

Fixing *Festo*: How the Foreseeability Test for the Doctrine of Equivalents Punishes Innovation (and What to Do about It)

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Introduction

Two generic drug companies, Company CC and Company I, are both attempting to develop a product that competes with Company P's patented slow-delivery version of the drug CuresAll, which uses a particular slow-release carrier.¹ Company CC typically takes the simplest and fastest route, following existing patents as closely as possible while still avoiding infringement. It follows Company P's patent and develops its slow-release version of the drug using a different carrier that everyone knows can be substituted for the claimed carrier, but that is not covered by the literal terms of Company P's patent claims. Company I takes a more innovative route, attempting to improve on existing patents and take them in new directions, while still avoiding infringement. It develops its own slow-release version of the drug using a new carrier it develops itself in-house, and which is also not covered by the literal terms of Company P's patent claims.

Company P sues both for patent infringement. Since both use carriers not covered by the literal terms of Company P's patent claims, both successfully defend themselves against the literal infringement portion of the suit. However, Company P also asserts the doctrine of equivalents against both, arguing that, while the new versions may be outside the literal scope of its claims, they are insubstantially different from those claims and

¹ This hypothetical is based on two companion cases heard by the Federal Circuit in 2004, *Glaxo Wellcome v. Impax Labs*, 356 F.3d 1348 (Fed. Cir. 2004) and *SmithKline Beecham Corp. v. Excel Pharms.*, 356 F.3d 1357 (Fed. Cir. 2004), involving the same patent, U.S. Patent No. 5,427,798 (filed Aug. 12, 1993) (issued June 27, 1995).

therefore should be found to be infringing. In defense, Company CC and Company I both note that Company P amended its claims during prosecution, narrowing them to cover only the particular slow-release carrier Company P was using, and therefore prosecution history estoppel limits the scope of equivalents Company P can now claim.

Given that the goal of the patent system, as set forth in the Constitution, is to foster innovation, an outside observer might predict that innovative Company I would be more likely to be successful in its defense, because it has moved the slow-release drug field forward by developing a new carrier. Company CC, meanwhile, made only an obvious modification to Company P's product, and it is really just free-riding on the patent. In fact, however, because of the analysis of prosecution history estoppel under the doctrine of equivalents, the very *opposite* result is likely to occur.

The analysis the Supreme Court and the Federal Circuit have set forth for determining whether a patentee is estopped from claiming infringement under the doctrine of equivalents is whether the patentee should have foreseen that it was giving up the asserted equivalent when it narrowed the scope of its claim during prosecution. Under this analysis, because Company CC used a carrier that everyone in the art knew was easily substituted for the claimed carrier, it made a change that was clearly foreseeable by Company P, and so Company CC cannot infringe under the doctrine of equivalents. Conversely, because Company I developed an innovative new carrier previously unknown to the art, it made a change that was *not* foreseeable, and so Company I may be found to infringe under the doctrine of equivalents²—despite being an innovator who really created a new product and advanced the state of the art. Thus, the Supreme Court's

² Whether it in fact infringes or not will depend on whether or not its new carrier is in fact “equivalent” to the claimed carrier.

foreseeability test may tend to *punish* innovation, rather than reward it, which is contrary to the purposes of the patent system.

[summarize possible solutions]

Overview

Part I of this Article provides some background on patent law, including the purpose of the patent system, the nature of the patent right, and the basic requirements for patentability. Part II then discussed the basic doctrines of patent infringement, both literal and under the doctrine of equivalents including the historical underpinnings and modern contours of the doctrine of equivalents. Part III provides a hypothetical that explores some unforeseen complications of the foreseeability test currently used in doctrine of equivalents analysis. Part IV then describes some possible solutions to address the problems created by the foreseeability analysis. Part V concludes.

I. Patent Law Background

A. Purpose of the Patent System

United States patent law is based primarily on utilitarian incentive theory. Inventions and the progress of science are good, but they are difficult and costly to develop. Once made, however, they are often easily appropriated by competitors, who can then sell them at a lower price because they did not have to pay the costs of research and development. To alleviate this difficulty and get more inventions, society therefore provides incentives for developing inventions, in the form of protection from competition.

This utilitarian basis is set forth in the Constitution itself. Article I, Section 8, clause 8, gives Congress 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.” In response, Congress very early on passed the first Patent Act, in 1790. Most of the current Patent Act was put in place in 1952, with several revisions in subsequent years.

B. The Patent Right

The right conferred by a patent is spelled out in 35 U.S.C. § 154(a)(1): “Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the *right to exclude* others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.” Thus, the patent right is a *negative* right, right to exclude others; a patent does not give its holder a right to *do* anything. For example, even if a patentee has a rock-solid patent on a pharmaceutical, it cannot sell the drug without FDA approval.

The negative patent right is also important in the context of blocking patents. If a subsequent invention infringes an existing patent but is nonetheless patentable over that patent (*i.e.*, is not anticipated or rendered obvious by that patent), then the two patents are said to “block” each other, and neither patentee can practice the new invention without the permission of the other. For example, if the first patent is to a drug, and the second patent is to an improved version of the drug that is sufficiently similar to infringe but sufficiently different to still be patentable (the original patent might cover the core active molecule, the second the same core molecule with changed side chains that reduce side effects), either patentee will need a license from the other if it wishes to produce the improved drug. If the improvement is sufficiently valuable, the blocking patents will typically lead the parties to a licensing agreement of some type.

C. Patentability Requirements

The basic requirements for patentability, as defined by the provisions of Title 35 of the United States Code, are patentable subject matter, utility, novelty, nonobviousness, and compliance with the disclosure requirements. Patentable subject matter is defined in § 101, which sets forth broad categories of subject matter eligible for protection: “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” This provision is interpreted very broadly. Utility is also set forth in § 101, which requires that the invention must be “useful.”³ Like patentable subject matter, utility is interpreted very broadly.

Novelty is also based in § 101 (the invention must be “new”), while § 102 provides the rules for determining novelty. Section 102 has two main categories of analysis, true novelty and loss of right to patent/statutory bars. Novelty refers to true newness compared to what went before—if someone else has done what the inventor did before the inventor did it, the inventor is not entitled to a patent.⁴ The statutory bars come into play when the invention has not been made previously, but a technical defect causes the loss of right to patent.⁵ Statutory bars arise when someone—including the patentee—in some way publicizes the invention more than one year before the date of the application. The related doctrine of nonobviousness is found in § 103. Even if the same exact invention has not been made before, it is not patentable if it would have been obvious to one having ordinary skill in the relevant art. That is, the invention must represent more

³ 35 U.S.C. § 101. Some decisions also place the utility requirement in § 112, which requires that the inventor describe “the manner and process of making and using” the invention. 35 U.S.C. § 112 ¶ 1. If the invention has no utility, the inventor cannot teach others how to “use” it.

⁴ See 35 U.S.C. § 102(a), (e), (g). Section 102(f), regarding derivation from another, is also often classed as a statutory bar.

⁵ See 35 U.S.C. § 102(b), (c), (d).

than a trivial advance over what was done before. Nonobvious is often considered the most important requirement—it has been called “the ultimate condition of patentability.”⁶

Finally the disclosure requirements of enablement, written description, and best mode are located in § 112. The enablement requirement obliges the inventor to describe the invention sufficiently “to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use” the invention. The written description requirement calls for the inventor to provide “a written description of the invention” that demonstrates to the world what it is that the inventor invented and that the inventor invented what is being claimed. The best mode requirement obliges the inventor to reveal to the world what the inventor, at time of filing, believed to be the best way of carrying out the invention. Section 112 also requires that the patentee include claims “particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” Section 112 further defines particular claim formats, including “means-plus-function” claims in ¶ 6:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

II. Infringement

A. Literal Infringement

As noted above, a patent confers the right to exclude others. The mechanism for enforcing these exclusion rights is set forth in § 271(a): “[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or

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imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” That is, the patentee is entitled to exclude those who infringe the patent.

The patent claims are what determine the rights under a patent. Patent claims are commonly analogized to the “metes and bounds” of a real property deed—they define exactly what property right is, and are the key to deciding the rights of the patentee (and therefore also the rights of the public). Infringement is assed in terms of the claims.

The infringement analysis has two steps. First, the claims are construed to figure out what they mean (a process generally called “claim construction” or “claim interpretation”). Second, the construed claims are applied to the accused device (or process or composition of matter, as relevant).⁷ To have a literal infringement, the accused device must have an element meeting *every* limitation of the claim, as properly construed.⁸ If even a single claim limitation is missing in the accused device, there can be no infringement. Thus, the proper construction of every claim term is extremely important.

In practice, claim construction is a difficult and confusing process, governed by many “canons of construction.” In 2005, the Federal Circuit concluded that its claim construction jurisprudence had become a confusing morass, with different panels taking

⁷ Under *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), claim construction is a matter of law, to be decided by the court, while application of the construed claim to accused device is a matter of fact, to be decided by the jury. A further consequence of the holding that claim construction is a matter of law is that the Federal Circuit reviews claim construction rulings without deference to the District Court. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998).

⁸ This article follows the preferred convention in referring to the individual parts of a claim that must be met by the accused device as limitations, while the corresponding parts of the accused device are called elements. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F. 3d 558, 563 n.1 (Fed. Cir. 2000) (*Festo VI*) (“It is preferable to use the term ‘limitation’ when referring to claim language and the term ‘element’ when referring to the accused device.”), *rev’d on other grounds*, 535 U.S. 722 (2002); *see also SmithKline Beecham Corp. v. Excel Pharms.*, 214 F. Supp. 2d 581, 588 n.13 (noting and following this preference).

different approaches to the problem. In an attempt to clarify and unify its claim construction rules, the court took the issue *en banc* in *Phillips v. AWH Corp.*⁹ In *Phillips*, the court clarified that what it was looking for during claim construction is the “ordinary and customary meaning of a claim term,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.”¹⁰ The court concluded that “[t]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.”¹¹ The court also gave the patent specification (the text of the patent document) the pre-eminent role in making this determination.¹²

The next step is to determine whether the accused device infringes the properly construed claim. For literal infringement, the accused device must have an elements corresponding to each limitation of the claim. If even a single claim limitation is missing in the accused device, there can be no infringement.

B. The Doctrine of Equivalents

If the patentee cannot show literal infringement, the doctrine of equivalents comes into play. Under the doctrine of equivalents, even if some element of the device fails to meet a claim limitation literally, the device may still infringe if it contains an element that

⁹ 415 F.3d 1303 (Fed. Cir. 2005).

¹⁰ *Id.* at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

¹¹ *Id.* at 1313.

¹² See *id.* at 1315-1317 (discussing the use of the specification in claim construction); see also *id.* at 1313 (“Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.”); *id.* at 1317 (“It is therefore entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description [in the specification] for guidance as to the meaning of the claims.”).

is deemed to be equivalent to the claim limitation. The doctrine of equivalents has a long and contentious history, and its application has often been confusing and controversial.

1. Historical Development

a. *Winans v. Denmead*

The Supreme Court typically traces the doctrine of equivalents to its decision in *Winans v. Denmead*.¹³ *Winans* was actually not a doctrine of equivalents case at all, but rather a basic literal infringement case from the period before the doctrine of equivalents was treated as a separate analysis. However, the infringement analysis used by the court does set out the basic parameters of the doctrine of equivalents analysis that is used today, and the Court still refers to *Winans* in its modern doctrine of equivalents jurisprudence.¹⁴ In *Winans*, the Court held that the scope of the patent is not absolutely limited to the words of the claims; the court is permitted to go outside them if the accused device should rightfully fall within the scope of the claim but happens not to, because of the specific wording of the claims.¹⁵ Justice Campbell, joined by three other Justices, dissented, arguing that the claims should be limited to their literal terms.¹⁶

b. *Graver Tank v. Linde Air Prods.*

The modern history of the doctrine of equivalents begins with *Graver Tank v. Linde Air Prods.*¹⁷ In *Graver Tank*, the Court described the rationale behind the doctrine of equivalents:

¹³ 56 U.S. 330 (1854). Other commentators trace the concept back further, to . See . The first use of the term “doctrine of equivalents” appears to have been in . See *id.*

¹⁴ See, e.g., [Warner-Jenkinson, *Festo*].

¹⁵ 56 U.S. at .

¹⁶ *Id.* at (Campbell, J., dissenting).

¹⁷ 339 U.S. 605 (1950).

[T]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing [and] encourage the unscrupulous copyist. The essence of the doctrine [of equivalents] is that one may not practice a fraud on the patent.¹⁸

The rationale behind the doctrine of equivalents is that often it is too easy for a competitor to make an insubstantial change in accused device that takes it out of the literal scope of the claims, but that does not really remove from the ambit of what the inventor invented. In this situation, the competitor makes no real contribution to the field, and is simply dodging the literal terms of the claim. Allowing this conduct would largely destroy the value of a patent, as competitors could too easily appropriate the idea behind the patent without being guilty of literal infringement. To address this problem, courts allow the patentee to recover under the doctrine of equivalents, to prevent the competitor from taking improper advantage of a “loophole” in the details in the claims. In effect, the doctrine of equivalents allows expansion of claims beyond literal interpretation creating a sort of “halo” around the claims. Under *Graver Tank*, if those of skill in the art knew that the asserted equivalent element could easily be substituted for the claimed structural limitation, then the accused device should be deemed infringing. To assess infringement under the doctrine of equivalents, *Graver Tank* formalized the “function/way/result” test: To infringe, the accused equivalent must perform substantially the same function, in substantially the same way, to achieve substantially the same result, as the claim limitation.¹⁹

Graver Tank also had a dissent by Justice Black, joined by Justice Douglas. According to Justice Black, the statute provided a Congressional mandate that the

¹⁸ *Id.* at .

¹⁹ *Id.* at .

applicant must specifically claim the subject matter of the patent. Claims are therefore the key to the rights of the patentee, and what is not claimed is dedicated to the public. According to Justice Black, the majority's invocation of the doctrine of equivalents undercuts this rationale by allowing coverage of embodiments that were not specifically part of the claim. Such an expansion of coverage is "unjust to the public," impinging on its rights. Furthermore, it harmed competition, as competitors could no longer rely on claims to assess if they infringe, but instead were forced to rely on predictions of how a court might later expand the claims under the doctrine of equivalents.

This dispute between the majority and dissent echoes that seen in *Winans*, and it demonstrates the persistent and ongoing tension the doctrine of equivalents creates between fairness to the patentee (strict literalism makes it difficult to enforce patents and reduces their value) and notice to competitors (once the claim scope goes beyond its literal wording, it becomes difficult for competitors to know what does and does not infringe). This tension is the root of the difficulties in generating a precise formulation for the doctrine of equivalents, and it continues to confound modern doctrine of equivalents jurisprudence.²⁰

In *Graver Tank*, S. Ct. explicitly established the doctrine of equivalents as an equitable doctrine. [flesh out—relevant to later arguments]

Prior to *Graver Tank*, the doctrine of equivalents was a well accepted but very narrow doctrine. After *Graver Tank*, the doctrine was subject to significant expansion (with occasional narrowing counter-thrusts). As a consequence of this expansion, attorneys began having difficulty predicting infringement. Literal infringement was (relatively)

²⁰ See also 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 (1998).

straightforward, but the doctrine of equivalents was a wild-card—the attorneys could not reliably predict when a court might apply it, as function, way, and result were all somewhat fuzzy. In addition, the function/way/result analysis worked pretty well for simple mechanical devices, but it became tricky when applied to chemical, computer, and especially biotechnology inventions. Indeed, the analysis often simply did not make sense, but courts tried to make it fit, because the Supreme Court had established it as the test to use. These problems led the Supreme Court to revisit the issue in 1997.

c. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*

The Federal Circuit had also perceived problems with the doctrine of equivalents, and it therefore considered the issue *en banc* in *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*²¹ The issue was very contentious in the Federal Circuit, generating five separate opinions (a majority opinion issued *per curiam*, a concurrence, and three dissents; five of the twelve judges on the court joined one or more of the dissents). The Supreme Court granted certiorari, noting that “[t]he significant disagreement within the Court of Appeals for the Federal Circuit concerning the application of *Graver Tank* suggests, however, that the doctrine [of equivalents] is not free from confusion. We therefore will endeavor to clarify the proper scope of the doctrine.”²²

The Court first affirmed the basic vitality of the doctrine of equivalents, and that it survived the enactment of the 1952 Patent Act.²³ However, the Court noted that it

share[d] the concern of the dissenters below that the doctrine of equivalents, as it has come to be applied since *Graver Tank*, has taken on a life of its own, unbounded by the patent claims. There can be no denying that the doctrine of

²¹ 62 F.3d 1512 (Fed. Cir. 1995) *rev'd*, 520 U.S. 17 (1997).

²² *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997).

²³ *See id.* at 25-28.

equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement.²⁴

The Court then identified two important limitations on the doctrine of equivalents that help restrain its application. First, the Court endorsed the all-elements rule, as espoused by Judge Nies in her dissent from the Federal Circuit's ruling.²⁵ Under this rule, the doctrine of equivalents is to be analyzed on an element-by-element basis, rather than by considering the claim as a whole—that is, the accused device must have an element corresponding to each claim limitation, either literally or by equivalence.²⁶

Second, the Court discussed the limiting role of prosecution history estoppel.²⁷ Under this rule, matter surrendered during prosecution cannot be recovered later, even if it is technically equivalent; the patentee is estopped by what he or she did during prosecution, and cannot assert as an equivalent something that was specifically surrendered during prosecution.²⁸ However, the Court declined to make such surrender absolute, holding that courts need to look into the reason for the amendment, to see if it was made for a reason related to patentability, before finding an estoppel.²⁹

The Court then addressed the application of prosecution history estoppel to the case before it. It noted that the record provided no explanation for the claim limitation at issue, and then introduced what has become known as the “*Warner-Jenkinson* presumption”:

²⁴ *Id.* at 28-29.

²⁵ *See id.* at 29-30.

²⁶ *See id.*

²⁷ *See id.* at 30-33.

²⁸ *See id.* at 30-31.

²⁹ *See id.* at 30-33. Prosecution history estoppel is discussed in more detail in Part II.B.2, *infra*.

Where no explanation [for an amendment] is established, . . . the court should presume that the PTO had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents as to that element.³⁰

The Court rejected the use of equitable factors, such as the subjective intent of the infringer and copying by the infringer, in the doctrine of equivalents inquiry, in keeping with the generally “objective approach to infringement.”³¹ The Court conceded that *Graver Tank* had suggested that such factors might be used, but concluded that the better approach was to move away from the equity roots espoused in that opinion, in favor of the more objective approach. The Court similarly rejected the proposition that equivalents should be limited to those described in the patent specification, or at least to those “known” at the time the patent issued.³² The Court declined, however, to address the issue of who should decide doctrine of equivalents issues, accepting for the time being the Federal Circuit’s determination that the doctrine of equivalents, as an infringement issue, was a matter of fact to be decided by the jury.³³

Finally, the Court addressed alternative formulations for determining equivalence.³⁴ The Federal Circuit’s decision had adopted the “insubstantial differences” test, which required looking at whether the accused infringing device was insubstantially different from the claimed device, rather than adhering closely to *Graver Tank*’s “function/way/result” test.³⁵ The Court concluded that the actual words of the test were

³⁰ 520 U.S. at 33.

³¹ *Id.* at 34-36.

³² *See id.* at 37.

³³ *See id.* at 37-39.

³⁴ *See id.* at 39-40.

³⁵ *See id.*; *see also Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, (Fed. Cir. 1995) (discussing the insubstantial differences test), *rev’d*, 520 U.S. 17 (1997).

irrelevant, and that key was for a court to keep in mind the all-elements rule, focusing on whether the accused device contained an element identical or equivalent to each limitation of the patent claim.³⁶ The Court noted that the different formulations might be better suited to different situations, and a court should be free to apply what best fits.³⁷

2. Prosecution History Estoppel and Foreseeability: *Festo*, *Johnston*, and Beyond

After *Warner-Jenkinson*, the lower courts (particularly the Federal Circuit) struggled with how to apply prosecution history generally, and the *Warner-Jenkinson* presumption specifically. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,³⁸ the *en banc* Federal Circuit considered many of these issues. The Supreme Court again granted certiorari, and its opinion wrought a major change in the doctrine of equivalents, particularly the application of prosecution history estoppel.

a. Prosecution History Estoppel

During patent prosecution, the patent examiner will frequently reject a claim, because the invention is found in the prior art or is obvious from that art, or because the applicant failed to comply with the statutory disclosure provisions. The applicant is then typically forced to amend the claim to avoid that prior art or comply with the disclosure provisions (and/or argue why the rejections are improper). These amendments and arguments create prosecution history estoppel—the patentee is estopped by what he or she did during prosecution, and cannot later assert as an equivalent something that he or she specifically surrendered during prosecution to get the patent allowed. As noted in *Warner-Jenkinson*,

³⁶ See 520 U.S. at 40.

³⁷ See *id.* Under current practice, the issue is insubstantial differences, with function/way/result as one way of assessing whether the differences are insubstantial, in the appropriate factual circumstances. See, e.g., .

³⁸ 234 F. 3d 558 (Fed. Cir. 2000) (*Festo VI*), *rev'd*, 535 U.S. 722 (2002) (*Festo VIII*).

prosecution history estoppel serves as an important limit on the doctrine of equivalents. However, prosecution history estoppel is subject to some limitations of its own.

b. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*

The Supreme Court's most recent pronouncement came in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*³⁹ This case, originally filed in 1988, has generated a series of ground-breaking decisions that have dramatically reshaped the doctrine of equivalents. On July 5, 2007, the Federal Circuit released its latest (and probably final, unless the Supreme Court steps in for the third time) opinion, designated *Festo XIII*

Festo sued Shoketsu Kinzoku Kogyo Kabushiki Co. (SMC) for infringement of U. S. Patent Nos. 4,354,125 and B1 3,779,401, entitled “Magnetically Coupled Arrangement for a Driving and a Driven Member” and “Pneumatic Device for Moving Articles,” respectively. The patents claim variations on a “small gap” magnetically coupled rodless cylinder. Unable to show literal infringement, Festo asserted infringement under the doctrine of equivalents. SMC defended on the grounds that the prosecution history estopped Festo from asserting the doctrine of equivalents, because the limitations at issue—to “a pair of resilient sealing rings”⁴⁰ and “a cylindrical sleeve made of a magnetizable material”⁴¹—had been added during prosecution. Festo asserted that (1) SMC’s single two-sided sealing ring was equivalent to the claimed two single-sided sealing rings; and (2) SMC’s sleeve made of aluminum, a non-magnetizable material, was equivalent to the claimed sleeve made of a magnetizable material.⁴²

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⁴⁰ '401 Patent Claim 9; the '125 Patent contains a similar limitation. *See Festo VI* at 582-84.

⁴¹ '125 Patent Claim 1; the '401 Patent contains a similar limitation. *See Festo VI* at 582-84.

⁴² Festo asserted that even though aluminum was a non-magnetizable material, it had similar magnetic shielding properties to a magnetizable material.

The district court initially ruled in favor of SMC. On appeal, a Federal Circuit panel affirmed. The case then came back to the Federal Circuit on a GVR from the Supreme Court—the Court granted certiorari, vacated the panel’s original decision, and remanded for reconsideration in light of *Warner-Jenkinson*, which had been decided in the interim. On remand, the Federal Circuit decided to take the case *en banc* to resolve serious questions over the application of the doctrine of equivalents.

Two key Federal Circuit holdings are particularly relevant here. First, for purposes of applying prosecution history estoppel under *Warner-Jenkinson*, a “reason related to patentability” was not limited to prior art (§§ 102/103) rejections and amendments, but also include § 112 issues. Second, if a claim amendment created prosecution history estoppel, then *no* range of equivalents remained—*any* narrowing amendment to a claim limitation for a reason related to patentability surrendered *all* equivalents for that limitation. The Federal Circuit concluded that the flexible bar the court had been using had proved “unworkable” and that it should be replaced with a strict bar. This strict bar was much more predictable, gave potential competitors certainty in what they can and cannot do, and enforced the disclaimer effect of amendments.

The decision generated seven opinions, including four dissents. These dissents argued that the decision was not consistent with Supreme Court precedent, it effectively destroyed the doctrine of equivalents (a step that *Warner-Jenkinson* specifically declined to take), it upset the expectations of those who had prosecuted patents under the old flexible bar, and it employed reasoning for a favoring strict bar over a flexible bar that applied equally to the doctrine of equivalents as a whole. The Supreme Court then granted certiorari to reconsider the doctrine of equivalents.

The Supreme Court reversed the Federal Circuit. The court first noted that it was true that the limits of a claim should be clear, but the nature of language makes this difficult. Inherent linguistic uncertainties make it difficult to capture the nuances of an invention or to describe its full range precisely using only words. The doctrine of equivalents is therefore necessary to protect patentees, even if the doctrine does lead to some uncertainty.

The Court then considered the role of prosecution history estoppel. The court observed that prosecution history estoppel was an important limitation on the doctrine of equivalents, preventing the patentee from recapturing in litigation what it gave up in prosecution. Furthermore, if the patentee was able to describe something in the specification but then gave up in amending the claims, it cannot later assert that linguistic difficulty prevented it from claiming the full scope.

The Court agreed with the Federal Circuit's holding that amending a claim to comply with § 112 is a "reason relating to patentability" that may create an estoppel, because making an amendment is a concession that the invention was not patentable without the amendment. The Court then turned its attention to the strict bar. The Court noted that the Federal Circuit had avoided uncertainty by creating this strict bar, but such a bar is inconsistent for the reason for the doctrine of equivalents in the first place. Amending a claim is a concession that patent does not go as far as the original claim, but, as the Court pointed out, that is not the same as saying that the patentee gave up everything in between—linguistic imperfection may still get in the way of claiming the full scope to which the patentee is entitled.

The Court then held that the key to the issue is *foreseeability*. Courts cannot say that a patentee relinquished equivalents that it could not possibly have foreseen, particularly those equivalents that were peripheral to the reason for making the change in the first place. The court then went on to define three situations in which the patentee might not foresee that the amendment relinquished certain equivalents. First, later-developed equivalents would likely not be foreseeable, as it was unreasonable to expect a patentee to foresee something that did not exist at the time the patent was being prosecuted. Second, if the claim amendment was directed to a different aspect of the limitation than the one that the accused device does not meet literally (that is, the reason for making the amendment was peripheral to the equivalent), the patentee could not have foreseen that it was giving up that equivalent and is therefore not estopped from covering it under the doctrine of equivalents. Third, the Court created a “catch-all” provision, giving the patentee the opportunity to show some “other reason” (perhaps related to linguistic uncertainty) that it could not have foreseen or claimed the equivalent at issue.

The Court concluded that this flexible approach comports better with its precedents and with the real practice before the PTO. It also avoids upsetting the settled expectations of patentees who had prosecuted their patents under the old rules, and who had no hint of the dire consequences of making amendments; indeed, if patentees had known that a strict bar was going to apply, they might have appealed the rejections rather than amend the claims.

The Court then set forth the procedure for analyzing foreseeability. The Court placed the burden on the patentee to prove that the amendment did not surrender the particular equivalent at issue. Courts are to presume that the patentee abandoned everything

between the scope of the original claim and the scope of the amended claim, but the patentee is then allowed to rebut that presumption. Again, the Court held, the key to this rebuttal is foreseeability: Could the patentee have foreseen what it was giving up by making the amendment?

On remand,⁴³ the Federal Circuit again took up the case *en banc*. The court decided that *Festo* could not rebut the presumption of surrender based on the amendment being either tangential or for “some other reason” unforeseeable. However, it remanded the case to the district court to determine whether *Festo* should have foreseen that it was giving up the asserted equivalents to both limitations. On the issue of foreseeability, court said:

This criterion presents an objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment. Usually, if the alleged equivalent represents later-developed technology (e.g., transistors in relation to vacuum tubes, or Velcro® in relation to fasteners) or technology that was not known in the relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, would more likely have been foreseeable. Indeed, if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment.⁴⁴

The district court subsequently held that *Festo* should have foreseen that the amendments at issue gave up the asserted equivalents, and therefore *Festo* was estopped from asserting infringement under the doctrine of equivalents. The Federal Circuit affirmed that ruling. [Does this latest decision need more explanation here?]

⁴³ 344 F.3d 1359

⁴⁴ *Id.* at .

c. *Johnson & Johnston Assocs. v. R.E. Service Co.*

One other case on the foreseeability issue bears mentioning. In *Johnson & Johnston Assocs. v. R.E. Service Co.*,⁴⁵ the Federal Circuit *en banc* held that the failure to claim subject matter disclosed in the specification results in surrender of that subject matter to the public, and the patentee therefore cannot recapture that subject matter under the doctrine of equivalents. The court concluded that it would be improper to allow patentees to disclose broadly but claim narrowly, as this procedure would permit patentee to escape examination of broad claims, and then improperly expand those narrow claims based on the broad disclosure.⁴⁶

Judge Rader, joined by Judge Mayer, concurred. He endorsed the majority's results and reasoning, but he then proposed alternative reasoning. He observed that assessing equivalents infringement was difficult, and pointed to the tension between balancing the need for protecting inventions with the notice function of claims. He concluded that a good way to approach this problem would be to use a "foreseeability bar": If one of skill in the art would foresee that the patent should cover a particular variation on the invention, then the patentee is obligated to draft claims that would cover that variation. Such a foreseeability bar would provide an objective standard based on the claims and the prior art. It would place a premium on claim drafting, with the burden on the applicant. Here, since the patentee clearly foresaw the equivalent variant of its invention when it disclosed it in the specification, it was obligated to claim it—and since it failed to do so, it cannot recapture the variant under doctrine of equivalents. Judge Rader thus largely

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⁴⁶ Judge Newman dissented, arguing that the key purpose of patents is to obtain disclosure of useful information, and that it was therefore foolish and conflicted with this basic function to punish patentees who give extra information. *See id.* at (Newman, J., dissenting).

captured the Supreme Court's reasoning in *Festo*, even though *Johnston* issued shortly before *Festo* did.

d. Later Cases

Brief discussion of some or all of: *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1313 (Fed. Cir. 2006); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335 (Fed. Cir. 2007); *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290 (Fed. Cir. 2005); *Ranbaxy Pharms. Inc. v. Apotex, Inc.*, 350 F.3d 1235 (Fed. Cir. 2003); *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355 (Fed. Cir. 2003); *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352 (Fed. Cir. 2003)

e. Foreseeability in Context

The foreseeability test adopted in *Festo* completes an interesting evolution of the law governing the doctrine of equivalents. Under *Graver Tank*, the fact that one of skill in the relevant art would know of the equivalence worked in favor of finding infringement under the doctrine of equivalents. In *Warner-Jenkinson*, the accused infringer had argued that equivalents should be limited to those disclosed in the specification, or at least (as the dissenters in the Federal Circuit opinion had suggested) to those known in the art at the time of the invention; the Supreme Court rejected this position but not outright, indicating that the knowledge of skilled practitioners could be relevant in determining what is an equivalent. Then came *Festo* and *Johnston*, which held that foreseeability and linguistic difficulty are the keys to applying the doctrine of equivalents. Under this formulation, if the patentee could foresee equivalents and/or describe them in the specification, then applying the doctrine of equivalents was inappropriate. Thus, if one of skill in the art knew of the equivalence, or it was disclosed in the specification, it was foreseeable, and

foreclosed application of the doctrine of equivalents. This holding represents a complete reversal from *Graver Tank* (and it is difficult to reconcile with what the Court said in *Warner-Jenkinson*).

Placing the role of foreseeability into context reveals the astounding complexity of the current doctrine of equivalents analysis. Literal infringement represents the standard rule of infringement, requiring that the accused device have an element literally meeting each and every claim limitation. The doctrine of equivalents serves an exception to that rule, allowing coverage beyond the literal terms of the claims if the device has an element that is merely “equivalent” to each claim limitation. Prosecution history estoppel serves as an exception to the doctrine of equivalents, excluding certain limitations from this expansion of coverage based on the patentees conduct during prosecution. Finally, lack of foreseeability serves as an exception to prosecution history estoppel, allowing the coverage despite the conduct if the otherwise excluded embodiment was unforeseeable. Thus, Judge Rader, in his concurrence in *Festo IX*, has accurately characterized foreseeability as an “exception[] to an exception to an exception to the standard rule of infringement.”⁴⁷

3. After-arising Equivalents

According to many observers, including Judge Rader, one of the primary functions of the doctrine of equivalents is to accommodate patents to after-arising technology.⁴⁸ In many cases, a patent may use terminology that is tightly linked to the technology in use at

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⁴⁸ See *Festo VI*, F.3d. at (Rader, J., concurring); Christopher A. Cotropia, “After-Arising” Technologies and Tailoring Patent Scope, 61 N.Y.U. ANN. SURV. AM. L. 151 (2005); Robert Unikel & Douglas Eveleigh, Protecting Inventors, not Fortune Tellers: The Available Patent Protection for After-Developed Technologies, 34 AIPLA Q.J. 81 (2006).

the time, and this terminology may not fit later developments. In his dissent in *Festo VI*, Judge Rader illustrated this point with vacuum tubes and transistors—patent claims that referred to the “anode” and “cathode” of vacuum tube technology would not literally apply to the “collectors” and “emitters” of transistor technology, and thus a device that substituted a transistor for a vacuum tube would not literally infringe, even though the resulting device would be only minimally changed from the original. Furthermore, if the patent had been drafted before the invention of the transistor, the patentee could not possibly have drafted a claim that would cover the transistor. In this situation, the doctrine of equivalents steps in and the changed device is found infringing, in the interest of preventing after-arising equivalent from rendering a swath of patents worthless.

This role is also important with claim limitations expressed in means-plus-function format, pursuant to § 112 ¶ 6. Under the statute, such limitations are to be interpreted as covering “the corresponding structure, material, or acts described in the specification and equivalents thereof.”⁴⁹ The Federal Circuit has held that such equivalents are to be assessed as of the filing date of the patent. Thus, after-arising equivalents cannot literally infringe a means-plus-function limitation. Again, in order to preserve the value of patents in the face of changing technology, such after-arising equivalents may be found to infringe under the doctrine of equivalents.

[Need to flesh this out more, bring in scholarship]

C. The Reverse Doctrine of Equivalents

The reverse doctrine of equivalents is an equitable counterpart to the doctrine of equivalents. It traces its roots to the Supreme Court’s decision in *Boyd Power-Brake*

⁴⁹ 35 U.S.C. § 112 ¶ 6.

Co. v. Westinghouse. The accused infringer had made a dramatic improvement in the claimed triple-valve train brake. The Court found that the improved brake was so different from and so much better than the claimed brake that even though it fit within the literal scope of the claims, the improved brake did not infringe:

The patentee may bring the defendant within the letter of his claims, but if the latter has so far changed the principle of the device that the claims of the patent, literally construed, have ceased to represent his actual invention, he is as little subject to be adjudged an infringer as one who has violated the letter of a statute has to be convicted, when he has done nothing in conflict with its spirit and intent.

The reverse doctrine of equivalents is potentially a very powerful doctrine, and is thus a great favorite with commentators who see it as a cure for various ills of the patent system.⁵⁰ However, in practice, it has very rarely been applied since *Boyden Power-Brake*, and never by the Federal Circuit.

III. Unforeseen Complications of Foreseeability

The *Festo/Johnston* foreseeability test for the doctrine of equivalents may in some instances have the undesired side effect of punishing innovation. This section explores that unexpected side effect in terms of a hypothetical, analyzed first under traditional doctrine of equivalents jurisprudence (as exemplified by *Graver Tank*) and then under the foreseeability test set forth in *Festo*. This hypothetical is based on the facts and outcome of two companion cases involving the same patent: *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*⁵¹ and *SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*⁵² (because Glaxo and SmithKline have merged, the plaintiff in both cases is really

⁵⁰ See, e.g., [Merges & Nelson, others]

⁵¹ 356 F.3d 1348 (Fed. Cir. 2004).

⁵² 356 F.3d 1357 (Fed. Cir. 2004).

GlaxoSmithKline). The same Federal Circuit panel (Judges Rader, Plager, and Gajarsa) heard both cases on the same day and subsequently issued two largely overlapping opinions.

A. The Hypothetical

Company P has a patent claiming a slow-release version of drug D, using a particular slow-release carrier X.⁵³ The claims as filed were not limited to any particular slow-release carrier, but during prosecution the Examiner required Company P to add the limitation to carrier X, the only slow-release carrier disclosed in the patent specification.⁵⁴ Company CC now sells a slow-release version of drug D using a different carrier X' that is molecularly very similar to the claimed carrier X and that everyone knows can be substituted for X.⁵⁵ Company I sells a different version using a new carrier Y it developed itself. Carrier Y is molecularly different from X and was not previously known as a slow-release carrier.⁵⁶ Company P then sues both for patent infringement. Because neither uses Carrier X, as required by the claims, neither infringes literally.⁵⁷ Company P therefore asserts infringement under the doctrine of equivalents.

B. Analysis under Prior Law

1. Liability of Company CC

Under the traditional doctrine of equivalents analysis, as set forth in *Graver Tank* and its progeny, CC would almost certainly be found to infringe. One of the key factors in

⁵³ The drug in the actual cases was the anti-depressant bupropion hydrochloride; the carrier was hydroxypropyl methylcellulose (HPMC). *See Glaxo*, 356 F.3d at ; *SmithKline*, 356 F.3d at .

⁵⁴ The examiner had rejected the claims that did not recite HPMC for lack of enablement under § 112. *See Glaxo*, 356 F.3d at ; *SmithKline*, 356 F.3d at .

⁵⁵ The defendant's carrier in *Glaxo* was hydroxypropyl cellulose (HPC). *See Glaxo*, 356 F.3d at .

⁵⁶ The defendant's carrier in *SmithKline* was polyvinyl alcohol (PVA). *See SmithKline*, 356 F.3d at .

⁵⁷ *See Glaxo*, 356 F.3d at ; *SmithKline*, 356 F.3d at .

this analysis was whether one of skill in the art knew that the asserted equivalent could be substituted for the claimed structure, and that was certainly the case here. X and X' are very similar molecules that can easily be interchanged, and everyone of skill in the relevant art knew that either could be substituted for the other. Because of these known similarities, X' is insubstantially different from X. In addition, because it is molecularly so similar, carrier X' performs substantially the same function, in substantially the same way, to achieve substantially the same result as carrier X. Company CC made a simple change and would almost certainly have been found to be infringing under the traditional doctrine of equivalents analysis.

2. Liability of Company I

The fate of Company I under the traditional doctrine of equivalents analysis is less clear. Carrier Y is a new molecule, not previously known in the art, and not as closely related to carrier X as carrier X'. However, as long as new carrier Y is truly equivalent to the old carrier X, as measured by the insubstantial differences and function/way/result tests, and one of skill of art would recognize it as such, Company I would probably have been found infringing.

However, under some older Federal Circuit precedent, Company I might have been found not to infringe. The Federal Circuit issued a short series of decisions in the mid-1990s holding that the patentability of the alleged equivalent was a factor to be considered *against* equivalence.⁵⁸ The rationale behind these cases was that if an alleged

⁵⁸ See Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1128 (Fed. Cir. 1996) (Nies, J., additional views) (“A substitution in a patented invention cannot be both nonobvious and insubstantial.”); *see also* Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575 (Fed. Cir. 1996); Nat’l Presto Indus., Inc. v. West Bend Co., 76 F.3d 1185 (Fed. Cir. 1996); Hoganas AB v. Dresser Industries, Inc., 9 F.3d 948 (Fed. Cir. 1993); Zygo Corp. v. Wyko Corp., 79 F.3d 1563 (Fed. Cir. 1996). The court also referenced this concept in another case involving the ’798 patent. *See* Glaxo Wellcome, Inc. v. Andrx Pharm., Inc., 344 F.3d 1226, 1233 (Fed. Cir. 2003) (“Although this fact may be weighed by the district court, particularly if there is an

equivalent was so different from the prior art (including the asserted patent) as to be nonobvious and thus justify its own patent, it could not be “insubstantially different” from that patent.⁵⁹ Thus, if carrier Y is truly novel and patentable, then Company I might not have been found to infringe under the doctrine of equivalents.

C. Analysis under Current Law

1. Liability of Company CC

Under the current “foreseeability” analysis as set forth in the *Festo* decision, Company CC would almost certainly be found *not* to infringe. One of the key factors in this analysis is again whether one of skill in the art knew that the asserted equivalent could be substituted for the claimed structure, as was certainly the case here. Now, however, this easy interchangeability weighs heavily *against* equivalents infringement. In the foreseeability analysis, if the substitute was so well known, then it was incumbent upon the patentee to foresee the substitution and then draft the patent and its claims to cover the substitute. Since Company P failed to do so, it is now estopped from reclaiming this substitute via the doctrine of equivalents. Company CC made a foreseeable change and is therefore almost certainly not infringing under the modern doctrine of equivalents analysis.⁶⁰

issue of ‘insubstantial’ change with respect to equivalency, separate patentability does not automatically negate infringement.”)

⁵⁹ In fact, for a brief time, Judge Nies of the Federal Circuit was pushing for a test that would have used “nonobviousness as the test for the insubstantial change requirement” under the doctrine of equivalents. *See Roton Barrier*, 79 F.3d at (Nies, J., additional views). This push appears to have faded out after Judge Nies’s death in 1996. *But see infra* notes and accompanying text (discussing the Federal Circuit’s decision in *Festo XIII*).

⁶⁰ This was the holding of the *Glaxo* case—since HPC was a well-known substitute for the claimed HPMC, it was foreseeable and therefore could not be recaptured under the doctrine of equivalents. *See Glaxo*, 356 F.3d at .

2. Liability of Company I

Again, the fate of Company I under the modern doctrine of equivalents analysis is less clear. Company I created a new carrier, carrier Y, that was not known in the prior art. Because it did something new, one of skill in the art could not possibly have known about carrier Y as a substitute for carrier X, and therefore Company P could not have foreseen this change by the infringer. As a consequence, as long as the new carrier Y is truly equivalent to the old carrier X (as measured by the insubstantial differences and function/way/result tests), and one of skill of art would now recognize it as such, Company I would likely be found infringing.⁶¹

However, as was the case under the traditional doctrine of equivalents analysis, Company I might have been found not to infringe. The Federal Circuit line of decisions holding that the patentability of the alleged equivalent was a factor to be considered *against* equivalence—because if an alleged equivalent was so different from the prior art as to be nonobvious and thus justify its own patent, it could not be “insubstantially different” from that patent⁶²—was potentially revived recently. In its most recent decision in the *Festo* line, the Federal Circuit went back to these cases from the mid-1990s and cited them approvingly.

We have not directly decided whether a device—novel and separately patentable because of the incorporation of an equivalent feature—may be captured by the doctrine of equivalents, although we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least

⁶¹ This was in effect the holding in the *SmithKline* case—if PVA was in fact not formerly known as a sustained-release carrier, its use was unforeseeable, and so it might be recaptured under the doctrine of equivalents. *See SmithKline*, 356 F.3d at . The court actually concluded that the record was not entirely clear on whether one of skill in the art would have known about the substitution of PVA for HPMC, and so it remanded for determination of factual issues; however, the legal conclusions was clear. *See id.* at .

⁶² *See infra* notes and accompanying text.

considerably more difficult to make out. But there is a strong argument that an equivalent cannot be both non-obvious and insubstantial.⁶³

If the Federal Circuit is really serious about reviving this rule, then it might render Company I non-infringing, if carrier Y is truly novel and patentable.

D. The Problem

Setting aside the specifics of the foreseeability analysis and looking at the big picture reveals a problem with this outcome. Given that the goal of the patent system, as set forth in the Constitution, is to foster innovation, an outside observer might predict that Company I would be more likely to be successful in its infringement defense, because it is an innovator that really created a new product and advanced the state of the slow-release drug art by developing a new slow release carrier. Company CC, meanwhile, made only an obvious modification to Company P's product, a modification that everyone in the field already knew about, and it is therefore really just free-riding on the patent—exactly the sort of thing the doctrine of equivalents was created to address in the first place. Thus, the foreseeability test, as currently applied, may tend to *punish* innovation and reward patent dodging.

Seen in this light, the outcome in the SmithKlineGlaxo cases might actually be the *worst* possible outcome, from the perspective of fostering innovation—the copycat gets off scot-free, while the innovator gets hit with infringement liability. The problem would seem to lie not with the treatment of Company CC—the logic behind the foreseeability analysis seems to fit Company CC, in that Company P wrote its specification and drafted its claims the way it did with full knowledge of alternatives, and so it does not seem

⁶³ *Festo XIII*, (footnotes omitted) (citing).

unfair to deny Company P coverage of those foreseeable alternatives.⁶⁴ However, that logic should apply even more strongly to someone who is truly an innovator—so why is only Company I, the innovator, being punished?

IV. Some Possible Solutions

A partial salve may come from the fact that the innovator can probably get its own patent (after all, if the alternative was not foreseeable, it seems hard to argue that it was obvious—those two doctrines should be largely symmetric, as noted by at least one commentator), setting up a pair of blocking patents. Company I's patent would then block P (or anyone else) from using carrier Y with D. Company I and Company P could then work out a licensing agreement.

For the actual SmithKlineGlaxo cases, *Festo* XIII provides another partial solution. The court held that

An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown.⁶⁵

This holding would actually settle the *SmithKline* case, as the assertedly “new” carrier, PVA, was a molecule well known in the art; it was just (arguably) not known to be a slow-release carrier. However, the issue remains for a Company I that develops an entirely new molecule for use as a carrier, or for any other asserted equivalent that truly did not exist at the time of the patent.

⁶⁴ But see *Graver Tank* ([rationale behind DOE, reasoning for liability]).

⁶⁵

However, those solutions do not fully address the problem, and I would like to come up with a better solution. My first instinct was that Company CC and Company I should be treated the same way—if copycat Company CC does not infringe, it makes no sense to say that innovator Company I does—so I started looking for ways to reach this result.

One possibility might be to reformulate the foreseeability analysis, shifting the focus from whether the patentee should have foreseen that it was giving up a *particular* accused embodiment, to whether the accused embodiment is a member of a *class* that the patentee should have foreseen it was giving up. Under that analysis, Company P should have known that by limiting the claims to its particular carrier X, it was giving up the class of other sustained-release carriers; it should not matter whether a particular accused member of that class was known at the time or not. This analysis was essentially that used by the district court in *SmithKline*:

The fact that the patentee included HPMC into the patent claims confirms that scientific knowledge of this category of polymers existed at the time of the claim amendments. Thus, when redrafting claims 14-15 and 18-19, the patentee could have attempted to claim all hydrogel-forming polymers as the mechanism to control the release rate of bupropion hydrochloride, rather than claim only HPMC.

This more broadly drafted limitation would also have encompassed yet-to-be discovered hydrogel-forming polymers. Because PVA, like HPMC, is a hydrogel-forming polymer, the redrafted claims would have literally encompassed PVA. For this reason, the court concludes that at the time of the claim amendments, one skilled in the art could have reasonably drafted the claims to encompass PVA; therefore, Glaxo is unable to meet its burden under *Festo*.⁶⁶

This approach, however, might create some possible problems. Suppose, for example, that Company P had in fact tried all the existing carriers, and only carrier X worked. In this situation, it would make sense for Company P to narrow its claims to that embodiment. If carrier Y then comes along and also works, then the after-arising

⁶⁶ *SmithKline Beecham Corp. v. Excel Pharmas.*, 214 F. Supp. 2d 581, 592 (E.D. Va. 2002).

technology issues are implicated, and perhaps Company P should be allowed to assert the doctrine of equivalents. On the other hand, if that were true, then Company P could have avoided raising the foreseeability issue in the first place by limiting its claims to carrier X from the beginning, so that it would not have to amend them later, thus avoiding prosecution history estoppel.⁶⁷

In some cases, defining the “class” with sufficient precision for the test to work might also be difficult. The ideal case in which to apply this analysis is one like the SmithKlineGlaxo cases, with clear evidence of a class of well known substitutes like X’. However, the existence of such a class will not always be so clear. This ambiguity would invite potential or accused infringers to spend time and money searching for references they can use to define “classes” of similar substitutes, with the patentee then arguing that these are not really equivalents to the relevant limitation. The new analysis might thus open up a whole new front in the litigation battle, making an already complex and protracted process even more so

The test might also need some kind of limiting factor, so that it only applies in certain particular circumstances—perhaps only certain types of cases are suitable for this analysis, and those types would need to be identified. [Need to develop this]

Another way to reach this outcome is via the reasoning revived in *Festo XIII*, under which Company I did not infringe because it did something nonobvious, and something that is so different as to be nonobvious is highly unlikely to be insubstantially different. However, note the implications of this combination of rules: If the substitution is obvious, then the patentee should have foreseen it and claimed it, and is therefore entitled

⁶⁷ Unless the foreseeability analysis always applies, even in the absence of a claim amendment. Cf. *Johnston* (Rader, J., concurring).

to no equivalence. If, on the other hand, the substitution is not obvious, then it cannot be insubstantially different, and therefore the patentee is entitled to no equivalence. Under these rules, the foreseeability argument is unwinnable, and no amended claim can escape prosecution history estoppel and be infringed under the doctrine of equivalents—the return of the Federal Circuit’s complete bar.

[I’m still struggling with figuring out the best solution here—it may turn out that the outcome obtained, despite its problems, is the best among a series of poor alternative scenarios]

One possibility is to discard this whole framework and instead follow a path suggested by Judge Plager in his dissent in *Hilton Davis* (and reiterated in his concurrence in *Festo VI*): The Court should return the doctrine of equivalents to its roots in equity. This change would take the decision from the jury and place it in the hands of judges, who could then develop standards over time, just as with other hard-to-pin-down concepts like fraud, etc. The more I look at how convoluted these doctrines are becoming (unforeseeability as an “exception[] to an exception to an exception to the standard rule of infringement”), the more I think that may be the only way out of the morass. [Also tie into British/Lord Hoffmann “common sense” claim interpretation? Need to do more research on this!]

[Some other issues to think about:

Does the reverse doctrine of equivalents have a role?

Can the *Wilson Sporting Goods* hypothetical claim analysis be adapted to be of use?

Is the *Gentry Gallery* analysis on written description relevant?

Issue with the concerns raised in *Johnston* (claim narrowly then expand via DOE)?

Should the analysis be different for amended and unamended claims?

V. Conclusion