From the Unforeseeability Exception to Foreseeability Estoppel: The Federal Circuit’s Effort to Limit the Doctrine of Equivalents

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Abstract
A person can infringe a patent under the doctrine of equivalents (“DOE”) which may be limited by prosecution history estoppel (“PHE”). The Supreme Court in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002), finalized the basic doctrine of PHE in the context of claim amendment. A narrowing amendment of a claim results in a presumption that a patentee has surrendered the scope between the
original claim and amended claim, but the patentee is allowed to rebut the presumption by proving any of three exceptions. Among those exceptions is the “unforeseeable” exception under which a patentee may show that the alleged equivalent was unforeseeable at the time of amendment. This article found that the Federal Circuit case law has transformed the “unforeseeable” exception into “foreseeability” estoppel which may completely bar the application of DOE.

Keywords: Doctrine of Equivalents, Prosecution History Estoppel, Patent Infringement, Claim Amendment, Foreseeability
I. Introduction

Under 35 U.S.C. § 271(a), a person can literally infringe a patent or infringe a patent under the doctrine of equivalents (“DOE”). DOE helps establish patent infringement even though some element of the claim cannot be found on the accused product (or process). Under DOE, patent infringement is found if the accused product has an equivalent element insubstantially different from the missing element of the claim, or if such equivalent element “performs substantially the same function in substantially the same way to obtain substantially the same result” as the missing element of the claim can do.

DOE has been recognized by the Supreme Court since Winans v. Denmead, 56 U.S. 330 (1853) and O’Reilly v. Morse, 56 U.S. 62 (1853). The landmark case is Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605 (1950), which illustrates the fundamental ideas of DOE. In 1997, the Supreme Court in Warner-Jenkinson Co. v.

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1 See DeMarini Sports v. Worth, 239 F.3d 1314, 1331 (Fed. Cir. 2001) (“Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, i.e., when ‘the properly construed claim reads on the accused device exactly.’”).
3 See id. at 29-30.
4 See id. at 30-31.
Hilton Davis Chem. Co. reinstated DOE in the post-1952 Patent Act era and also reaffirmed Graver Tank as part of the fundamental rules of DOE.

While DOE makes a claim scope literally undefined, courts have imposed some limitations on DOE. Among them is prosecution history estoppel (“PHE”). In 2002, the Supreme Court of the United States in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (“Festo 2002”) finalized the basic doctrine of PHE in the context of claim amendment. There, the Supreme Court stated that “a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.” That is, a narrowing amendment creates a presumption that a patentee surrenders all equivalents which fall between the original claim and amended claim. But, a patentee may overcome such presumption by proving any of three exceptions: the “unforeseeable” most-cited case related to DOE).

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12 See id. at 102-11.
13 See id. at 102-07; see also James Farrand, Seth Weisberg, Rickard Killworth & Victoria Shapiro, “Reform” Arrives in Patent Enforcement: The Big Picture, 51 IDEA 357, 429 (2011) (describing the all elements rule, prosecution history estoppel, no vitiation rule, express exclusion rule, disavowal or disclaimer rule, dedication rule, ensnarement rule, and all advantages rule).
15 PHE can be applied based on arguments made during the prosecution. See Cordis Corp. v. Medtronic Ave, Inc., 511 F.3d 1157, 1177 (Fed. Cir. 2008) (“[A]n applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter.”).
exception, the “tangential” exception, and “other reason” exception. Since *Festo 2002*, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) has issues several decisions about those three exceptions to PHE. This article is intended to explore the Federal Circuit case law regarding the “unforeseeable” exception. Specifically, this article discusses the standard for determining whether an accused equivalent would have been “foreseeable.”

In this article, Part II briefly discusses the concept of DOE. Part III elaborates the PHE rules behind *Festo 2002* and the following Federal Circuit decision in 2003 that describes those rules including the definitions of those three exceptions. Part IV analyzes the cases addressing the “unforeseeable” exception. The review of those Federal Circuit cases indicates that any narrowing amendments more likely lead to a finding of foreseeable equivalents.

II. Doctrine of Equivalents

A. Determination of Equivalency under *Graver Tank*

The *Graver Tank* Court developed a flexible standard of DOE. The standard required that equivalency must be “determined against the context of the patent, the prior art, and the particular circumstances of the case.” While recognizing the function-way-result test as a standard for proving equivalency, the *Graver Tank* Court

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18 See id.
21 Id.
22 See id. at 608.
did not restrict the determination of equivalency to that test because “[e]quivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum.”23 The Graver Tank Court even cautioned that equivalency “does not require complete identity for every purpose and in every respect.”24 Therefore, “things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents.”25

While Prof. Timothy R. Holbrook calls the Graver Tank standard “a messy, fact-intensive endeavor,”26 the Graver Tank Court does offer four factors for determining equivalency.27 The first three factors include “the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform.”28 More importantly, the fourth factor requires courts to consider “whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.”29

B. All-Elements Rule and Claim Vitiation under Warner-Jenkinson

In 1997, the Warner-Jenkinson Court created two additional guidelines for applying DOE. The first one is called “all-elements rule.”30 As the Warner-Jenkinson Court noted,

23 See id. at 609.
24 See id.
25 See id.
29 See id.
30 See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1316 (Fed. Cir. 1998); see also
“[t]he determination of equivalence should be applied as an objective inquiry on an element-by-element basis.”\textsuperscript{31} The rational is that “[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention.”\textsuperscript{32} So, “the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.”\textsuperscript{33} However, the Warner-Jenkinson Court cautioned that “[i]t is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.”\textsuperscript{34} In fact, the all-elements rule was created by the Federal Circuit and then adopted by the Supreme Court.\textsuperscript{35} The modern view is that “courts must consider the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless.”\textsuperscript{36}

The second guideline is called “claim vitiation.”\textsuperscript{37} The Warner-Jenkinson Court mentioned in footnote 8 that “if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve.”\textsuperscript{38}

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\textsuperscript{31} See Warner-Jenkinson Co., 520 U.S. at 40.
\textsuperscript{32} See id. at 29.
\textsuperscript{33} See id.
\textsuperscript{34} See id.
\textsuperscript{35} See Nystrom v. Trex Co., Inc., 580 F.3d 1281, 1286 (Fed. Cir. 2009) (Rader J., dissenting) (“In Warner-Jenkinson, the Supreme Court adopted this court’s established ‘all-elements’ rule.”).
\textsuperscript{36} Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1359 (Fed. Cir. 2005).
\textsuperscript{38} Warner-Jenkinson Co., 520 U.S. at 29 n.8 (emphasis original).
ensures that DOE “will not vitiate the central functions of the patent claims themselves.”

Recently, the Federal Circuit in *Deere & Co. v. Bush Hog, LLC* provided its view on claim vitiation. The Federal Circuit considered claim vitiation as “not an exception to the doctrine of equivalents, but instead a legal determination that the evidence is such that no reasonable jury could determine two elements to be equivalent.” Therefore, courts can satisfy the determination by “simply noting that an element is missing from the claimed structure or process because the doctrine of equivalents, by definition, recognizes that an element is missing that must be supplied by the equivalent substitute.”

In addition to those two guidelines, the *Warner-Jenkinson* Court provided the proper timing for evaluating equivalency or interchangeability which The *Graver Tank* Court did not address. The *Warner-Jenkinson* Court held that the proper timing is “the time of infringement, not at the time the patent was issued.”

Moreover, the *Warner-Jenkinson* Court expressed its open mind on the case law development of DOE. While cautioning that either the function-way-result test (or, triple identity test) or the insubstantial differences test may have its limits, without “micromanaging the Federal Circuit’s particular word choice for analyzing

39 *Id.* at 30.


41 *Id.* at 1356 (quotation omitted).

42 *Id.* at 1356-57.

43 See *Warner-Jenkinson Co.*, 520 U.S. at 37.

44 See *id.* at 39-40 (“There seems to be substantial agreement that, while the triple identity test may be suitable for analyzing mechanical devices, it often provides a poor framework for analyzing other products or processes. On the other hand, the insubstantial differences test offers little additional guidance as to what might render any given difference ‘insubstantial.’”).
equivalence," the Warner-Jenkinson Court showed its expectation “that the Federal Circuit will refine the formulation of the test for equivalence in the orderly course of case-by-case determinations.”

Currently, under the Federal Circuit case law, the “insubstantial differences” test simply requires that “[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial.” But, the Warner-Jenkinson Court has commented that “the insubstantial differences test offers little additional guidance as to what might render any given difference ‘insubstantial.’” On the other hand, under the “triple identity” test or “function-way-result” test, the Federal Circuit case law requires a patentee to show “on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product.” The “function-way-result” test is “particularly suitable for analyzing the equivalence of mechanical devices.”

C. Question of Fact

The Graver Tank Court and Warner-Jenkinson Court both have held that infringement under DOE is a question of fact. With respect to evidence, the Graver Tank & Mfg. Co., 339 U.S. at 609 (“A finding of equivalence is a determination of fact.”);
Tank Court has held, “Proof can be made in any form: through testimony of experts or others versed in the technology; by documents, including texts and treatises; and, of course, by the disclosures of the prior art.” Thus, courts are required to balance “credibility, persuasiveness and weight of evidence” to make a “final determination.”

III. Prosecution History Estoppel under Festo

PHE is a limitation on DOE. In 2002, the Supreme Court in Festo 2002 established clear guidance on PHE in the context of claim amendment. The Festo 2002 Court answered two questions: what kind of claim amendment may trigger PHE and whether PHE may be overcome. In 2003, the Federal Circuit in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359 (Fed. Cir. 2003), responded to Festo 2002 and provided clear rules for implementing Festo 2002. Both Festo 2002 and Festo 2003 decisions provide useful guidelines of applying PHE.

A. What Triggers Prosecution History Estoppel

Considering that DOE “allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes,” the Supreme Court in Festo 2002 reaffirmed the necessity of

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Warner-Jenkinson Co., 520 U.S. at 37 (“[W]ith regard to the objective nature of the doctrine, a skilled practitioner’s knowledge of the interchangeability between claimed and accused elements is not relevant for its own sake, but rather for what it tells the fact-finder about the similarities or differences between those elements.”).


See id. at 609-10.


PHE by stating that “[w]hen, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.”58 Under Festo 2002, a narrowing amendment may result from the patentee’s effort to meet “any requirement of the Patent Act.”59 What may trigger PHE is a narrowing amendment used to overcome any rejection under 35 U.S.C. §§ 101 (usefulness and patent-eligibility requirements), 102 (novelty requirement), 103 (non-obviousness requirement), or 112 (disclosure requirements) may trigger PHE.60 Even for a narrowing amendment “unrelated to patentability, the Festo 2002 Court reinstated that “the court might consider whether it was the kind of reason that nonetheless might require resort to the estoppel doctrine.”61 But, the Supreme Court cautioned that “[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent’s scope or raise an estoppel.”62

To clarify which amendment triggers PHE under Festo 2002, the Federal Circuit in Festo 2003 (en banc) provided several rules. First, “a narrowing amendment made to comply with any provision of the Patent Act, including § 112, may invoke an estoppel.”63 Second, “a ‘voluntary’ amendment may give rise to prosecution history

58 Id. at 733-34.
59 See id. at 736 (“[A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.”).
60 See id. (“The claimed subject matter must be useful, novel, and not obvious. 35 U.S.C. §§ 101-103 (1994 ed. and Supp. V). In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. § 112 (1994 ed.).”).
61 Id. at 735.
62 Id. at 736-37.
63 Festo 2003, 344 F.3d at 1366.
estoppel.” 64 Third, “a narrowing amendment [is treated] as having been made for a ‘substantial reason related to patentability’ when the record does not reveal the reason for the amendment.” 65 In 2004, the Federal Circuit in Honeywell 2004 further clarified that “rewriting a dependent claim into independent form, coupled with the cancellation of the original independent claim, constitutes a narrowing amendment when the dependent claim includes an additional claim limitation not found in the cancelled independent claim or circumscribes a limitation found in the cancelled independent claim.” 66

Moreover, the Federal Circuit in Festo 2003 elaborated a series of questions asked prior to the application of PHE. The first inquiry is “whether an amendment filed in the [USPTO] has narrowed the literal scope of a claim.” 67 If the answer is yes, the second inquiry is “whether the reason for that amendment was a substantial one relating to patentability.” 68 “When the prosecution history record reveals no reason for the narrowing amendment,” 69 it is presumed that “the patentee had a substantial reason relating to patentability.” 70 The patentee must rely only on “the evidence in the prosecution history record” to “show that the reason for the amendment was not one relating to patentability.” 71 If the answer to the second question is yes or the patentee fails to rebut that presumption, the third question relates to “the scope of the subject

64 Id.
65 Id.
67 Id.
68 Id.
69 Id. at 1366-67.
70 Id. at 1367.
71 Id.
matter surrendered by the narrowing amendment.” It is presumed that “the patentee has surrendered all territory between the original claim limitation and the amended claim limitation.” “The patentee may rebut that presumption of total surrender by demonstrating” any of those three exceptions created by Festo 2002. Finally, if the rebuttal succeeds, PHE does not apply. Otherwise, the patentee is barred from asserting DOE against the alleged equivalent in question.

B. Three Exceptions

Because of language imperfection of the amended claim, the Festo 2002 Court did not expect that “a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered” or should “foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted.” The question is “what equivalents were surrendered during the prosecution of the patent, rather than [to impose] a complete bar that resorts to the very literalism the equivalents

72 See id.
73 See id.
74 See id.
75 See id.
76 See id.
77 See Festo 2002, 535 U.S. at 738 (“After amendment, as before, language remains an imperfect fit for invention.”). While the Festo 2002 Court recognized that “[b]y amending the application, the inventor is deemed to concede that the patent does not extend as far as the original claim,” id., the Supreme Court worried that “[t]he narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is.” Id.
78 See id.
79 See id.
rule is designed to overcome."\textsuperscript{80}

To avoid a complete bar of DOE in the context of claim amendment, the \textit{Festo 2002} Court created three exceptions. The first exception or “unforeseeable” exception is that “[t]he equivalent may have been unforeseeable at the time of the application.”\textsuperscript{81} The second exception or “tangential” exception is that “the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question.”\textsuperscript{82} The third exception or “other reason” exception is that “there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.”\textsuperscript{83} Proving any of those three exceptions can help the patentee “overcome the presumption that prosecution history estoppel bars a finding of equivalence.”\textsuperscript{84}

The Federal Circuit in \textit{Festo 2003} further elaborated several applicable rules for each exception. Regarding the “unforeseeable” exception, the Federal Circuit held that it is “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.”\textsuperscript{85} The determination of unforeseeability “depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment.”\textsuperscript{86} Courts “may hear expert testimony and

\textsuperscript{80} Id.
\textsuperscript{81} Id. at 740.
\textsuperscript{82} Id.
\textsuperscript{83} Id. at 740-41.
\textsuperscript{84} Id. at 741.
\textsuperscript{85} \textit{Festo 2003}, 344 F.3d at 1369.
\textsuperscript{86} Id.
consider other extrinsic evidence relating to the relevant factual inquiries.”

In addition, the Federal Circuit provided an absolute rule that “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.”

Regarding the “tangential” exception, the Federal Circuit in *Festo 2003* held that it “asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.” The inquiry focuses on “the patentee’s objectively apparent reason for the narrowing amendment” and “the context in which the amendment was made.” When “the public notice function of a patent and its prosecution history is to have significance,” the Federal Circuit required that courts must look to “the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record.” So, courts must rely on the prosecution history record mainly. But, it is not sure that under what circumstance courts may consult with expert testimony. Moreover, while admitting that it “cannot anticipate the instances of [the second exception],” the Federal Circuit provided an exclusionary rule that “an amendment made to avoid prior art that contains the equivalent in question is not tangential[, because] it is central to allowance of the claim.”

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87 *Id.*
88 *Id.*
89 *Id.*
90 *Id.*
91 *Id.* at 1340.
92 *Id.* at 1369.
93 *Id.* at 1370.
94 *Id.* at 1369.
95 *Id.*
Regarding the “other reason” exception, the Federal Circuit in Festo 2003 did not create another phrase for this inquiry. The original phrase for the inquiry used by the Supreme Court was “some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.” This phrase was considered “vague” by the Federal Circuit which, therefore, held that the “other reason” exception “must be a narrow one.” The only situation the Federal Circuit can image is “shortcomings of language” which prevents the patentee from “describing the alleged equivalent when it narrowed the claim.” In addition, the Federal Circuit required courts to limit the determination to the prosecution history record. One example is that “a patentee may not rely on the third [exception] if the alleged equivalent is in the prior art.” However, the Federal Circuit showed its unwillingness to foreclose evidence outside the prosecution history record.

Those three exceptions to PHE now can be determined according to the Federal Circuit’s guidelines. Those guidelines, however, are not absolute. As the Federal Circuit held, “[b]ecause we cannot anticipate all of the circumstances in which a patentee might rebut the presumption of surrender, we believe that discussion of the relevant factors encompassed by each of the rebuttal criteria is best left to development on a case-by-case basis.” Therefore, the rules of each exception may be changed from time to time, depending on the specific fact pattern of a case.

96 Id. at 1370.
97 Id.
98 Id.
99 See id.
100 Id. (referring to Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352 (Fed. Cir. 2003)).
101 See id. (“We need not decide now what evidence outside the prosecution history record, if any, should be considered in determining if a patentee has met its burden under this third rebuttal criterion.”).
102 Id. at 1368.
C. Question of Law

Prior to 1997, PHE had been considered as a question of law by the Federal Circuit. The Warner-Jenkinson Court seemed to agree because it mentioned in footnote 8 that courts may grant a summary judgment of no infringement under DOE if PHE is established. While the Supreme Court has never reviewed that issue, the Federal Circuit has treated PHE as a question of law ever since. In Festo 2003, the Federal Circuit reaffirmed that PHE is a question of law. First, the Federal Circuit recognized PHE as “equitable in nature,” so the application should be “guided by equitable and public policy principles.” Second, the Federal Circuit held that its case law has treated PHE as a question of law and has been recognized by the Supreme Court in Warner-Jenkinson.

In Festo 2002, the Supreme Court addressed PHE and three exceptions, but did not mention whether the determination of PHE or three exceptions should be a question of law or question of fact. When the case was remanded, the Federal Circuit decided to answer whether the determination of any exception is a question of law or question of fact.

104 See Warner-Jenkinson Co., 520 U.S. at 29 n.8 (“[U]nder the particular facts of a case, if prosecution history estoppel would apply or if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve.”).
105 See Philippe Signore, On the Role of Juries in Patent Litigation (Part 1), 83 J. PAT. & TRADEMARK OFF. SOC’Y 791, 807-08 (2001);
106 See Festo 2003, 344 F.3d at 1367-68.
107 Id. at 1367 (quotation and citation omitted).
108 See id. at 1368 (“The Supreme Court has recognized that, as a legal limitation on the application of the doctrine of equivalents, prosecution history estoppel is a matter to be determined by the court.” (citing Warner-Jenkinson, 520 U.S. at 39 n. 8)).
fact. The Federal Circuit in *Festo 2003* held that any exception to PHE is a “question of law to be determined by the court, not a jury” because it is a question related to PHE.

**IV. Foreseeability Rules under Federal Circuit Case Law**

Thought, the Federal Circuit in *Festo 2003* has clarified the applicable rules of each exception. Because the case-by-case analysis is a basis for the application of those three exceptions to PHE, the application in reality is shown from the Federal Circuit case law.

**A. Alleged Equivalents Covered by the Original Claim**

If an alleged equivalent is covered by the original claim, it would be held foreseeable. In *Ranbaxy Pharms. Inc. v. Apotex, Inc*., the Federal Circuit affirmed the district court’s denial of a preliminary injunction moved by the patentee because the patentee was unlikely to prove infringement under DOE. The patent-in-suit related to a process of making amorphous cefuroxime axetil. The original version of the representative claim at dispute included a “highly polar organic solvent.” During the prosecution, the examiner rejected some claims because “highly polar organic solvent”

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109 *See id.* at 1365.

110 *Id.* at 1367.

111 *See id.* at 1368 (“Questions relating to the application and scope of prosecution history estoppel thus fall within the exclusive province of the court.”).


113 *See id.* at 1237.


115 *See Ranbaxy Pharms. Inc.*, 350 F.3d at 1237-38.
was indefinite and because a prior art patent disclosed acetone as a “highly polar organic solvent.” The applicant then added dependent claims into some independent claim, and the broad limitation became “the highly polar organic solvent is selected from the group consisting of a sulfoxide, an amide and formic acid.” On the other hand, the accused process used “acetic acid” as a solvent. 

The patentee asserted the “unforeseeable” exception, but the defendant argued that “acetic acid is a foreseeable equivalent to formic acid that could have and should have been included in the original claim.” The Federal Circuit found that the patentee “stated that formic acid and acetic acid, as homologs, are readily known by chemists to exhibit similar properties and are therefore equivalent.” The original claim would have literally included “acetic acid.” Therefore, the Federal Circuit held that the “unforeseeable” exception could not be established.

116 See id. at 1238.
117 See id.
118 See id.
119 See id. at 1241.
120 Id.
121 Id. While the Federal Circuit did not disclose where it found the statement of the patentee, the appellate brief filed by the patentee did state:

Formic acid and acetic acid solvents are the first and second compounds in the series of carboxylic acids. Compounds that are related to each other as members of the same series are called “homologs.” When homologs are adjacent to each other in a series - as formic acid and acetic acid are - the patent law has held that they are obvious variants of one another, because chemists ordinarily expect adjacent homologs to exhibit substantially similar functional properties.

122 See Ranbaxy Pharms. Inc., 350 F.3d at 1241.
123 See id.
In Research Plastics, Inc. v. Federal Packaging Corp.,124 although the Federal Circuit remanded the case because of incorrect claim construction, it did affirm that the district court correctly applied PHE.125 The patent-in-suit related to the structure of a caulking tube.126 Figure 1(a) shows the patented caulking tube.

![Patented Caulking Tube](image1)

(a) Patented Caulking Tube127 and (b) Infringing Caulking Tube128

During the prosecution, the claim at dispute was amended to avoid a prior art.129 The amended claim included a phrase “said ribs each occupying an area that is less than 0.5% of the area of said tube, and said ribs extending to said rear end of said hollow

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125 See id. at 1292, 1298-99.
126 See id. at 1292, 1299.
127 See See Brief for Plaintiff-Appellant at 8-9, Research Plastics, Inc. v. Federal Packaging Corp., 421 F.3d 1290 (Fed. Cir. 2005) (No. 04-1605), 2004 WL 4977760 (“As described by representative claim 10 and shown below, the ‘433 Patent recites a hollow tube body (30) and a plunger (32) received within the body. Ribs (38) are defined extending inwardly from an inner periphery (36) of the hollow tube (30). The claim recites that the tube (30) extends from a rear end (33) to a nozzle end (34). The ribs (38) extend to the rear end (33).”).
128 See id. at 11.
129 See Research Plastics, Inc., 421 F.3d at 1293.
tube body.” The new limitation was intended to distinguish the claimed invention from the prior art because the ribs of the prior art were “positioned near the nozzle end of the tube.” On the other hand, the alleged equivalent was a rib “extending to a point short of the rear edge of the tube.” The infringing product is shown in Figure 1(b).

The Federal Circuit held that the alleged equivalent was foreseeable because “rib placement was a point of differentiation.” The holding was based on the evidence that the applicant used the rib position to distinguish the claimed invention from the prior art. This determination indicates that a change of the relative placement of a claimed feature may always be foreseeable.

In Integrated Tech. Corp. v. Rudolph Techs., Inc., the Federal Circuit reversed the district court’s judgment of infringement under DOE because PHE applied. The patent-in-suit related to integrated circuit probe card inspection equipments. The claim at dispute originally recited “a window with a flat surface contacted by said probe tip.” Then, it was amended to overcome a rejection related to patentability, and a new limitation “in a first state where said probe tip is driven in contact with said window

130 Id. (emphasis added).
131 Id.
132 Id. at 1299.
133 Id. at 1298.
134 See id. The second exception was not met because “the purpose of the amendment was to avoid rejection based on rib placement.” Id. The third exception was not established because the applicant “could have claimed ribs placed in the region between the nozzle end and the rear end of the tube, so long as it disclaimed the location adjacent to the nozzle,” id. (emphasis added), or described “ribs placed rearward from the nozzle end, yet not extending completely to the rear edge.” Id. (emphasis added).
136 See id. at 1355.
137 See id.
138 Id. at 1356.
with a first force” was added. On the other hand, the alleged equivalent was characterized as “in a first state when the probe tip is five microns above the viewing window, and in a second state when the probe tip touches the window.”

The Federal Circuit found that the original claim literally covered the alleged equivalent. Therefore, the alleged equivalent would have been foreseeable at the time of the amendment.

B. Alleged Equivalents Covered by Other Canceled Claim

If an alleged equivalent is covered by other canceled claim, it would be held foreseeable. In *Mycogen Plant Science, Inc. v. Monsanto Co.*, the Federal Circuit affirmed the district court’s judgment of non-infringement which applied PHE. The patent-in-suit related to “a gene that encodes a pesticidal protein of the soil bacterium *Bacillus thuringiensis* (‘Bt’).” The claim at dispute was not amended during the prosecution. Instead, another claim reciting “said DNA sequence is at least about 85% homologous to a native insecticidal protein gene of Bt” was canceled during the prosecution. The cancellation was filed to respond the enablement rejection. On the other hand, the alleged equivalent was a gene having “a level of homology with the

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139 *Id.*
140 *Id.* at 1359.
141 See *id.*
142 See *id.*
143 *Mycogen Plant Science, Inc. v. Monsanto Co.*, 91 F. App’x 666 (Fed. Cir. 2004).
144 See *id.*
145 *Id.*
146 See *id.* at 667.
147 *Id.*
148 See *id.*
149 See *id.*
native $Bt$ gene of about 78 percent and a frequency of usage of plant-preferred codons of about 51 percent.” The Federal Circuit found that the claim at dispute was not broader enough to cover the alleged equivalent while the cancelled claim could.

The patentee asserted that it should have been permitted to present evidence regarding the unforeseeability of the alleged equivalent. But, the Federal Circuit stated that “the fact that [the applicants] originally claimed coverage of genes bearing 85 percent similarity to the native $Bt$ gene is itself evidence that the applicants foresaw the possibility of less homologous genes.” Therefore, the “unforeseeable” exception could not be proved.

C. Alleged Equivalents Covered by Prior Art

If an alleged equivalent had been covered by the prior art, it would be held foreseeable. In *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, the Federal Circuit upheld the district court’s judgment of non-infringement under DOE. The patent-in-suit related to a power supply. The claim at dispute originally recited “multiplier,” and later was amended to recite “switching analog multiplier circuit” to overcome a rejection based on novelty and indefiniteness. The Federal Circuit found that the prior

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150 *Id.*
151 *See id.*
152 *See id.* at 668.
153 *Id.*
154 *See id.*
156 *See id.* at 1354.
157 *See id.*
158 *See id.*
159 *See id.* at 1355.
art cited by the examiner “disclosed a power supply containing a non-switching multiplier.” 160 Because “a non-switching multiplier was known in the art,” 161 the Federal Circuit held that it “would have been foreseeable at the time of the amendment.” 162

In Talbert Fuel Sys. Patents Co. v. Unocal Corp., 163 the Federal Circuit affirmed the district court’s ruling which applied PHE. 164 The patent-in-suit related to a gasoline fuel composition. 165 The claim at dispute originally recited no boiling temperature range. 166 To reject the original claim, the examiner cited several references one of which showed a boiling range of 390°F–420°F. 167 Then, to overcome the rejection, the applicant amended the original claim to recite “a boiling range of 121°F–345°F.” 168 On the other hand, the accused fuel had a boiling point ranging from 373.8°F–472.9°F. 169 The Federal Circuit found that the alleged “boiling point” equivalent started at 373.8°F which is between the 345°F upper limit of the claim at dispute and the 390°F of the prior art. 170 The range of the alleged “boiling point” equivalent was partially embraced by the prior art. 171 Therefore, because of the applicant’s “clear disclaimers of such

160 Id. at 1357.
161 Id.
162 Id.
164 See id. at 1360.
165 See id. at 1357.
166 See id. at 1358.
167 See id.
168 Id.
169 See id. at 1360.
170 See id. at 1359.
171 See id.
higher-boiling fuels,” the Federal Circuit held that the alleged equivalent “cannot be deemed to have been unforeseeable when [the] amendments were made.”

D. Alleged Equivalents Known to the Applicant

If an alleged equivalent had been known to the applicant at the time of the amendment, it would be held foreseeable. There are several scenarios. First, an information disclosure statement (“IDS”) submitted by the applicant may include some reference which describes the use of the alleged equivalent in the art. The Federal Circuit in *Glaxo Wellcome, Inc. v. Impax Labs., Inc.* and *Smithkline Beecham Corp. v. Excel Pharms., Inc.* was confronted with a patent related to “controlled sustained release tablets containing bupropion hydrochloride.” The specification disclosed a drug formulation containing hydroxypropyl methylcellulose (“HPMC”) which helps achieve the claimed sustained release. Because the examiner considered HPMC as essential to the claimed release rate, the applicant was required to amend the original claim to recite HPMC; otherwise the enablement requirement would not be met. On the other hand, the alleged equivalents in *Glaxo Wellcome, Inc.* and *Smithkline Beecham Corp.* were two hydrogel-forming polymers, hydroxypropyl cellulose (HPC), a hydrogel-forming compound, and polyvinyl alcohol (“PVA”), respectively.

The Federal Circuit in *Glaxo Wellcome, Inc.* affirmed the district court’s application

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172 Id.
173 Id. at 1359-60.
174 *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348 (Fed. Cir. 2004).
175 *Smithkline Beecham Corp. v. Excel Pharms., Inc.*, 356 F.3d 1357 (Fed. Cir. 2004).
176 *Glaxo Wellcome, Inc.*, 356 F.3d at 1349-50; *Smithkline Beecham Corp.*, 356 F.3d at 1359.
177 See *Glaxo Wellcome, Inc.*, 356 F.3d at 1352; see also *Smithkline Beecham Corp.*, 356 F.3d at 1361-62.
178 See *Glaxo Wellcome, Inc.*, 356 F.3d at 1352; see also *Smithkline Beecham Corp.*, 356 F.3d at 1362.
179 See *Glaxo Wellcome, Inc.*, 356 F.3d at 1351; see also *Smithkline Beecham Corp.*, 356 F.3d at 1360.
of PHE, but in Smithkline Beecham Corp. it remanded the district court’s finding of foreseeability. In Glaxo Wellcome, Inc., the Federal Circuit found that showed that HPC appealed as a known sustained release hydrogel-forming polymer like HPMC in several prior art documents including what was submitted by the applicant in the IDS. Therefore, the Federal Circuit held that the applicant knew that HPC would have been an equivalent at the time of the amendment. The patentee failed to rebut PHE. On the other hand, in Smithkline Beecham Corp., while considering PVA as a later-developed technology for being used as a sustained release ingredient for bupropion hydrochloride, the Federal Circuit found that the patentee admitted that “PVA and HPMC are functional equivalents in retarding the release of bupropion hydrochloride from an ingested tablet.” With these contradictory facts, the Federal Circuit concluded that “the record does not disclose whether HPMC and PVA were recognized as interchangeable sustained release hydrogel-forming polymers used in the art of pharmaceutical formulation at the time the claims were amended.”

Second, the conclusion of knowledge may result from the patentee’s admission during the prosecution. In Amgen Inc. v. Hoechst Marion Roussel, Inc., the Federal Circuit affirmed the district court’s holding that the alleged equivalent was foreseeable.

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180 See Glaxo Wellcome, Inc., 356 F.3d at 1349.
181 See Smithkline Beecham Corp., 356 F.3d at 1359.
182 See Glaxo Wellcome, Inc., 356 F.3d at 1355.
183 See id.
184 See id. at 1356.
185 See Smithkline Beecham Corp., 356 F.3d at 1364-65.
186 Id. at 1365.
187 Id.
188 Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293 (Fed. Cir. 2006).
at the time of the amendment. The patent-in-suit related to recombinant deoxyribonucleic acid technology for producing the hormone erythropoietin (“EPO”). The claim at dispute had been through three preliminary amendments. The first preliminary amendment broadly covered either an isolated human EPO or monkey EPO. The second preliminary amendment embraced an EPO made from the amino acid sequence for EPO and a fragment thereof. The final preliminary amendment removed the features of a non-human monkey EPO and the use of a fragment. Rather, the final version was limited to “only a human EPO product having the complete amino acid sequence of [a DNA sequence drawing].” That is, the claim at dispute recited a human EPO made from a 166-amino acid sequence defined in such drawing. On the other hand, the alleged equivalent was an EPO made from a 165-amino acid sequence.

The Federal Circuit found that during the prosecution the applicant informed the examiner that human EPO has a 165-amino acid sequence when filing the third preliminary amendment. Because “the patentee admittedly knew about the 165-amino acid [sequence] at the time of the third preliminary amendment,” the Federal Circuit held that the alleged equivalent would have been foreseeable at the time of the third preliminary amendment.

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189 See id. at 1316.
190 See id. at 1295.
191 See id. at 1310.
192 See id.
193 See id.
194 Id.
195 See id. at 1299, 1313.
196 See id. at 1310.
197 See id. at 1313.
198 See id.
preliminary amendment. 199

Third, the finding of knowledge may be based on the patentee’s argument during the litigation. In Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 200 the Federal Circuit reversed the district court’s judgment of infringement under DOE and held that PHE should have applied. 201 The patent-in-suit related to a fixation device for bone connection. 202 The claim at dispute originally recited a “seat means including a vertical axis and first threads.” 203 When the examiner rejected the claim on several grounds including obviousness and novelty, 204 the applicant responded by amending the original claim to recite “said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel.” 205 As the applicant explained to the examiner, the thread limitation was limited to “seat threads extend toward the channel to a depth below the top of the stabilizer when it is in the channel.” 206 On the other hand, the alleged equivalent referred as an undercut or recess was treated by the Federal Circuit as not including “threads extending to a depth below the top of the stabilizer.” 207

The Federal Circuit agreed with the district court’s holding that the alleged

199 See id.


201 See id. at 1344.

202 See id. at 1339.

203 Id. at 1340.

204 See id.

205 Id. (emphasis original).

206 Id. at 1343 (quoting the applicant’s response) (emphasis original).

207 Id. (quotation omitted).
equivalent was foreseeable. First, the evidence showed that the use of an undercut or recess was “an old and well known fundamental of basic machining” at the time of the amendment. Second, when arguing literal infringement, the patentee suggested that “an ‘undercut’ was known in the art to serve effectively as a thread.” Therefore, the patentee did not rebut PHE by the “unforeseeable” exception.

Fourth, the infringer’s activity may cause a finding of knowledge. In *Honeywell 2008*, the Federal Circuit affirmed the district court’s application of PHE. The patents-in-suit related to a “surge control system maintains [which] a minimum level of airflow through the compressor at all times.” The patented technology applied to aircrafts. The patented invention used a set of adjustable inlet guide vanes (“IGV”) to control the minimum flow in the compressor to prevent surges. The disputed limitation which was not included in the original claim described a mechanism applying IGVs and using “the position of these guide vanes in the surge control system.” On the other hand, the alleged equivalent was characterized as using a “static pressure differential” as an indicator of surge only if the engine is in a low flow and “IGV position” as an indicator of whether the engine is in a high or low flow.

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208 *See id.*
209 *See id.*
210 *Id.*
211 *See id.* at 1344.
212 *Honeywell Int’l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304 (Fed. Cir. 2008) [hereinafter, “*Honeywell 2008*”].
213 *See id.* at 1307.
214 *Id.*
215 *See id.*
216 *See id.*
217 *Id.*
218 *See id.* at 1313.
The “foreseeability” question was “whether the use of IGV position to detect high flow and low flow was later-developed technology and thus unforeseeable at the time of the amendments during the prosecution process.”\textsuperscript{219} The Federal Circuit held that the use was foreseeable and based its decision on the product development history of the infringer.\textsuperscript{220} While recognizing that the infringing product was developed after the claim amendment,\textsuperscript{221} the Federal Circuit affirmed the district court’s finding of foreseeability.\textsuperscript{222} The infringer’s product development showed that the use of IGV position as a low flow indicator had been known in the art.\textsuperscript{223} One old patent suggested that IGVs “were routinely used in surge control systems and affected the air flow rate.”\textsuperscript{224} Finally, the experts from both parties demonstrated that using IGV position was known as a solution in 1970s or at least at the time of the amendment.\textsuperscript{225}

Last, a term used by the applicant in other relevant patent may suggest that the alleged equivalent was known to the applicant. In \textit{Energy Transp. Group, Inc. v. William Demant Holding A/S},\textsuperscript{226} the Federal Circuit upheld that the district court applied PHE to limit DOE.\textsuperscript{227} Two patents, No. 4,731,850 (“850 Patent”) and No. 4,879,749 (“749 Patent”), were involved,\textsuperscript{228} and both related to “to technology for reducing acoustic

\begin{itemize}
\item \textsuperscript{219} Id.
\item \textsuperscript{220} See id. at 1313-14.
\item \textsuperscript{221} See id. at 1313.
\item \textsuperscript{222} See id. at 1314.
\item \textsuperscript{223} See id. at 1313.
\item \textsuperscript{224} Id. at 1314.
\item \textsuperscript{225} Id.
\item \textsuperscript{226} Energy Transp. Group, Inc. v. William Demant Holding A/S, 697 F.3d 1342 (Fed. Cir. 2012).
\item \textsuperscript{227} See id. at 1347.
\item \textsuperscript{228} See id.
\end{itemize}
feedback in a programmable digital hearing aid.” The 749 Patent was a divisional application of the 850 Patent. But, only the 749 Patent related to the issue of PHE. The process claim at dispute originally recited “means for receiving signals indicative of the frequency gain and feedback characteristics.” To overcome the examiner’s rejection, the claim was amended to replace the “means for receiving” limitation with “means for receiving signals from the hearing aid and measuring phase and amplitude.” On the other hand, the alleged equivalent was characterized as “determining the effect of phase and amplitude.”

The Federal Circuit found that the applicant knew the use of “determining” at the time of the amendment. Both the 850 Patent and 749 Patent shared a common specification. Because the applicant used the “determining” language in the 850 Patent, the Federal Circuit held that the alleged equivalent was foreseeable at the time of the amendment.

E. Foreseeability Determination under the Original Claim

In 2007, the Federal Circuit in Festo 2007 rejected a “foreseeability test [which]

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229 Id.
230 See U.S. Patent No. 4,879,749, front page.
231 See Energy Transp. Group, Inc., 697 F.3d at 1358-60.
232 Id. at 1359.
233 Id. (emphasis added).
234 Id. at 1360.
235 See id.
236 See id. at 1347.
237 See id. at 1360.
requires application of the function/way/result or insubstantial differences test.”239 The Federal Circuit clarified that an alleged equivalent “is foreseeable if it is disclosed in the pertinent prior art in the field of the invention.”240 Alternatively, the Federal Circuit held that an alleged equivalent “is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment.”241 This rule applies “even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown.”242

In Festo 2007, the Federal Circuit affirmed the district court’s finding of foreseeability as a result of non-infringement under DOE.243 The patent-in-suit related to a motor assembly.244 The claim at dispute originally did not recite a sleeve which was, however, included in a dependent claim.245 When submitting to the USPTO a German patent as a prior art showing the use of a sleeve made of non-magnetic material, the applicant amended the claim at dispute to recite “a cylindrical sleeve made of a magnetizable material.”246 On the other hand, the alleged equivalent was a sleeve made of “a non-magnetizable material, aluminum alloy.”247

The Federal Circuit held that “use of non-magnetizable sleeves (including aluminum sleeves) was foreseeable under the original broader claim.”248 The patentee

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239 Id. at 1379.
240 Id.
241 Id. (emphasis added).
242 Id. at 1382.
243 See id. at 1370.
244 See id. at 1371-72.
245 See id. at 1372.
246 See id. at 1373-74.
247 See id. at 1374.
248 Id. at 1382.
argued that “sleeve” was used to “shield against magnetic field leakage,” but the Federal Circuit found that the claimed sleeve “was not designed to shield the magnetic field but rather to enclose the magnets.” The German patent the applicant submitted also indicated that a sleeve could be made of a non-magnetic material. In addition, the specification of the patent-in-suit showed “the possibility of using a non-magnetic material for the sleeve.” While describing that the use of magnetic material for the sleeve could reduce undesirable braking forces, the specification did not mandate such use. Therefore, the Federal Circuit concluded that “use of an aluminum alloy sleeve was foreseeable at the time of amendment” and that PHE applied.

In Schwarz Pharma, Inc. v. Paddock Labs., Inc., the Federal Circuit affirmed the district court’s ruling that PHE barred the finding of the infringement under DOE. The patent-in-suit related to “pharmaceutical compositions containing Angiotensin Converting Enzyme (ACE) inhibitors combined with stabilizers to prevent certain types of degradation,” such as “cyclization, discoloration (through oxidation), and hydrolysis.” Two claims were involved, and each claim recited a stabilizer limitation. One claim recited a “metal containing stabilizer,” and the other claim

249 Id. at 1375.
250 Id. at 1382.
251 See id.
252 Id.
253 See id. at 1383.
254 See id.
255 Schwarz Pharma, Inc. v. Paddock Labs., Inc., 504 F.3d 1371 (Fed. Cir. 2007).
256 See id. at 1372.
257 See id.
258 See id. at 1372-73.
recited “an alkali or alkaline earth-metal salt.” Because of the examiner’s rejection, those two stablizer limitations were amended as “an alkali or alkaline earth metal carbonate.” On the other hand, the alleged equivalent was “magnesium oxide” (MgO). The Federal Circuit found that MgO fell within the definition of “metal containing stabilizer” and that the patentee’s expert described “an alkali or alkaline earth-metal salt” as embracing MgO. Therefore, the Federal Circuit held that MgO clearly fell within “the territory between the language of the original and the amended claims.”

Moreover, the Federal Circuit rejected the patentee’s argument that MgO was unforeseeable because MgO was not “known as a stabilizer against the specific degradation pathway of cyclization or for the specific drug category of ACE inhibitors.” The question was whether the alleged equivalent was within the field of the invention. While recognizing that “care must be taken not to sweep too broadly in defining the field of an invention,” the Federal Circuit critiqued that the definition the patentee offered was too narrow. Referring to the claim language, the Federal Circuit found that the claims at dispute began with “a pharmaceutical composition which contains.” So, the field of the invention was correctly found by the district court to be

259 See id. at 1373.
260 See id.
261 See id.
262 See id. at 1376.
263 Id. at 1376-77.
264 Id. at 1377.
265 See id.
266 Id.
267 See id.
268 See id.
“pharmaceutical compositions rather than being limited to pharmaceutical stabilizers that inhibit cyclization in ACE inhibitors.”

Therefore, the Federal Circuit concluded that “MgO was known as a stabilizer in the field of pharmaceutical compositions” and that the patentee failed to rebut the presumption.

F. Foreseeability and Suitability

An alleged equivalent does not have to be a promising choice of equivalents at the time of the amendment. In Duramed Pharms., Inc. v. Paddock Labs., Inc., the Federal Circuit held that the district court did no err in applying PHE to bar the finding of infringement under DOE. The patented technology related to “conjugated estrogen pharmaceutical compositions for use in hormone replacement therapies.” The claim at dispute originally recited “a moisture barrier coating.” A “moisture barrier coating” (“MBC”) was used to “to inhibit the absorption of moisture and reduce storage-related degradation.” The claim was then rejected by the examiner because of obviousness. After an interview with the examiner, the examiner agreed that the claim will overcome the rejection if it recites “ethylcellulose” as an MBC. The final version

269 Id.
270 Id.
271 See id.
272 Duramed Pharms., Inc. v. Paddock Labs., Inc., 644 F.3d 1376 (Fed. Cir. 2011).
273 See id. at 1378.
274 Id.
275 See id.
276 Id.
277 See id.
278 See id.
recited “a moisture barrier coating comprising ethylcellulose.” On the other hand, the alleged equivalent as an MBC was a “polyvinyl alcohol” (“PVA”).

The Federal Circuit relied on a Patent Cooperation Treaty (“PCT”) application to find that PVA had been used as an MBC for pharmaceutical compositions. The PCT application disclosed drug “formulations of PVA-based MBCs,” but also indicated some “technical drawbacks of using PVA as an MBC.”

The patentee asserted that a PVA had to be known as an MBC for conjugated estrogen. Relying on Schwarz Pharma, Inc., the Federal Circuit affirmed its rule for the definition of the field of the invention. As the Federal Circuit held, “when the language of both original and issued claims begins with the words ‘[a] pharmaceutical composition,’ that language defines the field of the invention for purposes of determining foreseeability.” So, the ultimate question was whether PVA MBCs had “been known in the field of pharmaceutical compositions as of the time of [the applicant’s] narrowing amendment.” Because the PCT application disclosed “PVA MBCs for use with pharmaceutical compositions,” the Federal Circuit held that PVA MBCs were foreseeable.

Alternatively, the patentee argued that the PCT application failed to disclose that

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279 See id.
280 See id.
281 See id. at 1380-82.
282 Id. at 1379.
283 Id.
284 See id. at 1380.
285 See id. (citing Schwarz Pharma, Inc., 504 F.3d at 1377).
286 Id. at 1380-81.
287 Id. at 1381.
288 Id.
289 See id.
PVA was suitable as an MBC because the application provided “only conclusory statements that the inventors had solved the technical drawbacks of PVA MBCs and lacks any data on the stability of the pharmaceutical compounds coated with [PVA MBCs].” The Federal Circuit disagreed. The Federal Circuit clarified that “foreseeability does not require such precise evidence of suitability” or “flawless perfection to create an estoppels.” As the Federal Circuit found, “even if the PCT disclosure indicates that PVA is less than ideal in some pharmaceutical uses as an MBC, it is still disclosed to be useful as such.” Thus, PVA was foreseeable at the time of the amendment.

G. Foreseeability Estoppel

Prof. Peter Lee has commented that “the foreseeability inquiry is highly factually intensive.” But, several rules can still be drawn from those Federal Circuit cases. The Federal Circuit in Festo 2003 opened a variety of evidence showing unforeseeability. Ironically, the Federal Circuit has relied on prior art documents, expert testimony, defendant’s activities, and patentee’s admission or arguments to determine that an alleged equivalent was foreseeable at the time of claim amendment. The standard for the “unforeseeable” exception makes the exception more like “foreseeability” estoppel which may completely bar the application of DOE.

290 Id.
291 See id.
292 Id.
293 Id.
294 Id.
295 See id.
The Federal Circuit case law could be summarized as follows:

- An alleged equivalent which falls within the original version of the claim or other canceled claim would be held foreseeable.
- An alleged equivalent disclosed by any prior art document cited by the examiner or submitted by the applicant would be held foreseeable.
- An alleged equivalent would be held foreseeable if the applicant had admitted or known the existence of such equivalent during the prosecution or had used such equivalent in other relevant patent.
- An alleged equivalent would be held foreseeable because it is covered by a broad claim interpretation made in the argument related to literal infringement.
- The original version of the claim at dispute governs the determination of the field of the invention; the particular function of the disputed element is irrelevant.
- An alleged equivalent is not required to exist as a suitable substitute of the disputed element at the time of the amendment.

Because the Federal Circuit case law has not shown any scenario where a patentee may successfully argue the “unforeseeable” exception, a complete bar of DOE may revive. The Federal Circuit imposes a higher bar on the patentee’s side. The higher bar is premised on an assumption that an applicant is free to add any substitute or equivalent of the disputed element at the time of amendment. That is not the case.

An applicant may have to wait for about 19 months for a first office action.

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297 Before the Supreme Court issued Festo 2002, some commentators had promoted the foreseeability bar which is similar to the “unforeseeability” exception. See Matthew J. Conigliaro, Andrew C. Greenberg, & Mark A. Lemley, *Foreseeability in Patent Law*, 16 BERKELEY TECH. L.J. 1045, 1064-73 (2001).

298 See Jonathan T. McMichael, Comment, *Producing Valuable Patents: The USPTO's Missed*
During that period, an alleged equivalent which was not considered as a substitute on the filing date may become a possible substitute at the time of amendment. While the applicant may be aware of the alleged equivalent, she cannot add it into the claim because of the new matter issue. As the Federal Circuit stated in *Smithkline Beecham Corp.*, “[t]he new matter doctrine prevents an applicant from adding new subject matter to the claims unless the specification shows that the inventor had support for the addition at the time of the original filing.” Because the specification does not disclose the alleged equivalent, the applicant is barred from adding the alleged equivalent into the claim. Consequently, PHE will definitely apply to the alleged equivalent.

The enablement requirement may also foreclose the inclusion of an alleged equivalent. Under 35 U.S.C. § 112, “the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” The determination of “undue experimentation” is based on the *Wands* factors including: “(1) the quantity 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.” The complex standard makes the enablement requirement uncertain for some technology.

Assume that in *Smithkline Beecham Corp.*, the original specification includes the alleged equivalent (PVA) as an ingredient of the claimed drug formulation, however,

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299 *Smithkline Beecham Corp.*, 356 F.3d at 1364.

300 ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) (quotation omitted).

301 Id. (quoting In re Wands, 858 F.2d 731, 737 (Fed.Cir.1988)).
without providing the release rate data of PVA. It is possible that the applicant has to remove PVA from the claims if the examiner finds that PVA cannot enable the claimed release rate. Because a human body is complex, the release rate of a drug formulation cannot be predicted if no human experiment has been done. The applicant must test a drug formulation with the use of PVA and its release rate inside a human body, so that she can present the evidence of enablement. Without doing so, the applicant may not overcome the rejection under the enablement requirement. Maybe the applicant should be responsible for her mistake. But, if the use of PVA cannot enable an ordinary skilled person in the art to make a drug formulation of the claimed release rate, such person may not consider PVA as an equivalent to achieve the claimed release rate. Therefore, it is not reasonable to require the applicant to foresee PVA as an equivalent at the time of amendment.

The new matter doctrine and enablement requirement limit an applicant’s capability to add an alleged equivalent into the claim. The foreseeability standard developed by the Federal Circuit may be too flexible to go beyond what an applicant may expect at the time of amendment in the context of the issues related to new matter or enablement. As a result, once a claim is amended, any equivalent will be held foreseeable.

V. Conclusion

Claim amendment triggers PHE if the amended claim is narrower than the original one. The result of PHE is that a patentee is presumed to surrender the protective range between the original claim and amended claim. But, a patentee is allowed to rebut the presumption by proving any of three exceptions. A patentee may show that the alleged
equivalent was unforeseeable at the time of amendment, that the amendment is tangential to the alleged equivalent, or that there is some reason that the applicant could not properly include the alleged equivalent in the claim.

With respect to the “unforeseeable” exception, this article found that the development of the Federal Circuit case law may show a higher bar. Although the Federal Circuit allows a patentee to use extrinsic evidence to prove unforeseeability, a variety of evidence increases the likelihood that the Federal Circuit may support the finding of foreseeability. An alleged equivalent will be found foreseeable at the time of amendment easily under a broad range of circumstances. The only way for a patentee to be saved from PHE may be to include in the original specification as many equivalents as possible. Therefore, when amendment is required during prosecution, a patentee may amend the claim while including more equivalents. The effect of PHE, then, may be eliminated.