 U.S.C. § 112(2) is to provide competitors with certainty of patent scopes).

202. *See* London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991) (explaining that the patent examiner and applicant agree to the metes and bounds of the claims and the issued patent offers fair public notice as to the claims); *see also* Anand Gupta, *Patent Law: the Supreme Court Reinforces the Validity of the Doctrine of Equivalents in* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 23 S. ILL. U. L.J. 123, 148 (1998) (stating the *Warner-Jenkinson* decision is sensible and appropriately balances the competing patent policies).

203. *See* John F. Sweeney & James F. Bush, *The Doctrines of Equivalents and Prosecution History Estoppel: What Has* Warner-Jenkinson *Changed?*, 573 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 135, 156 (1999) (arguing that any changes made to the scope of claims should be clearly articulated in the prosecution history to provide public notice of subject matter abandoned).

204. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 576 (Fed. Cir. 2000), *cert. granted,* 121 S. Ct. 2519 (2001) (arguing prosecution history estoppel is not an area for speculation).

205. *See id.* at 639 (Newman, J., concurring and dissenting) (arguing the majority has concluded the balance of policies is "disadvantageous to the nation" and turned the doctrine of equivalents away from favoring the patentee's protection).

D. The Flexible Bar v. The Complete Bar

Astoundingly, *Festo* strayed from more than fifty Federal Circuit cases that previously applied the flexible bar rule.[206] Prior to *Festo*, the Federal Circuit relied upon two differing authorities for prosecution history estoppel, *Hughes Aviation v. United States*[207] and *Kinzenbaw v. Deere & Co.*,[208] both decided in a one-year period.[209] In *Hughes*, the court stated that prosecution history estoppel is a limitation on the doctrine of equivalents but is "within a spectrum ranging from great to small to zero."[210] The Federal Circuit repeatedly stated that prosecution history estoppel should not bar all equivalents.[211] In *Kinzenbaw*, the Federal Circuit refused to apply the "speculative" flexible bar rule and therefore refused to look closely at which limitations were amended and why.[212] These cases evidence an obvious conflict in the Federal Circuit's application of prosecution history estoppel and the doctrine of equivalents.[213]

Even after *Warner-Jenkinson*, the Federal Circuit held in *Hughes Aircraft Co. v. United States*[214] that the flexible bar approach was still valid.[215] However, the Federal Circuit Court in *Festo* decided to solely use the complete bar rule, based on its twenty years of experience as the

206. *See id.* at 613-15 (Michel, J., concurring and dissenting) (listing fifty Federal Circuit cases between 1983-2000 applying the flexible bar rule over the complete bar rule).

207. 717 F.2d 1351 (Fed. Cir. 1983).

208. 741 F.2d 383 (Fed. Cir. 1984).

209. *See* Kinzenbaw v. Deere & Co., 741 F.2d 383, 389 (Fed. Cir. 1984) (declining to use a speculative inquiry for prosecution history estoppel); Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1363 (Fed. Cir. 1983) (adopting the flexible bar approach to prosecution history estoppel).

210. *Hughes*, 717 F.2d at 1363.

211. *See* Black & Decker, Inc. v. Hoover Serv. Ctr., 886 F.2d 1285, 1295 (Fed. Cir. 1989) (stating prosecution history estoppel only bars equivalents as to prior art prompting the amendment, but does not bar all doctrine of equivalents applications); *see also* Dixie USA, Inc. v. Infab Corp., 927 F.2d 584, 588 (Fed. Cir. 1991) (agreeing prosecution history estoppel is generally not "a total preclusion of equivalence").

212. *See Kinzenbaw*, 741 F.2d at 391 (refusing to inquire whether a patent examiner would allow the claim if only the narrowing limitation was made).

213. *See Festo*, 234 F.3d at 573 (pointing out commentators' views that the two approaches appear to be "irreconcilable"); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 609-10 (Fed. Cir. 2000) (Michel, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (noting that in reviewing prior case law, it is evident the majority made a sudden turn contrary to the concept that case law should evolve consistently, gradually, and predictably).

214. 140 F.3d 1470 (Fed. Cir. 1998).

215. *See* Hughes Aircraft Co. v. United States, 140 F.3d 1470, 1476-77 (Fed. Cir. 1998) (holding that *Warner-Jenkinson* did not require the complete bar approach and reiterated that courts must determine the exact "subject matter the patentee actually surrendered").

patent court of appeals.[216] The court explained that the flexible bar approach is unworkable because the "line of surrender" is not clearly drawn.[217] The goal of the court's approach was to provide notice to both the patentee and the public of surrendered subject matter, and to reduce case-by-case litigation when determining the subject matter of claims.[218] Furthermore, the court rationalized that the benefits of the flexible bar approach, which provides patentees more protection, do not outweigh the uncertainties of the flexible bar approach to competitors.[219]

Judge Lourie specifically wrote a concurring opinion in *Festo* to help explain this drastic change to the complete bar approach.[220] The concurrence points out that numerous appeals argue equivalence with the hope that one panel may find equivalence even though another panel may not.[221] Judge Lourie further claims that patent attorneys cannot fully depend on the doctrine of equivalents when drafting claims because the statute requires claim precision.[222] The doctrinal change rests upon the policy that even though it is easier for copiers to avoid infringement, the benefits of new technologies will outweigh these rare injustices.[223]

However, *Festo* dissenters consider the majority's rule a "bar by amendment."[224] Judge Michel argues that courts will no longer consider the substance of a claim rejection, applicant's remarks and amendments,

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216. *See Festo*, 234 F.3d at 574-75 (holding that the notice function becomes the paramount policy of patents and therefore certainty to the public of a patent's scope is essential).

217. *See id.* at 575 (arguing that patentees draw the line near the prior art and competitors draw the line near the literal claim language).

218. *See id.* at 577 (arguing the approach reduces transaction costs for patentees and the public).

219. *See id.* at 577-78 (stating the complete bar approach allows technology advances that previously may not have occurred due to fear of litigation).

220. *See Festo*, 234 F.3d at 596 (Lourie, J., concurring) (explaining how the court extended the Supreme Court's complete bar to the doctrine of equivalents).

221. *See id.* (Lourie, J., concurring) (explaining how the flexible bar approach did not work).

222. *See id.* at 596-97 (Lourie, J., concurring) (explaining how patent attorneys often settle with narrowing claims assuming that later they will rely on the doctrine of equivalents); *see also* Michael O. Sutton & Christopher G. Darrow, *Recent Developments in Patent Law*, 9 TEX. INTELL. PROP. L.J. 429, 444 (2001) (explaining a practical effect of *Festo* is more appeals if inventors do not amend based on the examiner's rejections).

223. *See Festo*, 234 F.3d at 597 (Lourie, J., concurring) (stating that the *Festo* decision will "encourage innovation, lessen uncertainty, and diminish the volume of unnecessary litigation" while also protecting the patentee's disclosed claim scope).

224. *See id.* at 600 (Michel, J., concurring and dissenting) (arguing that estoppel lost its meaning and inquiry of looking to whether a reasonable competitor would consider the applicant to have surrendered subject matter); Alan P. Klein, *The Doctrine of Equivalents: Where It Is Now, What It Is*, 83 J. PAT & TRADEMARK OFF. SOC'Y 514, 514 (2001) (stating that *Festo* does not allow the doctrine to apply for any reason to any amended claim).

the type of technology at issue, or prior art.[225] This is harmful and unfair to patentees as they now have no recourse under the doctrine of equivalents even if the nature of amendments did not surrender subject matter.[226] Following *Festo*, copyists only need to review the patent prosecution history and make trivial modifications related to an amended claim to avoid infringement.[227] A Delaware district court actually held that *Festo* did not intend this harsh result and asserted that a balance must be struck between public notice and protection of inventors.[228]

E. *Effect of the Complete Bar Rule on Patent Prosecution*

Festo will certainly have a major impact on patent prosecution.[229] Patent attorneys will need to draft claims that do not require amendments.[230] This strategic modification varies greatly from the prior practice of initially submitting broad claims and later narrowing claims by amendment during prosecution.[231] Consequentially, this may actually lead to more

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225. *See Festo*, 234 F.3d at 600 (Michel, J., concurring and dissenting) (arguing that the majority held that merely because an amendment was made, the complete bar rule should apply); *see also* Michael O. Sutton & Christopher G. Darrow, *Recent Developments in Patent Law*, 9 TEX. INTELL. PROP. L.J. 429, 443-44 (2001) (arguing a practical effect of *Festo* will be the lack of consideration for closeness to prior art, the type of invention, and its advancement of technology).

226. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 600 (Fed. Cir. 2000) (Michel, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (referring to *Graver Tank* and arguing that the majority opinion turns a patent into a "hollow and useless thing").

227. *See id.* at 600-01 (Michel, J., concurring and dissenting) (arguing that copyists can easily exploit *Festo*, which actually may even eliminate the doctrine of equivalents); *see also* Michael O. Sutton & Christopher G. Darrow, *Recent Developments in Patent Law*, 9 TEX. INTELL. PROP. L.J. 429, 444 (2001) (commenting how easy it will now be for competitors to copy without infringing by merely changing an insignificant element previously amended).

228. *See* Creo Prods., Inc. v. Presstek, Inc., No. 99-525-GMS, 2001 WL 637397, at *9-10 (D. Del. May 11, 2001) (holding that estoppel applied after carefully reviewing the substance of the amendment and considering the policy underlying *Festo*).

229. *See generally* Brief of Amicus Curiae Chiron Corp. at 6-7, *Festo* (No. 00-1543) (noting that additional work will be created due to an increase in the number of claims proposed in each application and the use of fuzzy words will increase the patent prosecution time); Noreen Krall & Celeste B. Filoia, *The Doctrine of Equivalents: An Analysis of the* Festo *Decision*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 373, 383 (2001) (commenting that patent attorneys must consider *Festo* while writing and prosecuting claims).

230. *See* Noreen Krall & Celeste B. Filoia, *The Doctrine of Equivalents: An Analysis of the* Festo *Decision*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 373, 383 (2001) (commenting that patent attorneys must be careful to avoid both obtaining inadequate protection and drafting claims too narrowly); *see also* Michael O. Sutton & Christopher G. Darrow, *Recent Developments in Patent Law*, 9 TEX. INTELL. PROP. L.J. 429, 444 (2001) (stating how practitioners may be able to avoid the effects of *Festo*).

231. *See Festo*, 234 F.3d at 624 (Linn, J., concurring and dissenting) (speculating that applicants will submit narrow claims and avoid amendments due to the harsh consequences

first action allowances because of more precise claims and more thorough prior art searches.[232] However, *Festo* also retroactively affects the scope of more than one million existing patents, which in turn affects existing licensing agreements.[233]

Festo will also hinder the current negotiation system of patent prosecution by creating a disincentive for applicants and the PTO examiner to agree upon language defining the scope of their claims.[234] The PTO anticipates that applicants may resist amendments based on patent examiner rejections and patentees may use the means-plus-function more often to maintain equivalents.[235] The PTO also expects that examiners will increasingly reject claims based on indefiniteness and lack of a written description, which leads to more appeals to the courts and the PTO Board of Patent Appeals and Interferences.[236]

In addition, the PTO foresees an increase in the number of applications filed, more abandonment of applications once amended, and more claims submitted in independent form.[237] Likewise, the PTO envisions more reissues to broaden claims within two years of a patent issuance and more

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of amending narrow claims); Petitioner's Brief at 40, *Festo* (No. 00-1543) (commenting that the benefits of *Festo* will never come to fruition because artificial narrowing and the elimination of give-and-take in the examination process will only distort the proper scope a patentee deserves); U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 38, *available at* http://www.uspto.gov/web/offices/com/advisory/notices (considering a new approach to file narrow claims and broaden during continuations).

232. U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 35, *available at* http://www.uspto.gov/web/offices/com/advisory/notices.

233. Noreen Krall & Celeste B. Filoia, *The Doctrine of Equivalents: An Analysis of the* Festo *Decision*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 373, 384 (2001).

234. S. Jay Plager, *Challenges for Intellectual Property Law in the Twenty-First Century: Indeterminacy and Other Problems*, 2001 U. ILL. L. REV. 69, 74 (2001).

235. U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 37, *available at* http://www.uspto.gov/web/offices/com/advisory/notices.

236. *Id.* at 34; *see also* Petitioner's Brief at 39, *Festo* (No. 00-1543) (noting that if examiners reject a claim, the patentee's only choice may be to refuse amendment and appeal to the Federal Circuit).

237. U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 36, *available at* http://www.uspto.gov/web/offices/com/advisory/notices; *see also* Amy E. Burke & John F. Sweeney, *The Doctrine of Equivalents, Prosecution History Estoppel, and* Festo*: What Will Be the Impact of the Federal Circuit's Decision?*, 616 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 355, 366 (2000) (commenting on a potential increase in the number of patent applications submitted, but stating that the increase could be hindered by inventors' fear to disclose inventions to the public because of how easy it will be to copy the invention without infringing).

re-examination requests.[238] As a result, the PTO concludes that some potential benefits may stem from *Festo,* including higher quality applications and increased revenues.[239] However, these benefits come with additional costs for examination of more complex applications, more appeals, and longer examination periods.[240]

IV. BIOMEDICAL INDUSTRY AND THE NEW *FESTO* PATENT PROTECTION

Several companies have taken strong anti-*Festo* stances. Chiron Corporation ("Chiron"), a biotechnology company, considers *Festo* a dramatic alteration to the patent law landscape.[241] Another company, Celltech Group PLC ("Celltech"), is already facing the retroactive effects of *Festo* because one of the company's licensees is refusing to pay royalties due to amendments Celltech made during prosecution.[242] ASTA Medica Aktiengesellschaft ("ASTA Medica"), a pharmaceutical company, considers *Festo*'s only accomplishment was "providing potentially infringing poachers with ready access to low-hanging fruit."[243] ASTA Medica also believes *Festo* is an arbitrary punishment for making amendments during patent prosecution.[244] These companies would probably agree with Justice Plager that *Festo* "is a second-best solution to an unsatisfactory situation."[245]

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238. U.S. PATENT AND TRADEMARK OFFICE: Meeting Slides, *Patent—Public Advisory Committee Meeting*, Feb. 28, 2001, at 39, *available at* http://www.uspto.gov/web/offices/com/advisory/notices. The PTO notes that there will probably be more requests by third parties to re-examine claims to potentially invalidate claims creating prosecution history estoppel if amendment is required. *Id.*

239. *See id.* at 40 (anticipating benefits due to narrower claims, better disclosures by applicants, and increased fees for filings and petitions).

240. *Id.* at 41.

241. Brief of Amicus Curiae Chiron Corp. at 5, *Festo* (No. 00-1543).

242. Brief of Amicus Curiae Celltech Group PLC at 1, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025107.

243. Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 4-5, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025099.

244. *Id.* at 7.

245. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 591 (Fed. Cir. 2000) (Plager, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001).

A. Festo *is a Real Problem*

Amgen, Inc. v. Hoechst Marion Roussel[246] demonstrates how critical the doctrine of equivalents is to the biotechnology industry.[247] Amgen has patents for recombinant DNA products described as including 166 amino acids.[248] A copyist produced a variant containing 165 amino acids by deleting the last amino acid from Amgen's patent.[249] The court applied the "function-way-result" test and found the variant equivalent to Amgen's patent.[250] Therefore, by disclosing how to make this useful protein to treat diseases, skilled competitors can easily create functional equivalents with no substantial changes.[251] Without the doctrine of equivalents, Amgen would have lost its deserved protection.[252] ASTA Medica has felt the reality of *Festo*, divesting part of its company and its corresponding patents.[253] This *Festo* related consequence is particularly unfair because the only justification the Federal Circuit provides for this rule is to "promote the certainty with which subsequent infringers may skirt liability."[254]

Celltech, which owns a patent for humanized antibodies, is now a powerless licensor.[255] Celltech designed this antibody to avoid decreased effectiveness and side effects of antibodies made from non-human sources.[256] Celltech licensed this technology to MedImmune, Inc. ("MedImmune"), a biopharmaceutical company, requiring payment of royalties from products made within the scope of Celltech's patent.[257] Subsequently, MedImmune began to market a humanized antibody identical to Celltech's patent except for one different amino acid in the 1,320 amino acid sequence.[258] Celltech filed an infringement suit in England based on the doctrine of equivalents, but that court is awaiting the Supreme Court's decision in *Festo*.[259] MedImmune is claiming a bar to the use of the doctrine of equivalents by Celltech because of amendments

246. 126 F. Supp. 2d 69 (D. Mass. 2001).

247. Amgen, Inc. v. Hoechst Marion Roussel, 126 F. Supp. 2d 69, 133 (D. Mass. 2001); Brief of Amicus Curiae Chiron Corp. at 15, *Festo* (No. 00-1543).

248. *Amgen*, 126 F. Supp. 2d at 132-33.

249. *Id.*

250. *Id.* at 134.

251. Brief of Amicus Curiae Chiron Corp. at 15, *Festo* (No. 00-1543).

252. *Id.*

253. Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 8, *Festo* (No. 00-1543).

254. *Id.*

255. Brief of Amicus Curiae Celltech Group PLC at 5, *Festo* (No. 00-1543).

256. *Id.* at 5-6.

257. *Id.* at 6.

258. *Id.*

259. *Id.* at 7.

made during patent prosecution.[260] Astoundingly, Celltech may lose its right to royalties if *Festo* is affirmed.[261]

B. *Biomedical Concerns Regarding* Festo

The novelty, obviousness, and disclosure requirements continue to receive great focus in the biotechnology arena.[262] First, it is difficult for protein inventions to meet the novelty requirement, particularly if the invention stems from a natural protein by recombinant DNA technology.[263] Second, the obviousness requirement is difficult to meet if a claimed protein is a portion of a full amino acid sequence encoded by DNA.[264] Third, the preciseness and definiteness required in § 112 is difficult to meet because of examiners' rejections of "consisting essentially of" claim language and the predictions required of what one skilled in the art would reasonably believe is within the scope of the claims.[265] Lastly, the adequate description and enablement requirements of § 112 are difficult to meet because of the unpredictable nature of biotechnology and the desire to obtain patents of molecules with only slight variations in sequences.[266] International biotechnology companies who obtain U.S.

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260. Brief of Amicus Curiae Celltech Group PLC at 7, *Festo* (No. 00-1543).

261. *Id.*

262. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 421-49 (2000) (discussing the issues emerging with biotechnology inventions); S. Jay Plager, *Challenges for Intellectual Property Law in the Twenty-First Century: Indeterminacy and Other Problems*, 2001 U. ILL. L. REV. 69, 73-74 (2001) (commenting that *Festo* still leaves indeterminacy in the doctrine and questions whether less tangible fields of technology should have a different approach).

263. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 422 (2000) (explaining that the recombinant protein must be different from the natural protein patented). Also, it appears the PTO will patent a purified form of the natural protein. *Id.* at 423.

264. *See id.* at 425-27 (noting that obviousness of cloning DNA is not as simple as analogs and isomers in chemical inventions).

265. *See id.* at 439 (explaining that inoperativeness of a particular species of the invention does not necessarily mean that one skilled in the art knows whether or not it is part of the invention). Also, the PTO adopted the policy to reject the "consisting essentially of" language because it allows protection if substitutions are made that alter the characteristics of a claimed molecule. *Id.*

266. *See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 449 (2000) (noting that the PTO needs to allow broader claims for biotechnology inventions to offer adequate enablement). It is also noted that for the unpredictable field of biotechnology "the scope of enablement varies inversely with the scope of protection." *Id.* For example, genetic and immunological inventions are so unpredictable that they require more than one embodiment to obtain a broad enablement scope. *Id.*

patent protection on foreign filings face another difficulty—they must amend their application to meet the U.S. claim requirements.[267] ASTA Medica often faces this situation and amends claims as needed but never intends to surrender subject matter in the process.[268] With these difficulties, it is evident that the majority of bio-related inventions will always require amendments to clarify the novelty, non-obviousness, and disclosure of the invention.[269]

To protect patents from copyists, patent applicants will now need to claim all possible substitutions that may yield the same proteins.[270] For example, patents using amino acids will yield numerous problems for applicants.[271] Amino acids are interchangeable with other amino acids in a protein chain, which do not change the protein or its function, but would probably not infringe on the claimed protein.[272] In *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[273] the court noted that the claimed protein erythropoietin has over 3,600 analogs with the substitution of one amino acid and over one million analogs with the substitution of three amino acids.[274] Many of these analogs perform the identical function of the claimed protein, which makes it easy for copyists to simply change one amino acid and avoid infringement.[275] In Judge Michel's *Festo* dissent, he commented that the burden to claim all of these equivalent analogs is impossible for the applicant, let alone for the PTO to review.[276] This solution would burden the patent system and would not benefit the public.[277]

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267. Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 1-2, *Festo* (No. 00-1543).

268. *Id.* at 2.

269. *See id.* at 11 (commenting that practically, it is not always possible to "get it right" the first time).

270. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 617 (Fed. Cir. 2000) (Michel, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (commenting on how easy it will be for copyists to avoid liability in the biotechnology field).

271. *See id.* (noting that a protein must be claimed as a specific sequence of the amino acids, which will now be very easy for copyists to slightly modify and not infringe).

272. *Id.*

273. 927 F.2d 1200 (Fed. Cir. 1991).

274. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

275. *See Festo*, 234 F.3d at 617 (Michel, J., concurring and dissenting) (indicating that to avoid this infringement, applicants would need to claim every analog that functions equivalently to the claimed protein).

276. *See id.* (commenting that applicants would be forced to claim these equivalent sequences to ensure meaningful protection of the claimed invention).

277. *See* Brief of Amicus Curiae Chiron Corp. at 6-7, *Festo* (No. 00-1543) (noting that disclosing all variants in biotechnology inventions would require applications to have thousands of examples that would bury competitors in an abundance of useless and uninformative paperwork). Chiron also notes that a computer program could be developed to print out all variants, but the bulk would overwhelm competitors and the PTO. *Id.* at 14.

Due to *Festo*, initial investors of inventions are stripped of the protection they deserve, particularly in the rapidly evolving field of biomedical technology.[278] Future variations are difficult to predict and claim in written form, but since they come so rapidly, minor variations rob patents of their value.[279] Biotechnology's generic claims are often narrowed based on strict disclosure requirements of the PTO, which places the pioneer inventor in a losing situation.[280] However, when an improver comes along and crafts his claims so no amendments are required, he will obtain all of the equivalents.[281] This injustice nullifies the original company's massive investment and provides minor improvers undeserved protection.[282] Chiron is an illustration of a pioneer company that for years has

278. *See* Harold C. Wegner, *Biotechnology Patent Litigation: Dealing with* Festo, Johnson and Johnston *and Beyond*, 666 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 175, 183 (2001) (describing how *Festo* is a special problem for the biotechnology field); *Festo*, 234 F.3d at 620 (Linn, J., concurring and dissenting) (commenting how *Festo* increases the costs of patent prosecution and is detrimental to start-up companies and individual inventors who cannot bear the increased costs).

279. *See* James R. Farrand, *Expanded Doctrine of Equivalents Extends Patents Old and New*, 14 COMPUTER LAW. 1, 9 (1997) (commenting on this problem in the evolving computer industry); Jeffrey P. Kushan, Comment, *Protein Patents and the Doctrine of Equivalents: Limits on the Expansion of Patent Rights*, 6 HIGH TECH. L.J. 109, 115 (1991) (noting that new legal issues arose regarding defining the patent rights of initial patents for proteins and the development and patenting of next generation products).

280. *See* Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 774 (1998) (describing generic claims as the claim of classes of elements even if the invention only uses one class member). Graham notes this allows a patentee to claim variants and therefore easily claim equivalency. *Id.* at 775; Harold C. Wegner, *Biotechnology Patent Litigation: Dealing with* Festo, Johnson and Johnston *and Beyond*, 666 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 175, 183 (2001) (noting how brilliant biotechnology breakthrough inventors face the unpredictable public notice policy and are therefore required to narrow their claims resulting in zero equivalents "thanks to Festo").

281. *See* Harold C. Wegner, *Biotechnology Patent Litigation: Dealing with* Festo, Johnson and Johnston *and Beyond*, 666 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 175, 183 (2001) (expressing how minor improvers now have a better chance of using generic claims); Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 10, *Festo* (No. 00-1543) (commenting that it is well settled in American and English patent law that first inventors deserve a liberal construction of their claims and improvers deserve a narrower construction).

282. *See* William S. Galliani, *Patent Infringement Amidst Rapidly Evolving Technologies: New Equivalents, the Doctrine of Equivalents and the Reverse Doctrine of Equivalents*, 6 SANTA CLARA COMPUTER & HIGH TECH. L.J. 75, 77-78 (1990) (noting that this is an even larger problem for the biotechnology field because patents are allowed for evolving technologies).

been filing patent applications and amending them as needed.[283] Companies like Chiron will likely be the recipients of this unwelcome injustice. This inequitable result will undoubtly lead to a sharp decline in innovation and patents.[284]

Biomedical patent claims face great difficulty in obtaining full protection because of the inability to capture the real meaning of an idea in words.[285]

> Words can only approximate true contribution of the patentee to the useful arts to which the patentee is entitled to exclusive rights. The inability of words to completely capture the essence of an idea or machine leaves potentially valuable territory unclaimable at any reasonable cost. In these cases, the doctrine of equivalents functions to add the extra protection where that patentee could not have possibly claimed the valuable area of the patent.[286]

However, with *Festo*, this statement is now nullified and the doctrine of equivalents no longer functions to allow this added protection because of the impossibility to completely claim in words.[287] Chiron believes that *Festo* requires companies to use broad terms and imprecise adjectives to blur the scope of patent protection.[288] The company also asserts that the *Festo* majority is wrong in thinking that a literal claim scope is easier to decipher.[289] The inability of patentees to use language to describe claims creates uncertainty in claim scope, whether asserting literal or equivalent infringement.[290]

Festo has not reduced illegitimate competition, it has only encouraged it.[291] "The absence of a clear rule may be worse than having the 'wrong'

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283. Brief of Amicus Curiae Chiron Corp. at 16-17, *Festo* (No. 00-1543).

284. Petitioner's Brief at 42, *Festo* (No. 00-1543).

285. *See* Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 54 (1997) (asserting it is often impossible to claim the additional subject matter deserving protection).

286. *Id.*

287. *See* Brief of Amicus Curiae Celltech Group PLC at 4, *Festo* (No. 00-1543) (commenting on the difficulty to write claims in words and still balance between required specificity and comprehensiveness).

288. Brief of Amicus Curiae Chiron Corp. at 7, *Festo* (No. 00-1543).

289. *Id.* at 23.

290. *Id.*

291. *See* Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 791 (1998) (commenting on how problematic patent law is in the biotechnology industry); Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 13, *Festo* (No. 00-1543) (emphasizing how *Festo* rewards infringers and deprives inventors of their full protection under patent laws).

rule in place."[292] This uncertainty in the law hinders research and development in the biotechnology industry and the development of new and improved biomedical products.[293] The absence of a clear rule also provides large biotechnology companies legal weapons for use against small biotechnology companies who have pioneer inventions.[294]

After *Festo*, inventors may choose to refrain from publicly disclosing inventions in patents and instead resort to trade secrets for protection.[295] This option is risky because trade secrets are discoverable, but avoiding disclosure is less dangerous than unprotectable disclosures in a patent.[296] For biotechnology products, trade secret protection is virtually impossible because once a product reaches clinical trials, others can use reverse engineering to obtain the secrets.[297]

In opposition, some amici curiae assert that *Festo* is a taking of property and a violation of the Fifth Amendment.[298] This stance is rationalized as a taking back of compensation patentees received for disclosing inventions to the public.[299] As a patentee, Chiron asserts that *Festo* violates due process because of the lack of an opportunity to be heard on this rule that changes existing patent rights.[300] Therefore, *Festo* should not have a retroactive effect because it nullifies many existing patents.[301]

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292. Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 151, 173 (1995).

293. *See id.* (commenting on how the patent process cannot return to the days of refusing enforcement of claims based on "old combinations").

294. *See* Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 791 (1998) (commenting that the doctrine of equivalents creates economic difficulties for the biotechnology industry because it really does not "reduce the risk of illegitimate competition").

295. Petitioner's Brief at 40, *Festo* (No. 00-1543); Brief of Amicus Curiae Chiron Corp. at 9, *Festo* (No. 00-1543).

296. *See* Brief of Amicus Curiae Chiron Corp. at 9, *Festo* (No. 00-1543) (explaining that in biotechnology, inventors may decide to restrict early disclosure of their invention).

297. *Id.*

298. *Id.* at 27; Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 25, *Festo* (No. 00-1543); Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 7-8, *Festo* (No. 00-1543).

299. Brief of Amicus Curiae Chiron Corp. at 27, *Festo* (No. 00-1543).

300. *Id.* at 29.

301. *See id.* at 19 (asserting that *Festo* should apply prospectively); *see also* Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 21-22, *Festo* (No. 00-1543) (explaining that retroactive application of *Festo* prevents owners from obtaining the complete benefit of rights associated with the entire patent term); Brief of Amicus Curiae Celltech Group PLC at 8-9, *Festo* (No. 00-1543) (noting that licensees are provided incentives to use the "Festo roadmap" for avoidance of royalty obligations, which deprives licensors of their royalties without notice that their patent rights would be valueless).

Lastly, ASTA Medica notes that *Festo* is inconsistent with global patent law, and the harmonization goal of the United States.[302] The World Intellectual Property Organization, which includes the U.S. as a member, promotes harmonization and recently drafted a rule providing a wide range of equivalents.[303] It argues that *Festo* discriminates against foreign applicants because their patents will become useless in the U.S.[304]

However, some argue that *Festo* is not a concern for the biomedical industry, because patent applicants for biotechnology inventions can simply claim all of the equivalents by drafting claims broadly.[305] Applicants may write broad claims and still provide the required public notice, which would allow applicants to claim all possible equivalents.[306] In *Sage Products, Inc. v. Devon Industries, Inc.*,[307] Judge Rader noted that "as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure."[308] One commentator noted that patents should not become a mechanism to obtain protection of products and processes not actually invented by the patent holder.[309] Limiting the use of the doctrine of equivalents encourages new discoveries.[310] The limitation reduces fear of competitors from infringing on patents while attempting

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302. Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 13, *Festo* (No. 00-1543); Petitioner's Brief at 45, *Festo* (No. 00-1543).

303. Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 6, 13-14, *Festo* (No. 00-1543).

304. *See* Petitioner's Brief at 44-45, *Festo* (No. 00-1543) (explaining that foreign patentees will not be able to use the doctrine of equivalents under the *Festo* rule).

305. *See* Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 772-76 (1998) (noting that if an accused product is found equivalent to the patented product, it is likely the patented product could claim the equivalent with a more broad claim).

306. *Id.* at 774.

307. 126 F.3d 1420 (Fed. Cir. 1997).

308. Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1425 (Fed. Cir. 1997).

309. *See* Louis S. Sorell, *The Application of the Doctrine of Equivalents to Chemical Inventions: A Primer*, 11 ALB. L.J. SCI. & TECH. 225, 248 (2001) (stating that the doctrine of equivalents "is a slender reed upon which to base a claim of patent infringement").

310. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 597-98 (Fed. Cir. 2000) (Lourie, J., concurring), *cert. granted*, 121 S. Ct. 2519 (2001) (commenting on the enhancement of predictability to competitors that the complete bar rule provides); Derick E. Allen, Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.: *Is It Time for the Supreme Court to Resolve How the Doctrine of Equivalents Should be Applied?*, 15 ST. LOUIS U. PUB. L. REV. 157, 176 (1995) (commenting that limiting the doctrine of equivalents' scope enhances research and development).

to invent new and improved products.[311] Even though sporadic injustices will occur, development of innovative products by competitors with no fear of infringement will outweigh these threats.[312]

C. *Biomedical Cases Before and After* Festo

In the fifty cases that Judge Michel deemed to vary from *Festo*, only five involved biomedical issues.[313] Three of the five cases applied the flexible bar rule to arguments made during prosecution to evaluate whether estoppel arose and whether it barred the use of the doctrine of equivalents.[314] Two of the cases applied the flexible bar approach to amendments made during patent prosecution.[315] In two other biomedical

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311. *See* Derick E. Allen, Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.*: Is It Time for the Supreme Court to Resolve How the Doctrine of Equivalents Should be Applied?*, 15 ST. LOUIS U. PUB. L. REV. 157, 176 (1995) (noting the likelihood of efforts veering from pioneering inventions is unlikely because the rewards for the pioneers almost always outweigh the rewards from improvements).

312. *See Festo*, 234 F.3d at 597 (Lourie, J., concurring) (commenting how the unpredictable doctrine of equivalents creates too much fear and affects too many business decisions).

313. *See id.* at 613-15 (Michel, J., concurring and dissenting) (listing fifty prior cases varying from the *Festo* decision).

314. *See* Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1376 (Fed. Cir. 1999) (analyzing prosecution history as a whole to determine whether Upjohn surrendered "micronized glyburide formulations containing *any* type of lactose other than spray-dried lactose"). The court held that Mylan's formulations with anhydrous lactose and micronized glyburide did not infringe upon Upjohn's patent under the doctrine of equivalents. *Id.* Prosecution history estoppel precluded Upjohn from coverage under the doctrine of equivalents because Upjohn surrendered both hydrous and anhydrous lactose during its patent application. *Id.*; *see also* Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1567-68 (Fed. Cir. 1994) (reviewing the intended function demonstrated during the patent prosecution). After review of the prosecution history, the court held that the function of the protein tissue plasminogen activator, which has a critical role in dissolution of human fibrin clots, includes fibrin binding. *Genentech*, 29 F.3d at 1566-68. Therefore, the accused device did not infringe under the doctrine of equivalents because it did not function the same way or achieve the same results. *Id.* at 1568; *see also* Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1565-67 (Fed. Cir. 1990) (reviewing inventor's arguments to overcome examiner's prior art rejection). The court remanded the case to the district court to further evaluate the intent of the arguments made during patent prosecution. *Genentech*, 29 F.3d at 1567. The issue on remand was whether the arguments made surrendered the natural human growth hormone (HGH) structure in a continuation-in-part application that lead to a patent of a modified version of natural HGH. *See id.* at 1560, 1568.

315. *See* Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1253-54 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 993 (applying the flexible bar rule to an amendment to overcome § 103 and § 112 rejections); Merck & Co. v. Mylan Pharm., Inc., 190 F.3d 1335, 1342 (Fed. Cir. 1999) (applying the flexible bar rule to an amendment to avoid prior art and specify species).

cases, the district courts anticipated *Festo*, but still applied a flexible approach to amendments.[316]

In *Bayer AG v. Elan Pharmaceutical Research Corp.*,[317] the court completely evaluated the prosecution history using the flexible approach.[318] The court decided that Bayer surrendered surface areas of crystals in a pharmaceutical composition because their amendment identified a specific surface area range.[319] In *Merck & Co. v. Mylan Pharmaceutical, Inc.*,[320] the court evaluated the prosecution history of a species of polymers claimed for formulation of a Parkinson's disease drug.[321] The court determined whether Merck surrendered all originally claimed species when it narrowed the claim to a specific formulation.[322] In *Biogen,*

316. *See* Biogen, Inc. v. Amgen, Inc., 115 F. Supp. 2d 139, 146-47 (D. Mass. 2000) (applying the flexible bar rule to an amendment made to overcome an inadequate description rejection); Biogen, Inc. v. Berlex Labs., Inc., 113 F. Supp. 2d 77, 109-12 (D. Mass. 2000) (applying the flexible bar rule to an amendment to overcome examiner's obvious-type double patenting rejection).

317. 212 F.3d 1241 (Fed. Cir. 2000).

318. *See Bayer AG*, 212 F.3d at 1245, 1251 (examining prosecution history of a patent relating to pharmaceutical solid compositions, for example tablets, that have nifedipine crystals with a specific total surface area (SSA)).

319. *See id.* at 1245-46 (describing the intent of Bayer in claiming a particular SSA relating to the concern of absorption of nifedipine into blood and high bioavailability). The patent claimed a particular surface area of nifedipine crystals in the pharmaceutical compositions to address poor solubility while also maintaining a nifedipine sustained level in the blood. *Id.* Nifedipine is a compound that is a coronary vasodilator, which is used to control high blood pressure. *Id.* at 1245. Bayer originally claimed an SSA range of 0.5-6 m^2/g, but the examiner under § 112 rejected these ranges. *Id.* at 1251. Bayer then amended the range to 1.0-4 m^2/g to overcome the § 112 rejection. *Bayer AG*, 212 F.3d at 1251. The court evaluated the prosecution history to determine whether Bayer clearly surrendered the subject matter. *Id.* at 1252. The court applied an objective standard to determine "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.* Bayer made statements regarding the superiority of the new SSA range because it provided maximum bioavailability by maintaining high levels of nifedipine in the blood for long periods of time. *Id.* Bayer also asserted to the PTO that the dissolution rate of SSAs outside this range decreased. *Id.* at 1253. The court held the amendment, along with the arguments made, evidenced clear and unmistakable surrender regarding SSAs outside the range of 1.0-4 m^2/g, which in this case would eliminate the use of the doctrine of equivalents for Bayer. *Bayer AG*, 212 F.3d. at 1253.

320. 190 F.3d 1335 (Fed. Cir. 1999).

321. Merck & Co. v. Mylan Pharm., Inc., 190 F.3d 1335, 1337 (Fed. Cir. 1999) (explaining that the patents involved "controlled release formulation of a combination of the drugs levodopa and carbidopa, used to treat Parkinson's disease"). This controlled release was invented as a polymer vehicle to deliver the drugs together and based on side effects resulting from an immediate release formulation. *Id.* Following an evaluation of the narrowing amendment's prosecution history, the court concluded that Merck amended the formulation to overcome prior art rejection. *Id.* at 1341-42.

322. *See id.* at 1339 (explaining that the original application contained many species of polymers for the formulation; however, the examiner rejected this broad list and required

Inc. v. Amgen, Inc.,[323] the district court used the flexible bar approach to determine whether Biogen surrendered plasmid vector sequences without an element later added in an amendment.[324] In *Biogen, Inc. v. Berlex Laboratories, Inc.*,[325] the district court evaluated the full prosecution history to determine whether amending a gene construct by specifying a marker gene narrowed the claim, therefore surrendering subject matter.[326]

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the applicant to elect a species based on obviousness in relation to prior art). Merck's original list included in part, hydroxypropyl cellulose (HPC), hydroxypropyl methycellulose (HPMC), and polyvinyl acetate-crotonic acid (PVACA) copolymer. *Id.* In a second continuation-in-part application, Merck amended this formulation to only include the HPC/PVACA combination. *Merck*, 190 F.3d at 1339. The accused device in this case claimed a HPC/HPMC combination. *Id.* at 1339, 1341. The court stated that "estoppel is not automatic as to everything beyond the literal scope of the claim; its extent must be determined from what was relinquished, in light of prior art." *Id.* at 1341. However, after reviewing the prosecution history, the court held that Merck surrendered thirteen of its original polymers, one of which was used by Mylan in the accused device. *Id.* at 1341. Therefore, Merck was estopped from using the doctrine of equivalents against Mylan for any of these surrendered polymers. *Id.* at 1341-42. Even though Merck was estopped, the court based its conclusion on a flexible bar approach that required close examination of the prosecution history to determine what was surrendered and why. *Merck*, 190 F.3d at 1342.

323. 115 F. Supp. 2d 139 (D. Mass. 2000).

324. *See* Biogen, Inc. v. Amgen, Inc., 115 F. Supp. 2d 139, 147 (D. Mass. 2000) (allowing Amgen's summary judgment motion under the doctrine of equivalents). Biogen's patent was for a plasmid vector and in an amendment, Biogen claimed a specific structure of their plasmid vector. *Id.* A plasmid vector is defined as a DNA molecule capable of being replicated, with or without inserted genes, in host cells. *Id.* at 141 n.1. The amendment was made to overcome the disadvantages of prior art regarding the large distance between available sites for cloned gene insertions and the P subL promoter. *Id.* This claimed structure overcomes disadvantages of prior art by adding an *Eco* RI site downstream a short distance from the P subL promoter in a particular region. *See id.* at 147. The court analyzed the prosecution history and determined that a competitor would reasonably believe that Biogen surrendered any vector without this new *Eco* RI site and vectors with this new site before or after the claimed region. *See Biogen*, 115 F. Supp. 2d at 147 & n.19. The accused device was almost identical to the patented invention except it did not contain this Eco RI site in the exact same location. *Id.* at 143. Therefore, the court held that Biogen could not use the doctrine of equivalents in an infringement action against Amgen. *Id.* at 147.

325. 113 F. Supp. 2d 77 (D. Mass. 2000).

326. *See* Biogen, Inc. v. Berlex Labs., Inc., 113 F. Supp. 2d 77, 111-12 (D. Mass. 2000) (entitling Biogen to summary judgment in Berlex's infringement action based on an obvious-type double patenting rejection leading to a claim amendment by Berlex). Berlex's patent relates to expressing interferon genes in Chinese Hamster Ovary (CHO) cells. *Id.* at 84. The purpose of the patent is to use the CHO as host cells to introduce the interferon gene. *Id.* Once the construct integrates with the chromosome in the CHO cells, the interferon gene is transcribed into RNA, which is translated into protein by the CHO cells. *Id.* The net result is CHO cells with the interferon gene that produces the desired protein. *Id.* Berlex claimed that Biogen infringed its construct claims and its cell claims under the doctrine of equivalents. *See Berlex*, 113 F. Supp. 2d at 85. The construct claims describe a

The Federal Circuit and a district court have ruled on four biomedical cases since *Festo*.[327] In *Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc.*,[328] the Federal Circuit applied the *Festo* complete bar rule to an amendment relating to § 112.[329] During prosecution of a patent for an

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single DNA construct with interferon and DHFR genes as the means to transform CHO cells and the cell claims describing CHO cells with chromosomes having a single DNA construct of interferon and marker genes. *Id.* When Berlex amended these claims to overcome an existing patent that already surrendered the equivalent between multiple and single constructs, it narrowed the single construct even further by requiring Dihydrofolate reductase (DHFR) to be the marker gene. *Id.* at 77, 111. Berlex did not attempt to broaden the single construct to cover multiple constructs and defining DHFR; a common marker used in recombinant DNA technology. *Id.* The issue for the accused device is whether the Berlex patent also covers unlinked co-transformation, which inserts interferon and marker genes into CHO cells as two separate DNA constructs. *Id.* at 84. The Berlex patent does cover linked co-transformation, but the issue is whether it is broader, which would make the accused device infringe under the doctrine of equivalents. *Berlex*, 113 F. Supp. 2d at 84. After reviewing the prosecution history carefully, the court concluded that the Berlex patent was narrow and only included linked co-transformation, which estopped it from using the doctrine of equivalents. *Id.* at 111-12.

327. *See* Glaxo Group Ltd. v. Ranbaxy Pharms., Inc., 262 F.3d 1333, 1338 (Fed. Cir. 2001) (applying the *Festo* complete bar rule to an amendment to overcome a § 112(2) rejection); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., No. IP 96-1718-C-HIG, 2001 WL 912767, at *3 (S.D. Ind. June 14, 2001) (applying the *Festo* complete bar rule to amendments adding selecting steps and selecting means). The patentee argued for mitigation to the *Festo* complete bar, but the district court denied this argument. *Cardiac Pacemakers*, 2001 WL 912767 at *12. The patents at issue are for medical devices and methods for evaluating and treating abnormal heart conditions. *Id.* at *1. Cardiac Pacemakers amended a claim in the patent application regarding "selecting" modes of operation and "selecting" means for choosing a mode. *Id.* at *3. Cardiac Pacemakers argued that even though this claim was amended, the "selecting" clauses were not affected by the amendment. *Id.* at *3. Cardiac Pacemakers further contended that the "selecting limitations as a whole" were unaffected by the amendment and the unmodified claim language should not be relevant to the *Festo* analysis. *Id.* The court rejected this argument and would not apply the suggested flexible bar approach to determine whether the "selecting" clauses were affected by the amendment and whether anything regarding selection was surrendered. *Cardiac Pacemakers*, 2001 WL 912767 at *3. The court held that the flexible bar rule has too much uncertainty regarding whether subject matter was surrendered. *Id.* Therefore, the court denied use of the doctrine of equivalents relating to selection on the accused device without completely evaluating the prosecution history to determine the nature of the amendment. *Id.* The court held that the complete bar approach provides the required public notice of the patent system. *Id.*; Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1304 (Fed. Cir. 2001) (applying the *Festo* complete bar rule to an amendment adding an admixture limitation); *see also* Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 135 (D. Mass. 2001) (holding that the amendment was not related to patentability).

328. 262 F.3d 1333 (Fed. Cir. 2001).

329. *See* Glaxo Group Ltd. v. Ranbaxy Pharms., Inc., 262 F.3d 1333, 1338 (Fed. Cir. 2001) (holding that the narrowing amendment to meet the definiteness requirement of § 112 is related to patentability and completely bars assertion of any equivalents).

antibiotic, the examiner rejected the "highly pure, substantially amorphous form" description of the compound as indefinite.[330] Glaxo narrowed the claim to state, "'essentially free from crystalline material.'"[331] The accused device contained a percentage of crystalline material, but it was not clear what range "essentially free" would entail.[332] The court held that because the narrowing amendment related to patentability, no range of equivalents was available.[333] Notably, the court failed to address the range of equivalents possibly surrendered by Glaxo in making this amendment.[334]

Biovail Corp. International v. Andrx Pharmaceuticals, Inc.[335] involved a drug patent for the treatment of hypertension and angina.[336] The accused device and the patented product both contained porous membrane beads, but Biovail mixed the components of the beads during manufacturing and Andrx did not.[337] Because Biovail amended its application to state "admixture" to avoid prior art, the court automatically found estoppel and no range of equivalents.[338] Never did the court consider whether the patentee intended to surrender all products without "admixtures," nor did it consider the circumstances surrounding the amendment.[339]

It is apparent that the *Festo* ruling has helped courts reduce the analysis required for the doctrine of equivalents.[340] As a result, the new streamlined judicial analysis has hurt companies that previously made amend-

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330. *Id.* at 1338.

331. *Id.* at 1335.

332. *See id.* at 1337 (noting the district court's interpretation was that the range of equivalents was from 10-15% crystalline material).

333. *See id.* at 1338 (holding that Glaxo could not use the doctrine of equivalents for this limitation).

334. *See Glaxo*, 262 F.3d at 1338 (holding that Ranbaxy's sale of it's product would not harm Glaxo).

335. 239 F.3d 1297 (Fed. Cir. 2001).

336. Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1299 (Fed. Cir. 2001).

337. *See id.* (explaining the salt and sugar components of the Biovail beads and the Andrx bead, which has a core of sugar/starch with salts and other components surrounding the core).

338. *See id.* at 1304 (holding that because the reason for the amendment was related to patentability, Biovail was estopped from claiming any equivalents for infringement that did not contain an admixture).

339. *See id.* (ending its analysis with the complete bar rule).

340. *See* Petitioner's Brief at 21, *Festo* (No. 00-1543) (noting that easy infringement without liability is a high price to pay for the convenience of a bright line rule); Brief of Amicus Curiae Litton Systems, Inc. at 5, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1002689 (noting how "*Festo* rewrote the rule book").

ments during negotiations with the patent examiner.[341] In the process of making these amendments, these companies unknowingly gave up equivalents because during negotiations, most companies depended on the use of the doctrine of equivalents in potential infringement actions.[342]

V. PROPOSED RESOLUTION—THREE-PRONG MODIFIED FLEXIBLE BAR APPROACH

On June 18, 2001, the U.S. Supreme Court granted only one writ of certiorari without automatic remand—the *Festo* petition.[343] It would appear that the Supreme Court is taking this patent issue seriously. Amici curiae are also looking at this matter and have expressed their opinions to the Supreme Court—the majority of the briefs are not in favor of the complete bar rule.[344] *Festo* should not continue as the law. But now the issue is whether there is an appropriate way to balance the patentee's and competitor's needs, particularly for the biomedical industry.

The doctrine of equivalents requires affirmation of its existence and the complete bar rule requires reversal.[345] Substance must prevail over form.[346] The Supreme Court provided guidance to the Federal Circuit for defining an equivalent test used on a case by case basis.[347] A three-prong modified flexible bar test would satisfy this request of the Supreme Court.[348]

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341. *Festo*, 234 F.3d at 598 (Michel, J., concurring and dissenting); *see also* Brief of Amicus Curiae Chiron Corp. at 8, *Festo* (No. 00-1543) (commenting that current patentees rely on the doctrine of equivalents precedent).

342. Brief of Amicus Curiae Chiron Corp. at 8, *Festo* (No. 00-1543); *Festo,* 234 F.3d at 620 (Rader, J., concurring and dissenting).

343. Supreme Court Orders, Order List 533 U.S. (June 18, 2001), http://supreme.usatoday.findlaw.com/supreme_court/orders/2000/061801pzor.html.

344. *See* Appendix.

345. *See* Petitioner's Brief at 19, *Festo* (No. 00-1543) (requesting a reversal of *Festo* because it strikes at the heart of the patent system and reaches too far in excluding the doctrine of equivalents from the patent system). The Petitioner calls *Festo* a "crippling blow" to the patent system. *Id.* at 42.

346. *See id.* at 28 (noting that *Festo* favors form over substance as it requires a flawless original application and ignores the patent prosecution reality).

347. *See* Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 n.8 (1997) (indicating that the Court "expect[s] that the Federal Circuit will refine the formulation of the test for equivalence in the orderly course of case-by-case determinations, and [the Court] leave[s] such refinement to that court's sound judgment in this area of its special expertise").

348. *See* Peter Corcoran, *The Scope of Claim Amendments, Prosecution History Estoppel, and the Doctrine of Equivalents After Festo VI*, 9 TEX. INTELL. PROP. L.J. 159, 161 (2001) (commenting that the scope of estoppel should be determined by "objectively based, case-specific, factual inquiry into the nature of the amendment, the prior art, and other factors that prompted the amendment").

When a patentee cannot prove literal infringement, the doctrine of equivalents is asserted.[349] When this doctrine is asserted, three prongs may be used to analyze whether prosecution history estoppel bars the use of the doctrine.[350] The first prong requires identification of the limitation asserted as having equivalents.[351] The second prong requires identification of the equivalents asserted to the claim limitation found in the first prong.[352] The third prong requires evaluation of whether prosecution history estoppel bars use of the doctrine of equivalents.[353]

In evaluating the third prong, two sub-questions must be considered: (a) whether the claim limitation was amended for a reason related to patentability, as defined in *Festo*, hereby creating prosecution history estoppel[354] and (b) whether the amendment surrendered the asserted equivalents identified in the second prong.[355] If the first sub-question is answered affirmatively, the second sub-question is analyzed by considering intrinsic and extrinsic evidence[356] relating to: (1) obviousness;[357] (2)

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349. *Warner-Jenkinson*, 520 U.S. at 21.

350. *See* Richard L. Wynne, Jr., Warner-Jenkinson Co. v. Hilton Davis Chemical Co.: *How Can the Federal Circuit Control the Doctrine of Equivalents Following the Supreme Court's Refusal to Set the Standard?*, 50 OKLA. L. REV. 425, 450 (1997) (noting that the Federal Circuit needs to continually refine the doctrine of equivalents by developing a test that addresses patent law and doctrine of equivalents policies).

351. *Cf.* Pickholtz v. Rainbow Techs., Inc., 125 F. Supp. 2d 1156, 1161 (N.D. Cal. 2000) (stating the first part of the *Festo* test requires a district court to "determine which claim limitations are alleged to be met by equivalents"); *see also* ACLARA BioSciences, Inc. v. Caliper Techs. Corp., 125 F. Supp. 2d 391, 403 (N.D. Cal. 2000) (holding that prosecution history estoppel and the doctrine of equivalents should only apply to amended limitations in a claim and not the entire amended claim).

352. *Cf. Pickholtz*, 125 F. Supp. 2d at 1161 (stating the first part of the *Festo* test that a district court must perform). The proposed approach builds on this first part of *Festo's* test to clearly define the equivalents asserted. *Id.*

353. *See* Brief of Amicus Curiae United States at 13, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025650 (urging that analyses should begin with determining the relationship between prosecution history estoppel and the doctrine of equivalents).

354. *Cf. Pickholtz*, 125 F. Supp. 2d at 1161 (listing parts two and three of the *Festo* test required of district courts); Brief of Amicus Curiae United States at 8-9, *Festo* (No. 00-1543) (agreeing with *Festo* as to the types of amendments that should create prosecution history estoppel).

355. *See Festo*, 234 F.3d at 622 (Linn, J., concurring and dissenting) (noting that *Festo* does not define a narrowing amendment). This proposed part of the test does not consider narrowing because what one surrendered is the critical inquiry. *Id.*; *see also* Brief of Amicus Curiae Chiron Corp. at 23-24, *Festo* (No. 00-1543) (commenting that courts will still need to decide claim scope surrendered during prosecution).

356. Petitioner's Brief at 31, *Festo* (No. 00-1543); Brief of Amicus Curiae Chiron Corp. at 23, *Festo* (No. 00-1543).

357. *See* Alan P. Klein, *The Doctrine of Equivalents: Where It Is Now, What It Is*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 514, 522 (2001) (proposing the historical obviousness test

technology;[358] (3) claim words;[359] (4) amendment circumstances;[360] and (5) equivalents to amended limitation.[361] Under this test, even if an amendment exists related to patentability, there is still a range of equivalents available, which the patentee must demonstrate in the final analysis of the third prong.[362]

The test evolved after analysis of the consequences facing the biomedical industry following the *Festo* ruling. The biomedical industry needs special consideration, but because special treatment would only confuse the application of patent laws, this approach can be broadly applied to most industries.[363] The use of extrinsic evidence is critical to the factor analysis in part (b) of the third prong.[364] *Festo* only allows use of intrinsic evidence, such as the patent itself and the prosecution history.[365] Using extrinsic evidence will not decrease the certainty of claims.[366] Further,

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for the range of equivalents available after an amendment); Scott P. Zimmerman, *The Doctrine of Equivalents: A Call for Congressional Reinvigoration*, 40 IDEA 599, 625 (2000) (proposing that Congress adopt the obviousness test for the doctrine of equivalents and affirm the doctrine as a legal conclusion).

358. *See* Harold C. Wegner, *Biotechnology Patent Litigation: Dealing with* Festo, Johnson and Johnston *and Beyond*, 666 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 175, 183 (2001) (describing how *Festo* is a special problem for the rapidly evolving biotechnology field). *See generally* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 628 PRACTISING L. INST.—PATS., COPYRIGHTS, TRADEMARKS, AND LITERARY PROP. COURSE HANDBOOK SERIES 403, 421-64 (2000) (discussing the issues emerging with biotechnology inventions).

359. *Festo*, 234 F.3d at 624 (Linn, J., concurring and dissenting); Petitioner's Brief at 20, *Festo* (No. 00-1543).

360. Petitioner's Brief at 25, *Festo* (No. 00-1543); *Festo*, 234 F.3d at 599 (Michel, J., concurring and dissenting).

361. *Festo*, 234 F.3d at 620 (Linn, J., concurring and dissenting); Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 774-75 (1998).

362. *See Festo*, 234 F.3d at 613-15 (Michel, J., concurring and dissenting) (listing fifty prior cases varying from the *Festo* decision because the Federal Circuit applied the flexible bar rule).

363. *See* Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 151, 174 (1995) (favoring a flexible patent system based on sound principles over a "hodge podge" of laws that undermine patent goals).

364. Petitioner's Brief at 31, *Festo* (No. 00-1543); Brief of Amicus Curiae Chiron Corp. at 23, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (No. 00-1543), 2001 WL 1025109.

365. *See generally Festo*, 234 F.3d at 587-91 (reviewing only documentation in the prosecution history). *But see* Key Pharm. v. Hercon Labs. Corp., 161 F.3d 709, 716-17 (Fed. Cir. 1998) (allowing the use of extrinsic evidence to determine the scope of the claim "a pharmaceutically effective amount").

366. Brief of Amicus Curiae Chiron Corp. at 23, *Festo* (No. 00-1543).

sole use of intrinsic evidence seems not only at odds with public policy, but also with Supreme Court precedent.[367]

In part (b) of the third prong, the first factor of obviousness considers whether the substitution made in the accused device was obvious to one skilled in the art.[368] If obviousness exists at the time of infringement, the accused device is probably not equivalent.[369] The second factor of technology considers various aspects of the industry at issue. First, consideration of competition in the industry is critical because patents promote investment in innovation, which drives the economy.[370] Denying equivalents should not destroy competition by promoting the copying of other's inventions. Second, whether the industry is rapidly evolving is given weight because one skilled in the art becomes difficult to define.[371] Accelerated, innovative progress should not penalize rapidly evolving technologies by denying equivalents. Third, whether the product has a critical public benefit is a consideration so the inventor is not denied his rights for disclosing an important product or process to the public.[372] Lastly, since one of the purposes of the doctrine of equivalents is to accommodate "after-arising" technologies, consideration should be given to whether the patentee could have surrendered subject matter not yet existing.[373]

The third factor in part 3b of claiming scope in words considers the simplicity in describing claim scope while considering the industry at issue.[374] Inventors should not be placed "at the mercy of verbalism."[375]

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367. *See* Petitioner's Brief at 31, *Festo* (No. 00-1543) (commenting that use of extrinsic evidence should be allowed, which follows the *Warner-Jenkinson* rebuttable presumption allowing extrinsic evidence).

368. *See* Judge Paul R. Michel, *The Role and Responsibility of Patent Attorneys in Improving the Doctrine of Equivalents*, 40 IDEA 123, 129 (2000) (proposing an obviousness test for equivalent infringement analysis).

369. *Id.*

370. *Festo*, 234 F.3d at 639 (Linn, J., concurring and dissenting).

371. *See* Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 151, 155 (1995) (discussing some of the protection issues associated with rapidly evolving technologies).

372. *See* Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 6, *Festo* (No. 00-1543) (commenting how *Festo* incorrectly assumes all inventions benefit the public equally).

373. *Festo*, 234 F.3d at 620 (Rader, J., concurring and dissenting) (stating that "[b]ecause after-arising technology was not in existence during the patent application process, the applicant could not have known of it, let alone surrendered it"); Brief of Amicus Curiae Chiron Corp. at 25, *Festo* (No. 00-1543).

374. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 624 (Fed. Cir. 2000) (Linn, J., concurring and dissenting), *cert. granted*, 121 S. Ct. 2519 (2001) (commenting that *Festo* makes it difficult for claims draftsman to "perfectly describe a new and unobvious invention at an early stage of the development process").

The fourth factor of amendment circumstances takes into account the prosecution record including amendment explanations and arguments made between applicant and examiner.[376] Consideration of the intent of the amendment is also essential.[377] The fifth factor considers whether any equivalents were actually claimed.[378] This factor also considers whether equivalents were known or foreseeable at the time of amendment.[379] After contemplating these factors, the court can then determine whether prosecution history estoppel is a bar to a particular range of equivalents. Using a modified flexible bar approach would provide the best opportunity to reach a desirable and fair level of patent protection.

VI. CONCLUSION

The future of the patent system begs for reversal of *Festo*. The complete bar rule will eliminate the goals of the U.S. patent system and devalue the protection provided by patents. A modified flexible bar approach to the evaluation of prosecution history estoppel and the doctrine of equivalents is workable, but requires extensive judicial analysis. However, patent applicants can simplify this analysis by claiming equivalents known at the time of application and clearly documenting the intent and circumstances surrounding amendments. This extra work by both the court and patentee allows patents to provide the protection required by law. The doctrine of equivalents is an equitable doctrine and should therefore provide patentees and competitors equal and fair protection. The necessity of this protection is particularly critical in the biomedical industry to ensure capital investments for innovation, which leads to additional drugs, vaccines, and medical devices for improved world health.

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375. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950); Petitioner's Brief at 20, *Festo* (No. 00-1543).

376. *See* Petitioner's Brief at 23, *Festo* (No. 00-1543) (commenting that prosecution history should be construed from the viewpoint of a reasonable competitor); *see also Festo*, 234 F.3d at 599 (Michel, J., concurring and dissenting) (noting that competitors rely on the prosecution history record).

377. *See* Petitioner's Brief at 25, *Festo* (No. 00-1543) (describing that amendments to avoid prior art do surrender subject matter, but amendments to clarify or improve a description do not necessarily surrender subject matter).

378. *See* Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 6 J.L. & POL'Y 741, 774-75 (1998) (encouraging that equivalents, or variants, can be claimed by stating element classes even if only one member of the invention is used).

379. *See Festo*, 234 F.3d at 620 (stating that one cannot claim an equivalent not existing at the time of an amendment); *see also* Brief of Amicus Curiae United States at 10, *Festo* (No. 00-1543) (proposing a rebuttable presumption on a patentee that any amendment bars the use of the doctrine of equivalents).

APPENDIX: SUMMARY OF AMICI CURIAE BRIEFS REGARDING *FESTO* GRANT OF CERTIORARI

After grant of certiorari, sixteen amici curiae submitted briefs for the Petitioner, Festo Corp., five submitted neutral briefs, and six briefs were filed for the Respondent, Shoketsu Kinzoku Kogyo Kabushiki Co. As illustrated in the table, many intellectual property associations and various industries seek to provide potential solutions to the *Festo* problem. This appendix briefly summarizes amici curiae opinions expressed to the Supreme Court. Festo Corp. is seeking reversal of *Festo*, and Shoketsu Kinzoku Kogyo Kabushiki Co., is arguing to affirm the decision.

Amicus Curiae-Petitioner	**Summary of Opinion**
American Bar Ass'n	*Festo* violates public policy and abolishes the use of the doctrine of equivalents for most unexpired patents. It will place burdensome requirements on applicants to maintain broad claims and avoid amendments. *Festo* decreases incentives for innovation and discourages use of patents over trade secrets. Brief of Amicus Curiae American Bar Ass'n at 2-3, Festo Corp. v. Shoketsu Kinsoku Kogyo Kabushiki Co., 234 F.3d 558 (No. 00-1543), 2001 WL 1024048.
American Intellectual Property Law Ass'n	An objective standard of whether the applicant made any clear and unmistakable surrender during patent prosecution should be used when an amendment creates prosecution history estoppel. Brief of Amicus Curiae American Intellectual Property Law Ass'n at 2, *Festo* (No. 00-1543), 2001 WL 1025096.
ASTA Medica Aktiengesellschaft	The *Festo* decision is not in line with international patent law and inconsistent with the global harmonization of patent protection laws. Brief of Amicus Curiae ASTA Medica Aktiengesellschaft at 3, *Festo* (No. 00-1543), 2001 WL 1025099.
Bose Corp.	*Festo's* bright line rule unjustly upsets patentee's negotiated expectations of protection. In addition, *Festo* risks whether the patent system continues to provide incentives for innovation and investment in new and improved technologies. Brief of Amicus Curiae Bose Corp. at 2, *Festo* (No. 00-1543), 2001 WL 1040335.
Celltech Group PLC.	Biotechnology patents are especially subject to the fail-safe method for avoiding infringement liability that *Festo* established. For example, it would be as easy as substituting an amino acid without changing the function of a protein. Brief of Amicus Curiae Celltech Group PLC. at 2-3, *Festo* (No. 00-1543), 2001 WL 1025107.

Chiron Corp.	Biotechnology inventions particularly need the doctrine of equivalents for protection of scope of claims. *Festo* provides a road map for copyists to infringe without liability. For example, a copyist could simply change an amino acid in a sequence to avoid liability. The majority of current biotechnology patents are amended due to the evolving application of patent law to biotechnology inventions. Therefore, if affirmed, *Festo* should not be applied retroactively. Brief of Amicus Curiae Chiron Corp. at 3-4, *Festo* (No. 00-1543), 2001 WL 1025109.
Federal Circuit Bar Ass'n	The flexible bar rule may not be simple for courts to apply, but application is still possible. The flexible bar rule should continue so long as the asserted scope of equivalents is consistent with prosecution arguments, does not capture prior art, and does not claim scope existing prior to amendment. The patentee should carry the burden of proof. Brief of Amicus Curiae Federal Circuit Bar Ass'n at 2-3, *Festo* (No. 00-1543), 2001 WL 1025114.
Federation Internationale Des Conseils En Propriete Industrielle (FICPI)	The FICPI argues that *Festo* discourages disclosure of inventions by domestic and foreign inventors and devalues existing patents. *Festo* reverses years of precedent and sends a disturbing message to the international patent community that U.S. law is susceptible to drastic change at any time. The holding will likely detract inventors from filing in the volatile U.S. patent arena. Brief of Amicus Curiae Federation Internationale Des Conseils En Propriete Industrielle at 2-3, *Festo* (No. 00-1543), 2001 WL 1025117.
Houston Intellectual Property Law Ass'n	The inflexible bar rule of *Festo* changes the "rules of the game," altering the balances the PTO considers in issuing patents. If an amendment does not include an explanation, the patentee should be entitled to use extrinsic evidence and prosecution history. Brief of Amicus Curiae Houston Intellectual Property Law Ass'n at 17, 21, *Festo* (No. 00-1543), 2001 WL 1025169.
Intellectual Property Creators & the Society of Amateur Scientists	*Festo* encourages the misuse of another's discovery, yet disables the original discoverer's incentive to create an invention. Human minds need purpose, context, and function to work; therefore, there can be a correlation between legal certainty and technical precision. Brief of Amicus Curiae Intellectual Property Creators & the Society of Amateur Scientists at 3-4, *Festo* (No. 00-1543), 2001 WL 1025252.

Litton Systems, Inc.	*Festo* reduces the scope of settled patent rights, resulting in a taking without just compensation in violation of the Fifth Amendment. This ruling defies years of precedent; however, if affirmed, it should not retroactively divest many current patent holders of already negotiated rights. Brief of Amicus Curiae Litton Systems, Inc. at 8-9, Festo Corp. v. Shoketsu Kinsoku Kogyo Kabushiki Co., 234 F.3d 558 (No. 00-1543), 2001 WL 1002689.
Minnesota Mining & Manufacturing Co., Eli Lilly & Co., Henkel Corp., Johnson & Johnson, Pfizer, Inc., PPG Industries, Inc., Rexam Beverage Can Co., Sun Microsystems, Inc. and Verizon Communications, Inc.	Notice and certainty are not the paramount goals of patents. Deeming the flexible bar rule as unworkable is a premature conclusion based upon a few cases. Congress is the only entity that can balance public notice and patentee protection policies. Brief of Amici Curiae Minnesota Mining & Manufacturing Co. et al. at 5, *Festo* (No. 00-1543), 2001 WL 1025380.
National Bar Ass'n	*Festo* has created too many barriers between inventors and the patent system. It prevents dialogue between an applicant and an examiner and increases patent prosecution costs. To expend resources required to patent, inventors need incentives backed by robust patent laws. Brief of Amicus Curiae National Bar Ass'n at 4, *Festo* (No. 00-1543), 2001 WL 1025444.
National Intellectual Property Law Institute	Current patent holders' protection is at risk and the holders may have their rights divested in violation of the Fifth Amendment. Patentees and licensees should be able to rely on Supreme Court precedent to determine licensing and investment decisions. Brief of Amicus Curiae National Intellectual Property Law Institute at 2-3, *Festo* (No. 00-1543), 2001 WL 1025514.
Philadelphia Intellectual Property Law Ass'n	A range of equivalents should be available, regardless of prosecution history estoppel, as long as the patentee has not surrendered the accused product. Brief of Amicus Curiae Philadelphia Intellectual Property Law Ass'n at 2, *Festo* (No. 00-1543), 2001 WL 1025603.

Wisconsin Alumni Research Foundation, The Regents of the University of California, Massachusetts Institute of Technology; Washington Research Foundation, University of Pennsylvania, University of Minnesota, The Board of Trustees of the Leland Stanford Junior University, SUNY Research Foundation, Cornell Research Foundation, Inc., University of Florida, University of Utah, Oregon Health & Science University, University of Texas-Medical Branch, University of Vermont, M.D. Anderson Cancer Center-Houston, Cold Spring Harbor (Woods Hole Oceanographic Center), The American Council on Education, The Ass'n of American Universities, The National Ass'n of State Universities & Land-Grant Colleges, Council on Governmental Relations, and Research Corp. Technologies	*Festo* did not take into account that courts have historically considered the value of patents to the public in infringement actions. With today's unprecedented innovation, the Supreme Court should look to Congress to determine whether the doctrine of equivalents is the best device to serve public interest. Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. at 6-7, *Festo* (No. 00-1543), 2001 WL 1056915.
Amicus Curiae-Respondent	**Summary of Opinion**
Applera Corp. (Applied Biosystems & Celera Genomics), Applied Materials, Inc., Cisco Systems, Inc., Micron Technology, Inc., and Oracle Corp.	A balance is required between a patent system that effectively protects technology and a "patent landscape" that demonstrates a clear scope to continue innovation and decrease litigation costs. The patent process does not need additional tests and sub-tests, which makes the foreseeability exception of *Festo* superior to the flexible bar rule. Brief of Amicus Curiae Applera Corp. et al. at 2, 7, *Festo* (No. 00-1543), 2001 WL 1548692.

Consumer Project on Technology	The flexible bar approach discourages innovation and imposes increased costs. It imposes a high-price, short term solution for increased long term innovation. Competitors need to "toil in the field of disclaimed scope." Brief of Amicus Curiae Consumer Project on Technology at 3, *Festo* (No. 00-1543), 2001 WL 1397746.
Genentech, Inc.	*Festo* corrects a previous imbalance between patentees' and the public's rights and responsibilities. Patent attorneys can easily adapt to these new rules in the patent application and prosecution process. *Festo* helps the biotechnology industry because of the increased predictability for business decisions that stimulate investment and innovation. Brief of Amicus Curiae Genentech, Inc. at 2-3, *Festo* (No. 00-1543), 2001 WL 1480572.
Intel Corp., Cypress Semiconductor Corp., and United Technologies Corp.	Patents are required to protect investments in computer technology. However, it is more critical to have clear predicitability of claims that ensures new research does not infringe other patents. Brief of Amici Curiae Intel Corp. et al. at 1-2, *Festo* (No. 00-1543), 2001 WL 1576083.
International Business Machines Corp., Eastman Kodak Co., Ford Motor Co., E.I. DuPont De Nemours & Co., Agere Systems, Inc., and the Financial Services Roundtable	Product launches were difficult to plan and commercialize with the flexible bar approach. The complete bar approach should improve the PTO process because there will be better applications with more predictable scope. Brief of Amici Curiae Int'l Business Machines Corp. et al. at 5-6, *Festo* (No. 00-1543), 2001 WL 1397747.
MedImmune, Inc.	*Festo* provides increased certainty for the doctrine of equivalents and does not allow patentees to rewrite their prosecution history. This certainty in scope prevents wasteful litigation. Brief of Amicus Curiae MedImmune, Inc. at 3-4, Festo Corp. v. Shoketsu Kinsoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed Cir. 2000) (No. 00-1543), 2001 WL 1548693.
Amicus Curiae-Neutral	**Summary of Opinion**
Institute of Electrical & Electronics Engineers—United States of America (IEEE-USA)	The IEEE-USA proposes a foreseeable bar rule, which would apply regardless of any narrowing amendment. The proposed rule allows use of the doctrine of equivalents unless at the time of amendment the limiting effect of the amended-claim language relating to the accused product was foreseeable. Brief of Amicus Curiae The Institute of Electrical & Electronics Engineers—United States of America at 18, *Festo* (No. 00-1543), 2001 WL 1025309.

Patent, Trademark, & Copyright Section of the Bar Ass'n of the District of Columbia	Consistent nomenclature is required for fair application of the doctrine of equivalents. There is an issue of whether the *Festo* prosecution history estoppel bar applies to entire amended claims or only amended limitations within the claims. Brief of Amicus Curiae The Patent, Trademark, & Copyright Section of the Bar Ass'n of the District of Columbia at 2-3, *Festo* (No. 00-1543), 2001 WL 1025555.
Sean Patrick Suiter	The Supreme Court should reconsider whether the complete bar rule furthers the purposes of the patent system. These purposes should be balanced to the extent they further the patent system functions. A bright line rule may not be appropriate for the consistent resolution of this issue. Brief of Amicus Curiae Sean Patrick Suiter at 3-4, 26, *Festo* (No. 00-1543), 2001 WL 995289.
United States	The United States agrees with *Festo's* definition of amendments creating prosecution history estoppel. However, the United States proposes that this estoppel should raise a rebuttable presumption that the scope of the claim is the literal words. Brief of Amicus Curiae United States at 9-10, *Festo* (No. 00-1543), 2001 WL 1025650.
Vincent P. Tassinari	Tassinari proposes that if there is no reason for an amendment, the burden to establish a reason should fall on the alleged infringer. Allowing only intrinsic evidence requires patent attorneys to clearly document their reasons for filing amendments. If the patent attorneys fail to provide explanations, they will suffer a loss of claim scope. Brief of Amicus Curiae Vincent P. Tassinari at 3-5, *Festo* (No. 00-1543), 2001 WL 995291.