Practitioner Perspective on the Law of Inequitable Conduct, Claim Construction, and the Doctrine of Equivalents

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Introduction

There is surely no greater influence upon a patent litigation practice than the decisions of the Federal Circuit Court of Appeals. While the Supreme Court has taken a few key matters for consideration and decision, the Federal Circuit is effectively the court of last resort for almost all issues dealt with by the patent practitioner, including prosecutors as well as trial counsel. The desire for greater uniformity in patent law led to the creation of the Federal Circuit Court of Appeals in 1982.¹ During its brief existence, the court has begun to clarify black-letter patent law in a variety of areas, justifying the rationale for the court’s creation.² From a practitioner’s perspective, the court’s “clarification” process has generally enabled better advocacy and counseling of clients.³ But

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⁴ See Goldman, supra note 1, at 68.
⁵ But see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo IX), 344 F.3d 1359, 1375 (Fed. Cir. 2003) (Rader, J., concurring) (“At the pace of these changes in fundamental patent law, the noble objective of bringing more certainty to the doctrine of equivalents nonetheless exacts a price in unintended consequences.”). Judge Rader also remarked that “the
many agree that there is still a long way to go, as the court's view of the patent law in several important areas is only slowly evolving, which has caused some concern and frustration.

Clients seek opinions from counsel, which requires an informed and experienced view as to what can reasonably be expected to occur under given circumstances and what rights can reasonably be relied upon to support a substantial investment of time, money, and resources. For the patent practitioner, it is vital to be able to predict with reasonable certainty the scope of patent claims of interest to the client and the enforceability of those claims.

This Article focuses on the Federal Circuit's jurisprudence in three very important areas of patent law where the court has struggled to settle several issues. We discuss the two key areas which impact predictability and claim scope: claim construction, a necessary first step in any infringement or validity analysis and which impacts every aspect of client representation; and the doctrine of equivalents, including of course the Supreme Court's and Federal Circuit's decisions in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Finally, we will discuss patent enforceability in the context of inequitable conduct, a defense perhaps all too frequently asserted by accused infringers.

I. CLAIM CONSTRUCTION

A. Background

The language of the asserted claims must be construed before any determination can be made regarding infringement or invalidation of the creation of new rules is itself disrupting the fundamental principle of certainty in the scope of patent claims.” Id. at 1376.

4 (Festo VIII), 535 U.S. 722 (2002); see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo IX), 344 F.3d 1359 (Fed. Cir. 2003); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo VI), 234 F.3d 558 (Fed. Cir. 2000) (en banc). Because of this case's lengthy procedural history, the different Festo decisions are often referred to as Festo I, Festo II, etc. The Festo decisions that are discussed in this article will be referred to as Festo VI, Festo VIII, and Festo IX.

5 Although not discussed in detail here, two other developments at the Federal Circuit are worth noting. In Knorr-Bremse Systeme Fuera Nutzfahrzeuge GMBH v. Dana Corp., 344 F.3d 1336, 1336 (Fed. Cir. 2003), the court announced that it will reexamine whether it is appropriate for a trier of fact to draw an adverse inference regarding willful infringement against an accused infringer who obtains legal advice but does not produce that advice during discovery, because the advice is protected by the attorney-client and/or work product privilege. Moreover, in Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 867 (Fed. Cir. 2003), the court held that the exemption in 35 U.S.C. § 271(e)(1) does not protect infringing activity that is related to the development of a new drug product which is not already on the market. The court held that the safe harbor in section 271(e)(1) only encompasses drug development activities that are necessary to acquire information for FDA approval of a patented pioneer drug which is already on the market. Id.
Claim interpretation is a matter of law that is entrusted to the trial judge and reviewed on appeal using the de novo standard of review. The importance of this determination cannot be emphasized enough, since "to decide what the claims mean is nearly always to decide the case." To interpret claims, a court "should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." The words in a claim are normally given the ordinary and customary or "plain" meaning that would be attributed to those words by persons skilled in the relevant art, absent a clear teaching of a different meaning within the patent specification or the prosecution history. Moreover, courts can use dictionaries to help determine the meaning that those skilled in the art would have attributed to a disputed claim term; a practical problem is which dictionary or dictionaries should be used, and what to do when conflicting definitions are found.

If the intrinsic evidence does not resolve the ambiguity regarding a disputed claim term, extrinsic evidence (e.g., learned treatises and expert and inventor testimony) may be relied upon to "explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history." Courts, however, may not rely upon such extrinsic evidence "for the purpose of varying or contradicting the terms of the claims," or, in essence, their "plain" meaning.

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6 Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc); see also Markman, 517 U.S. at 384 (noting patent construction is decided first as a matter of law, and infringement is then submitted as a question for the finder of fact); Rockwell Int'l Corp. v. United States, 147 F.3d 1358, 1362 (Fed. Cir. 1998) ("The first step in any invalidity or infringement analysis is claim construction.").
7 Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).
9 Vitronics Corp., 90 F.3d at 1582.
11 Tex. Digital Sys., Inc., 308 F.3d at 1202.
12 Markman, 52 F.3d at 980.
13 Id. at 981; see also Vitronics Corp., 90 F.3d at 1584-85 (stating that reliance on extrinsic evidence is improper where the meaning of a disputed term can be determined from the record itself).
B. Practitioner Perspectives: Recent Federal Circuit Cases Presenting Claim Construction Issues

In order to better understand how the Federal Circuit applies the rules of claim construction to particular sets of facts, the following sections discuss recent cases that involved claim construction issues.

1. E-Pass Technologies, Inc. v. 3Com Corp.\(^{14}\)

The proper construction of the term "electronic multi-function card" was at issue in *E-Pass*.\(^{15}\) The asserted claim covered a method of substituting an electronic multi-function card for various credit cards, thus reducing the number of cards that a consumer must carry around.\(^{16}\) The accused products were personal digital assistants sold under the "Palm Pilot" trademark.\(^{17}\)

The district court interpreted the disputed term to mean "a device having the width and outer dimensions of a standard credit card," and based its interpretation in part on the credit card industry's standard definition of the term "card."\(^{18}\) The district court reasoned that imposition of the size limitation was proper because the invention must utilize the existing interface requirements of check terminals—that is, the invention must fit into an ATM machine's slot so that its magnetic strip could be read.\(^{19}\)

The Federal Circuit concluded that the district court's claim construction was incorrect.\(^{20}\) The panel first noted that the ordinary dictionary meaning of the term "card" did not have any dimensional requirements.\(^{21}\) Next, the court stated that there was no justification for reading the credit card industry's size limitations into this term because there was no suggestion in the industry's standards that they should apply outside the area of credit cards.\(^{22}\) The panel then looked to the specification of the patent-in-suit and found that the patentee had not given that term a definition that was different from its ordinary meaning.\(^{23}\) The Federal Circuit also rejected the lower court's reasoning that imposition of the size

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\(^{14}\) 343 F.3d 1364 (Fed. Cir. 2003).
\(^{15}\) Id. at 1365.
\(^{16}\) Id.
\(^{17}\) Id. at 1366.
\(^{18}\) Id. The American National Standards Institute set forth length, height, and thickness dimensions for credit cards in 1971. Id.
\(^{19}\) Id. at 1369-70.
\(^{20}\) Id. at 1365.
\(^{21}\) Id. at 1367.
\(^{22}\) Id. at 1368.
\(^{23}\) See id. at 1369 (noting that the patentee had expressed a preferred embodiment rather than a precise definition).
limitation was necessary in order to effectuate interchangeability with check terminals, noting that the specification disclosed alternatives to the traditional magnetic stripe interface between the card and machines.\textsuperscript{24}

The Federal Circuit's decision illustrates the potential breadth that a term such as "card" may receive based on its dictionary definition, with no suggestion of any size limitation in the specification or file history. But it is surely understandable why the district court felt it necessary to interpret the disputed term as including a dimensional restriction, especially since the invention was meant to serve as a substitute for multiple credit cards. How could the patent practitioner have ever, in the \textit{E-Pass} case, been able to reasonably predict the Federal Circuit's view?

2. Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc.\textsuperscript{25}

In \textit{Anchor Wall}, the parties disputed the proper construction of the terms "back surface," "protrusion," "mate," and "generally parallel."\textsuperscript{26} The patents-in-suit generally disclosed and claimed interlocking features of masonry blocks that could be stacked to form retaining walls that resisted ground pressure without requiring any additional support structure.\textsuperscript{27}

The district court read additional limitations from the written description and the file history into the plain dictionary meanings of the terms "back surface," "protrusion," and "mate."\textsuperscript{28} On appeal, the Federal Circuit reversed the district court's claim construction of these terms, and held that the ordinary dictionary meaning of each term was the proper interpretation.\textsuperscript{29} The court stated that the plain meaning of a claim term should not be changed based on a statement in the specification or file history unless the different meaning is clearly and unmistakably set forth therein.\textsuperscript{30}

\begin{itemize}
\item \textsuperscript{24} \textit{Id.} at 1369-70.
\item \textsuperscript{25} 340 F.3d 1298 (Fed. Cir. 2003).
\item \textsuperscript{26} \textit{Id. at} 1305.
\item \textsuperscript{27} \textit{Id. at} 1301.
\item \textsuperscript{28} \textit{Id. at} 1307-10. Based on a statement in the specification, the district court interpreted the "back surface limitation to require a back surface 'spanning the full width of the block.'" \textit{Id. at} 1307. The district court also interpreted the term "protrusion" to require a central narrow portion, again based on a statement in the specification. \textit{Id. at} 1308. Finally, based on both the specification and file history, the lower court construed the term "mate" to include the following two limitations: (1) "a close confinement of the protrusion" and the insert; and (2) "an ability to secure the blocks in place in a forwards and backwards direction." \textit{Id. at} 1309.
\item \textsuperscript{29} \textit{Id. at} 1307-10. Specifically, the Federal Circuit held that the disputed terms have the following meanings: (1) a "back surface" is "a surface at the back of the block"; (2) a "protrusion" is "something that protrudes"; and (3) to "mate" is to "join or fit together." \textit{Id. at} 1307-09.
\item \textsuperscript{30} \textit{Id. at} 1306.
\end{itemize}
The district court interpreted the term "generally parallel" to mean parallel throughout.\(^3\) It read the word "generally" out of this term because it felt that parallelism is a mathematical concept that is either true or false, and therefore there could be no such thing as "generally parallel."\(^3\) The Federal Circuit reversed this construction, and held that some amount of deviation from exactly parallel is the proper interpretation of this term.\(^3\) The court noted that using words of approximation in patent claims is permissible.\(^3\)

This case illustrates how difficult it can be to decide whether or not a statement in the file history or specification should limit the ordinary meaning of a disputed term. In order to limit the plain meaning of a term, the specification or file history must clearly set forth a different definition. Furthermore, the Federal Circuit's acceptance here (again) of so-called words of approximation explains why patent prosecutors frequently use such terms to avoid a strict boundary to a specified parameter.

3. Cordis Corp. v. Medtronic AVE, Inc.\(^3\)

In Cordis, the parties disputed the proper interpretation of the following language that was present in every asserted claim: "wall surface having a substantially uniform thickness and a plurality of slots formed therein."\(^3\) The patents-in-suit claimed balloon-expandable coronary stents.\(^3\)

The district court held that the phrase "plurality of slots formed" was limited to stents "in which the slots are formed by the removal of the material" from the wall surface.\(^3\) The trial judge imposed this limitation in part because Figure 1A was not included in the specifications of the patents-in-suit.\(^3\) Figure 1A disclosed a stent whose slots were formed by bending wire, not removing material, and was included in the specification of a patent that was the parent of one of the patents-in-suit.\(^3\) Thus, the lower court reasoned that the exclusion of Figure 1A, which disclosed slots formed by the non-removal of material, clearly limited the mean-

\(^{31}\) Id. at 1311 (defining "parallel" as "everywhere equal distant").
\(^{32}\) Id. at 1310.
\(^{33}\) Id. at 1311.
\(^{34}\) Id. at 1310-11.
\(^{35}\) 339 F.3d 1352 (Fed. Cir. 2003).
\(^{36}\) Id. at 1356.
\(^{37}\) Id. at 1354.
\(^{38}\) Id. at 1356.
\(^{39}\) Id. at 1357-58.
\(^{40}\) Id.
The Federal Circuit disagreed, and held that the “plurality of slots” can be formed by means other than by removing material from a wall surface, such as by constructing the wall with openings already built into it. The panel first noted that the plain meaning of the disputed phrase does not suggest by what process the slots must be made. Next, the court stated that nothing in the specifications contradicted this plain meaning. The panel held that Cordis’ decision not to include Figure 1A in the patents-in-suit did not mean that the asserted claims could not encompass slots created by bending wire (i.e., the non-removal of material). Indeed, the Federal Circuit remarked that Cordis probably decided not to include Figure 1A in its subsequent applications because Figure 1A’s wall surface was not of substantially uniform thickness, an essential limitation of the patents-in-suit. Moreover, the court held that nothing in the prosecution history showed that the patentee relied on the method of manufacturing the slots as a means of distinguishing the invention from the prior art.

The district court also interpreted the term wall surface having a “substantially uniform thickness” to require that the thickness of the wall surface not vary by 0.001 inch or more. The trial judge based this limitation on the patentee’s statement, during the reexamination of one of the patents-in-suit, that the wall thickness of the stent disclosed in the Ersek patent varied at different points and ranged from a minimum of 0.0035 inches to a maximum of 0.0045 inches, a difference of 0.001 inches. Based on these statements, the lower court ruled that the asserted claims did not include wall surfaces that varied in thickness by 0.001 inch or more.

The Federal Circuit reversed this interpretation. It first noted that the term “substantially” normally means “approximately,” and that, therefore, the ordinary meaning of “wall surface with a ‘substantially uniform thickness’” is that the walls must be of approximately uniform thickness. The court next held that

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41 Id.
42 Id. at 1356-57.
43 Id.
44 See id. at 1356-60 (construing the claim in part based on the prosecution history).
45 Id. at 1358.
46 Id.
47 Id. at 1358-60.
48 Id. at 1360.
49 Id. at 1360-61.
50 Id. at 1360.
51 Id. at 1362.
52 Id. at 1360-61 (quoting Antonsson Aff. ¶ 10).
there had not been a "clear and unmistakable disclaimer" based on
the patentee's remarks regarding the Ersek patent.\[^{53}\] It also noted
that Cordis did not distinguish the Ersek patent because the walls
of that patent varied in thickness.\[^{54}\] Instead, Cordis distinguished
that reference because "Ersek's walls were at least twice as thick
at the intersections of [the] strands as along the strands them-
selves."\[^{55}\] The panel held that, at best, the patentee's statements
were ambiguous, and as such could not constitute a "clear and un-
mistakable disclaimer."\[^{56}\]

Here, again, the Federal Circuit refused to read any limita-
tions into the claims from the specification or prosecution history
absent a clear directive to do so. As explained above, even an am-
biguous statement by a patentee does not limit the claims. The
disclaimer or different definition must be clearly set forth in the
specification or file history. The problems that Cordis encountered
because of its remarks regarding the Ersek patent should motivate
patent prosecutors to exercise care in what is said regarding prior
art references in order to avoid an adverse impact on claim inter-
pretation, as well as infringement under the doctrine of equiva-

tents.

4. Integra Lifesciences I, Ltd. v. Merck KGaA\[^{57}\]

In Integra, the parties disputed the meaning of the term "pep-
tide."\[^{58}\] The invention disclosed and claimed short peptide se-
quences that promoted cell adhesion to substrates in culture and in
vivo, and had the clinical potential to promote wound healing and
biocompatibility of prosthetic devices.\[^{59}\]

Merck, the accused infringer, argued that the district court
erred in construing the term peptide to embrace both linear and
cyclic peptides.\[^{60}\] It noted that the patents-in-suit did not expressly
refer to cyclic configurations.\[^{61}\] Moreover, Merck contended that a
statement made by the patentee during the prosecution of an unre-
lated application—that some of the patents-in-suit did not teach
cyclic peptides—further justified limiting the term peptide to only
linear peptides.\[^{62}\]

\[^{53}\] id. at 1361.
\[^{54}\] id.
\[^{55}\] id.
\[^{56}\] id.
\[^{57}\] 331 F.3d 860 (Fed. Cir. 2003).
\[^{58}\] id. at 868.
\[^{59}\] id. at 862-63.
\[^{60}\] id. at 868.
\[^{61}\] id.
\[^{62}\] id. at 868-69.
The Federal Circuit affirmed the district court’s interpretation and rejected both of Merck’s arguments. It first noted that the ordinary meaning of the term peptide “encompasses peptides of differing structural forms.” The court also stated that the specifications embrace both cyclic and linear forms, despite the fact that the patents did not expressly refer to cyclic peptides. Moreover, the court rejected Merck’s attempt to exclude cyclic forms based on the patentee’s statement that certain of the patents-in-suit do not teach cyclic peptides. The court noted that there was no basis in law to limit the asserted claims because the remark was made during the prosecution of an application unrelated to any of the patents-in-suit. Further, the court held that the alleged “admission” was ambiguous at best, and presumably did not evidence a clear disavowal of claim scope.

This case illustrates the breadth often given to claim terms based on their ordinary meaning to persons skilled in the art. Here, the fact that the specifications did not mention cyclic peptides was of no moment because Integra introduced evidence that those skilled in the art knew that the claimed peptide sequences existed on cyclic peptides.

C. Practitioner Perspectives: The Axiom That Courts Should Construe Claims to Preserve Their Validity

The axiom that claims should be construed, if possible, to sustain their validity is well-settled. However, “if the only claim construction that is consistent with the claim’s language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid.”

Surprisingly, this axiom is often relied upon by accused infringers to limit the potential breadth of claim terms during Markman determinations. In Karsten Manufacturing Corp. v. Cleveland Golf Co., the Federal Circuit described the opposing arguments
that patentees and accused infringers typically assert which impli-
cate this axiom:

The jurisprudence of claim construction reflects the difficult
balance between a patentee’s exhortation that courts should
read claims broadly and unlimited to the specific embod-
iments shown in the specification, and the rule that claims
should be construed sufficiently narrowly to preserve their
validity. In counterpart, an accused infringer often argues, as
in this case, that if the claims are read sufficiently broadly as
to reach the accused device, the claims also read on the prior
art and are invalid.\(^\text{72}\)

Moreover, an accused infringer may also argue that a pat-
etee’s proposed (broad) construction of a term renders a claim
invalid because under that interpretation the claim would fail to
satisfy the requirements of 35 U.S.C. \(\text{§} 112.\)\(^\text{73}\)

Therefore, a two-pronged argument that a claim should be
construed (narrowly) to preserve its validity or that a claim is inva-
lid under a patentee’s proposed (broad) interpretation is often a
powerful weapon in an accused infringer’s arsenal. These com-
plimentary arguments are frequently asserted in litigation and pro-
vide an excellent way to limit the potential breadth given to a dis-
puted term. On the other hand, a patentee can possibly defeat this
attack on the breadth of its claims by arguing that the invalidity
concerns are unclear or prematurely considered at the claim con-
struction stage.\(^\text{74}\)

II. THE DOCTRINE OF EQUIVALENTS

A patentee can prove infringement either literally or under the
doctrine of equivalents. Literal infringement of a claim exists
“when the properly construed claim reads on the accused device
exactly.”\(^\text{75}\) Conversely, an accused device that does not literally
infringe may still infringe under the doctrine of equivalents if each
limitation not already literally present in an accused device is

\(^{72}\) \textit{Id.} at 1384.

\(^{73}\) See 35 U.S.C. \(\text{§} 112\) (2000); \textit{Wang Labs., Inc.}, 197 F.3d at 1383 (affirming the district
court’s decision to limit the term “frame” to only cover character-based protocols because the
requirements of section 112 were not met as to other protocols); \textit{Genentech, Inc. v. Wellcome
Found., Ltd.}, 29 F.3d 1555, 1564-65 (Fed. Cir. 1994) (affirming the lower court’s decision to
construe a disputed term narrowly because the patentee’s other proposed interpretations were
“hopelessly overbroad” and raised enablement, written description, and definiteness concerns).

\(^{74}\) See, e.g., \textit{Rhine}, 183 F.3d at 1346 (rejecting as premature the accused infringers’ argu-
ment that a proposed construction renders a claim obvious).

\(^{75}\) \textit{Strattec Sec. Corp. v. Gen. Auto. Specialty Co.}, 126 F.3d 1411, 1418 (Fed. Cir. 1997)
(emphasis added).
equivalently present in that device. Thus, pursuant to the doctrine of equivalents the scope of a patent is not limited to its literal terms because it also embraces all equivalents to the claims described.

This doctrine was developed to prevent avoiding infringement by making insubstantial changes to a patented invention. The "triple identity" test is one that has been developed to determine equivalency between a claimed element and an accused product or process. Because the issues of infringement and equivalence are questions of fact normally tried to a jury, the doctrine of equivalents can be a very powerful weapon for patentees.

In an effort to ensure a reasonable and equitable application of the doctrine of equivalents, numerous checks on its appropriateness have developed over time. Limitations on the doctrine, including estoppel, the all elements rule, and dedication of unclaimed matter, have received recent attention from the Federal Circuit.

A. Prosecution History Estoppel

Prosecution history estoppel "can occur as a result of (i) amendments made to overcome patentability rejections or (ii) arguments made during prosecution that show 'a clear and unmistakable surrender of subject matter.'" The former form of estoppel, which is based on claim amendments, has been the subject of

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77 See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo VIII), 535 U.S. 722, 732 (2002) (stating that literal patent interpretation would enable unsubstantial substitutes to defeat a patent, thus defeating the value of the patent to inventors).
78 Id. at 731 ("[I]f patents were always interpreted by their literal terms, their value would be greatly diminished.").
79 Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 (1997); see also MODEL PATENT JURY INSTRUCTIONS § 8.3 (1998) (stating that either literal infringement or infringement under the doctrine of equivalents must be present in a claim). This test compares the claimed element and accused product (or process), and looks at whether or not there are substantial differences between the functions served by each, the way that each serve that function, and the result obtained by each. Warner-Jenkinson Co., 520 U.S. at 39. If the differences are insubstantial, the claimed element is equivalently present in the accused product or process. Id.
80 See Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1467 (Fed. Cir. 1998) (Mayer, C.J., concurring) ("To determine the scope of such equivalents, the district court must resolve questions of fact by resorting to the expertise of the fact finder."); Fromson v. Anitec Printing Plates, Inc., 132 F.3d 1437, 1446 (Fed. Cir. 1997) ("Equivalency is a question of fact, and findings thereon are reviewed for clear error."); Strattec Sec. Corp., 126 F.3d at 1416 ("A determination of whether the properly construed claims encompass the accused structure "is a question of fact, to be submitted to a jury.").
much controversy in recent years.\textsuperscript{82} It limits the doctrine of equivalents by denying a patentee any equivalents to a claim limitation whose scope was narrowed during prosecution for reasons related to patentability.\textsuperscript{83} This form of estoppel thus “requires that the claims of a patent be interpreted in light of the proceedings in the PTO [Patent and Trademark Office] during the application process.”\textsuperscript{84} The Supreme Court described the rationale behind amendment-based estoppel as follows:

A rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim. . . . Were it otherwise, the inventor might avoid the PTO’s gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent.\textsuperscript{85}

The test for determining whether there is estoppel is as follows. First, there must have been a limiting amendment during the prosecution of the patent.\textsuperscript{86} If there was a limiting amendment, then a court must look at why the patentee amended the claim to add the limitation, because estoppel only applies to amendments that were made for a substantial reason related to patentability.\textsuperscript{87} The burden is on the patentee to explain why the amendment was not related to patentability.\textsuperscript{88} In other words, if the patentee fails to explain why an amendment was not substantially related to patentability, then a court must presume that it was.\textsuperscript{89} In order to reinforce the public notice function served by the prosecution history record, a patentee may only rely upon that record to rebut the Warner-Jenkinson presumption that an amendment was made for a reason related to patentability.\textsuperscript{90} Assuming that the patentee fails to explain why the amendment was not related to patentability, he or she may be estopped from asserting infringement of the

\textsuperscript{82} Because the following sections discuss only amendment-based estoppel, the subsequent use of the term “prosecution history estoppel” refers only to amendment-based estoppel, unless otherwise indicated.

\textsuperscript{83} Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1356 (Fed. Cir. 2003).


\textsuperscript{85} Id. at 734.

\textsuperscript{86} Pioneer Magnetics, Inc., 330 F.3d at 1356.


\textsuperscript{88} Id.

\textsuperscript{89} Id.

\textsuperscript{90} Pioneer Magnetics, Inc., 330 F.3d at 1356.
amended limitation under the doctrine of equivalents. The scope of that estoppel, i.e., what range of equivalents, if any, is still available, is the subject of the following sections.

1. Recent Developments: The Supreme Court's Decision in Festo VIII

In Festo VIII, the Supreme Court considered the proper scope of prosecution history estoppel and what types of narrowing amendments might give rise to that estoppel. The Court's decision in Festo VIII was widely anticipated within the patent community because of the Federal Circuit's controversial decision below in Festo VI. Two main issues were presented at both levels of appellate review.

a. What Narrowing Amendments Give Rise to Estoppel

In Warner-Jenkinson Co. v. Hilton Davis Chemical Co., the Supreme Court stated that prosecution history estoppel would apply to any limiting amendment that "had a substantial reason related to patentability." Although the Court clearly implied that amendments to avoid prior art rejections under 35 U.S.C. § 102 or obviousness rejections under section 103 would be substantially related to patentability, it did not define that term or catalog every reason that might raise any estoppel issue. Thus, the applicability of prosecution history estoppel to other limiting amendments, for example those made to comply with 35 U.S.C. § 112, was unclear.

In Festo VI, an en banc Federal Circuit tried to answer this question. It held that an amendment that narrows the scope of a claim for "any reason related to the statutory requirements for a patent will give rise to prosecution history estoppel." Thus, no longer was prosecution history estoppel limited to amendments that were made to overcome prior art rejections under sections 102 and 103, but estoppel would also now apply to narrowing amendments that were made to satisfy other patentability requirements, such as those under section 112. The Federal Circuit further held

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91 Id. at 1356-57.
94 Id. at 30-33 (stating that it saw no substantial reason to upset the current role).
95 See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo VI), 234 F.3d 558, 566-67 (Fed. Cir. 2002) (en banc) (stating that there are numerous statutory requirements that must be met before the issuance of a patent, and thus that relate to patentability).
96 Id. at 563.
97 Id. at 566-67 (35 U.S.C. § 112 requires that the patent application describe, enable and
that voluntary claim amendments would be given the same effect as amendments that were required by the PTO, thus establishing that both types of amendments could give rise to estoppel.\textsuperscript{98}

The Supreme Court agreed with the Federal Circuit that “a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.”\textsuperscript{99} The Court reasoned that the enablement, best mode, and written description requirements in section 112 must be satisfied before an application will be allowed to issue as a patent.\textsuperscript{100} Thus, a limiting amendment made to comply with section 112’s requirements clearly is substantially related to patentability.\textsuperscript{101}

\textbf{b. What Is the Scope of the Estoppel?}

The most controversial part of the Federal Circuit’s decision in \emph{Festo VI} was its holding that prosecution history estoppel is a complete per se bar against any range of equivalents for a narrowed claim element.\textsuperscript{102} In other words, the Federal Circuit established a bright-line rule that the scope of the estoppel for a narrowed claim element would be total, and that the narrowed element must be limited to its strict literal terms.\textsuperscript{103} Prior to \emph{Festo VI}, two divergent lines of Federal Circuit cases answered this question differently. One line of cases followed a strict approach of complete surrender and limited the patentee to no equivalents based on the estoppel, while the other line of cases adopted a flexible bar approach.\textsuperscript{104} The court reasoned that the new complete bar approach best served the notice function of the claims and reduced the public’s need to speculate as to the subject matter surrendered by an amendment.\textsuperscript{105}

The Supreme Court rejected this bright line rule, and held that a determination of the scope of estoppel requires an examination of the subject matter surrendered by the narrowing amendment, i.e., it must be done on a case-by-case basis.\textsuperscript{106} Under the framework established by the Supreme Court, courts must now presume

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\textsuperscript{98} \textit{Id.} at 568.


\textsuperscript{100} \textit{Id.}

\textsuperscript{101} \textit{Id.} at 735-37.

\textsuperscript{102} \textit{Festo VI}, 234 F.3d at 569.

\textsuperscript{103} \textit{Id.}

\textsuperscript{104} \textit{Id.} at 573.

\textsuperscript{105} \textit{Id.} at 576-77.

\textsuperscript{106} \textit{See Festo VIII}, 535 U.S. at 737-41 (stating that a per se rule prevents an inquiry into and examination of the subject matter surrendered by the narrowing amendment).
that a patentee surrendered the particular equivalent in question if he or she made a narrowing amendment for a purpose relating to patentability.\textsuperscript{107} The patentee can rebut this presumption if he or she can show that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."\textsuperscript{108} The Court provided some examples of situations where an estoppel should not be found:

There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.\textsuperscript{109}

2. Recent Developments: The Federal Circuit’s Decision in Festo IX on Remand from the Supreme Court

The Federal Circuit recently issued a decision in \textit{Festo IX} after the Supreme Court remanded that case. The sole issue before the court was whether Festo, the patentee, could rebut the presumption that it lost all equivalents between the original and amended claim limitations.\textsuperscript{110} The Federal Circuit considered the three examples that the Supreme Court set forth by which a patentee might rebut this presumption, and explained the types of evidence that may be considered for each.\textsuperscript{111} The court held that, as applied to the facts at hand, Festo could not rebut the presumption by arguing that the narrowing amendments bore no more than a tangential relation to the accused equivalents or that there was some other reason that it could not reasonably have been expected to describe the accused equivalents.\textsuperscript{112} The court did, however, remand the case to the district court to allow Festo to rebut the presumption by showing that the equivalents would have been un-

\textsuperscript{107}Id. at 740.
\textsuperscript{108}Id. at 741.
\textsuperscript{109}Id. at 740-41.
\textsuperscript{110}Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo IX), 344 F.3d 1359, 1363 (Fed. Cir. 2003).
\textsuperscript{111}Id. at 1368-70.
\textsuperscript{112}Id. at 1363.
foreseeable to one of ordinary skill at the time of the amendments. 113

The Federal Circuit first held that rebuttal of the presumption of surrender is a question of law to be decided by a court. 114 Even though rebuttal of that presumption may be subject to underlying facts, the Federal Circuit felt that lower courts could properly resolve these facts in making the ultimate determination as a matter of law regarding estoppel. 115

The court then considered the three ways identified by the Supreme Court whereby a patentee may overcome the presumption that it surrendered the scope of equivalents between the original and amended claim limitations. 116 Even though it declined to discuss the relevant factors encompassed by each of the rebuttal criteria, the court did provide some general guidance. 117

The court first addressed the rebuttal criterion that allows a patentee to show that an alleged equivalent would have been “unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered.” 118 It stated that this “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.” 119 Because this inquiry depends on underlying factual issues relating to the state of the art and the understanding of a person ordinarily skilled in the art, the Federal Circuit noted that lower courts may hear expert testimony and consider extrinsic evidence as to these issues. 120

The court next considered the criterion that requires a patentee to show that “the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question.” 121 It remarked that the plain meaning of this inquiry is “whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.” 122 Importantly, the court noted that only the prosecution history record may be used by a patentee to prove the reason for the amendment. 123 Ex-

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113 Id. at 1364.
114 Id. at 1368.
115 Id. The court noted that judges consider underlying factual issues in the area of claim construction, which is also a matter of law to be determined by a court. Id. at 1368 n.3.
116 Id. at 1368-70.
117 Id.
118 Id. at 1369 (quoting Festo Corp. v. Shoketsu Kinzoku Kabushiki Co. (Festo VIII), 535 U.S. 722, 738 (2002)).
119 Id.
120 Id.
121 Id. (quoting Festo VIII, 535 U.S. at 740).
122 Id.
123 Id.
trinsic evidence should only be considered, as necessary, to help interpret that record.\(^{124}\)

Finally, the court considered the third criterion that requires a patentee to show "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question."\(^{125}\) While noting that this category must be narrow, the court said that it may be satisfied "when there was some reason, such as the shortcomings of language, why the patentee was prevented from describing the alleged equivalent when it narrowed the claim."\(^{126}\) The court also stated that determination of this criterion should be limited to the prosecution history record, although it left open the possibility that evidence outside that record may be considered in this inquiry.\(^{127}\)

3. *Practitioner Perspectives: The Impact of Festo VI, VIII, and IX*

The Supreme Court's decision was a victory for patentees because it reversed the complete bar established by the Federal Circuit. In theory, some range of equivalents between the originally claimed element and the narrowed element should be available. In reality, the rebuttable presumption that a patentee surrendered all equivalents will make it very difficult to capture any equivalents beyond the literal scope of the amended claim element when the reason for the amendment was not explained.

Because the determination of prosecution history estoppel is a matter of law for courts to determine,\(^{128}\) courts may make pretrial determinations regarding whether there is estoppel, and if so, what the scope of that estoppel is.\(^{129}\) These determinations can be made in the context of a *Markman* ruling or motion for partial summary judgment.\(^{130}\) There is no doubt, however, that pretrial resolution of the estoppel issue will enhance judicial economy.

Finally, there is the issue of what types of evidence a patentee should use to rebut the presumption that estoppel bars a claim of equivalence. The Federal Circuit's decision in *Festo IX* implies that a patentee can only establish the second and third criteria by

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\(^{124}\) Id. at 1370.

\(^{125}\) Id. (quoting Festo VIII, 535 U.S. at 741).

\(^{126}\) Id.

\(^{127}\) Id.

\(^{128}\) See Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1356 (Fed. Cir. 2003) (explaining that prosecution history estoppel is a question of law reviewed by the courts).


\(^{130}\) See id.
using the prosecution history record. Although leaving open the possibility that extrinsic evidence may be used to prove these examples, the general rule established by the court will make these examples hard to establish. Because the Federal Circuit did allow for extrinsic and expert testimony regarding whether the alleged equivalent was unforeseeable, this category should be easier to establish.

Because the holdings in all the Festo decisions apply retroactively, there is little that can be done to resolve problems with issued patents. There are, however, several measures that prosecutors can take to help their clients avoid any estoppel with respect to future patents. Attorneys can draft and file claims that are reasonable in scope in view of the disclosure, avoiding broad claim language that is difficult to support under section 112. The plain objective is to avoid the need for limiting amendments. Moreover, the need to file narrowing amendments might be avoided if the application includes many independent claims of varying breadth—that is, claims over the entire spectrum. Here, one would hope that at least one of the claims would be unobjectionable, and thus issue without having to be amended.

In the event that an amendment must be made, the attorney should take several steps to minimize the effect of that amendment. The prosecutor should make clear what elements are being amended, since estoppel will only be found for those elements that are narrowed. One can separate the different elements by semicolons, for example, to clearly illustrate what elements have been amended. Moreover, an attorney should also explain the reason for making an amendment, and clearly describe what subject matter, if any, is being relinquished.

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131 See Festo IX, 344 F.3d at 1370 ("When at all possible, determination of the third rebuttable criterion should also be limited to the prosecution history record.").
132 Id.
133 Id. at 1369.
134 Id. at 1370 n.4 ("Consistent with Supreme Court precedent, the holdings of that Court and our own regarding the Festo presumption of surrender and its rebuttal apply to all granted patents and to all pending litigation that has not been concluded with a final judgment, including appeals.").
135 Benassi & Kjelland, supra note 129, at 306.
136 See id. (noting that the narrower the claim, the more likely it is that the examiner will allow it without requiring additional amendments).
137 Id.
138 See id. at 306-07.
139 Id.
140 Id. at 311.
B. The All Elements Rule

The all elements rule serves as another check upon the doctrine of equivalents. Under this rule, "there can be no infringement under the doctrine of equivalents if even one element of a claim or its equivalent is not present in the accused device." In other words, every claim element must be present in the accused device either literally or equivalently, because the doctrine of equivalents must be applied to the individual elements of the claim, not the invention as a whole. Therefore, "if a court determines that a finding of infringement under the doctrine of equivalents 'would entirely vitiate a particular claim element,' then that court should rule that there is no infringement under the doctrine of equivalents."

Practically speaking, the all elements rule is another powerful weapon that accused infringers can use to combat the doctrine of equivalents. It prevents the patentee, in essence, from removing limitations from the claims during the equivalency analysis. If presented with a situation where a claim element is undisputedly not present in the accused device, then no infringement under the doctrine of equivalents is possible. Moreover, the Federal Circuit recently indicated that it may rely upon the all elements rule to decide cases that were remanded to that court after the Supreme Court decided Festo VIII.

C. Public Dedication of Unclaimed but Disclosed Equivalents

In Johnson & Johnson Associates, Inc. v. R.E. Service Co., the Federal Circuit considered whether or not a patentee may capture, under the doctrine of equivalents, an unclaimed equivalent that was nonetheless disclosed in the patent. The patentee's invention was an assembly that prevented damage during assembly of printed circuit boards. Part of that assembly included a protective substrate. Although the specification stated that many
metals, including steel, may be used as the protective substrate, the claims only covered aluminum.150 Because the accused product used steel as the substrate, Johnson & Johnson argued that steel was equivalent to aluminum, and therefore infringed under the doctrine of equivalents.151

The patentee and accused infringers in Johnson & Johnson argued that divergent lines of Federal Circuit case law supported their respective positions.152 The accused infringers relied upon the court’s decision in Maxwell v. J. Baker, Inc.,153 where the court noted the established rule that “subject matter disclosed but not claimed in a patent application is dedicated to the public.”154 Johnson & Johnson argued that the Federal Circuit’s decision in YBM Magnex, Inc. v. International Trade Commission155 controlled, where the court stated that Maxwell did not create a new rule of law that the doctrine of equivalents could never encompass subject matter disclosed but not claimed.156

After hearing the case en banc, the Federal Circuit held that Johnson & Johnson could not invoke the doctrine of equivalents to extend its aluminum limitation to cover steel, since it disclosed but did not claim steel substrates.157 Thus, whenever “a patent drafter discloses but declines to claim subject matter, this action dedicates that unclaimed matter to the public.”158 The court reasoned that its decision would benefit the public because it would be able to better predict which equivalents inventions might encompass.159 Moreover, the court’s result was based on the notion that a patentee has an obligation to draft claims that capture all reasonably foreseeable ways of practicing his or her invention.160 Finally, the Federal Circuit also overruled YBM Magnex to the extent that it conflicted with the court’s current holding.161

The result in Johnson & Johnson therefore provides yet another defense to accused infringers against infringement under the doctrine of equivalents. Patent prosecutors will now be well-

150 Id. at 1049-50.
151 Id. at 1050-51.
152 Id. at 1051.
153 86 F.3d 1098 (Fed. Cir. 1996).
154 Id. at 1106 (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562-63 (Fed. Cir. 1991)).
155 145 F.3d 1317 (Fed. Cir. 1998).
156 Id. at 1322.
157 Johnson & Johnson Assoc., Inc., 285 F.3d at 1055.
158 Id. at 1054.
159 Id. at 1056-57 (Rader, J., concurring).
160 Id. at 1057 (Rader, J., concurring).
161 Id. at 1055.
advised to make sure that they claim every manner of practicing the invention that is disclosed in the specification.

III. INEQUITABLE CONDUCT

A. Background

Inequitable conduct can result in the unenforceability of a patent right when certain individuals associated with a patent's prosecution violate a duty of candor by intentionally disclosing, failing to disclose, or misrepresenting certain material information to the PTO. Every patent applicant has "a duty to disclose information that is material to the patentability of an invention." A breach of this duty can take several forms: an affirmative misrepresentation of a material fact, a failure to disclose material information, or submission of false, material information.

Based upon a recent Federal Circuit ruling in Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., the test for establishing inequitable conduct now involves in essence a three-part analysis. The party asserting the defense must show by clear and convincing evidence that the patent applicant failed to disclose or misrepresented "material" information to the PTO, and second, that this was done with an intent to deceive or mislead the PTO.

Once a party makes the initial threshold showings of materiality and intent, the court must then weigh the materiality and intent in light of all the circumstances and make a discretionary judgment regarding whether or not the patent should be rendered unenforceable. In other words, a district court "must determine whether the equities warrant a conclusion that the patentee has engaged in inequitable conduct." In making this equitable determination and in weighing the degrees of materiality and intent, the showing of intent can be proportionally less when balanced against high materiality. As alluded to above, a party who breaches its duty of candor, i.e., commits inequitable conduct, forfeits its right under any resulting patents in part because the party’s conduct harms both the PTO and the public.

163 Id. at 846.
164 Bristol-Myers Squibb Co., 326 F.3d 1226, 1233 (Fed. Cir. 2003) (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)).
165 Id.
166 Id. at 1234.
168 Bristol-Myers Squibb Co., 326 F.3d at 1234.
169 See Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1383
The Federal Circuit reviews a lower court’s findings of fact regarding materiality and intent for clear error, and reviews the ultimate determination of inequitable conduct under an abuse of discretion standard.170

With such a three-part test, and particularly with the element of “balancing the equities,” how does a patent practitioner reasonably opine on patent enforceability?

B. A Brief History of Inequitable Conduct at the Federal Circuit

Early in its history, the Federal Circuit “showed itself quite willing to substitute its assessment of the equities of a case for that of the trial court.”171 Because of this, the number of inequitable conduct defenses raised in patent infringement suits rose significantly, prompting Senior Circuit Judge Nichols to remark that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”172 At that time, the Federal Circuit viewed the ultimate question of whether inequitable conduct had occurred as a question of law, making appeal of this issue more attractive to accused infringers because of the less deferential standard of review.173

Realizing that the standard of review was exacerbating the problem, in Kingsdown Medical Consultants, Ltd. v. Hollister Inc.174 an en banc Federal Circuit held that it would hereinafter review inequitable conduct determinations using an abuse of discretion standard.175 In an apparent attempt to further discourage future parties from raising this issue on appeal, the court remarked that “[w]e, accordingly, will not simply substitute our judgment for that of the trial court in relation to inequitable conduct.”176

170 Bristol-Myers Squibb Co., 326 F.3d at 1234.
171 Goldman, supra note 1, at 85.
172 Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).
173 Goldman, supra note 1, at 85; see Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 n.4 (Fed. Cir. 1984) (discussing the “but it may have” inquiry); see also In re Jerabek, 789 F.2d 886, 890 (Fed. Cir. 1986) (stating that a balancing test is required for determining if inequitable conduct exists).
174 863 F.2d 867 (Fed. Cir. 1988).
175 Id. at 876. The court relied upon the doctrine’s equitable roots to justify the standard of review that it adopted. Id.
176 Id.
PRACTITIONER PERSPECTIVES

C. Practitioner Perspectives: Attractiveness of the Inequitable Conduct Defense

Patent suits typically involve issues that are highly technical and possibly difficult for jurors and/or judges to understand.\(^\text{177}\) The defense of inequitable conduct, however, does not center on issues of technology, but instead focuses on human conduct and motivation.\(^\text{178}\) Given these facts, it is not surprising that practitioners favor raising the inequitable conduct defense because it is less technologically complex, more emotional, and presumably more comprehensible to the fact finder.\(^\text{179}\) This tactic is sometimes referred to as a “try the person rather than the patent” strategy.\(^\text{180}\)

D. Practitioner Perspectives: Materiality Under 37 C.F.R. § 1.56

The rules promulgated by the Commissioner of Patents and Trademarks set forth, inter alia, standards of conduct for patent attorneys and agents prosecuting patent applications before the PTO.\(^\text{181}\) Specifically, 37 C.F.R. § 1.56 (“Rule 56”) states that “[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability.”\(^\text{182}\) That rule also defines when information is “material” to patentability, and further defines who is “associated with the filing or prosecution of a patent application” and is therefore under a duty to disclose material information.\(^\text{183}\)

Although Rule 56 “binds anyone practicing before the PTO, it does not control a court’s determination of whether inequitable conduct has occurred.”\(^\text{184}\) Specifically, the definition of material-

\(^\text{177}\) Kenneth R. Adamo, Recent Developments in Inequitable Conduct/The (Statutory) Duty of Disclosure/“Fraud” on the P.T.O., 73 J. PAT. & TRADEMARK OFF. SOC’Y 110, 119 (1991). Although the trial judge makes the ultimate determination on the inequitable conduct issue, a jury can function in an advisory role. Id. (“Where a jury is demanded, it is usual to let it function in an advisory capacity as to that issue, with its finding providing basis for the trial judge’s ruling.”).


\(^\text{179}\) Adamo, supra note 177, at 119.

\(^\text{180}\) Chisum, supra note 178, at 279.


\(^\text{182}\) 37 C.F.R. § 1.56(a) (2002).

\(^\text{183}\) 37 C.F.R. § 1.56(b)-(c) (2002).

\(^\text{184}\) Von Tersch, supra note 181, at 425.
ity in Rule 56 is only an "appropriate starting point for any discus-
sion of materiality, for it appears to be the broadest."\textsuperscript{185}

Around the time that the Federal Circuit was deciding to
change the applicable standard of review in \textit{Kingsdown}, the patent
bar "engaged in a concerted effort to change the standard of mate-
riality to make the inequitable conduct defense more difficult to
assert."\textsuperscript{186} That effort "culminated in a major revision of Rule 56
that took effect in March 1992."\textsuperscript{187} The pre-March 1992 version of
Rule 56 provided, in pertinent part, that "information is material
where there is a substantial likelihood that a reasonable examiner
would consider it important in deciding whether to allow the
application to issue as a patent."\textsuperscript{188} The post-March 1992 version of
Rule 56 provides, inter alia, that:

\begin{quote}
[I]nformation is material to patentability when it is not cumu-
lative to information already of record or being made of re-
cord in the application, and
\begin{enumerate}
\item It establishes, by itself or in combination with other
information, a prima facie case of unpatentability of a
claim; or
\item It refutes, or is inconsistent with, a position the appli-
cant takes in:
\begin{enumerate}
\item Opposing an argument of unpatentability relied
on by the Office, or
\item Asserting an argument of patentability.\textsuperscript{189}
\end{enumerate}
\end{enumerate}
\end{quote}

If the new definition of material information in revised Rule 56 is adopted by the courts, then the corresponding narrower duty
to disclose should make the defense of inequitable conduct more
difficult to establish.\textsuperscript{190} In fact, many people felt that "the PTO is
using its new rule to exhort the Federal Circuit to adopt a particu-
lar legal definition of inequitable conduct."\textsuperscript{191} Many commentators
debated the issue of whether or not the change in Rule 56 would
work a corresponding change in the law of inequitable conduct.\textsuperscript{192}

\begin{footnotes}
\textsuperscript{185} Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984).
\textsuperscript{186} Goldman, \textit{supra} note 1, at 88.
\textsuperscript{187} Id.
\textsuperscript{188} 37 C.F.R. § 1.56(b) (1991).
\textsuperscript{189} 37 C.F.R. § 1.56(b) (2002).
\textsuperscript{190} Anderson, \textit{supra} note 162, at 864-65.
\textsuperscript{191} R. Carl Moy, \textit{The Effect of New Rule 56 on the Law of Inequitable Conduct}, 74 J. PAT.
\textsuperscript{192} See id. at 259 (noting both sides of the debate and concluding that the change would
likely not work a corresponding change in the law of inequitable conduct). Compare Anderson,
\textit{supra} note 162, at 894 ("The courts should welcome the new standard for inequitable conduct,
which offers a narrower standard.") with Chisum, \textit{supra} note 178, at 296 ("It is not certain
that the courts will adopt the altered PTO Rule 56 standard for the inequitable conduct defense,

Unfortunately, the effect of Rule 56’s change on the law of inequitable conduct remains unclear. The Federal Circuit’s clearest statement on this issue came in *Dayco Products, Inc. v. Total Containment, Inc.* In *Dayco*, three of the patents-in-suit were filed and prosecuted after the 1992 revision to Rule 56 came into effect. The district court decided the case under the post-1992 standard of materiality.

The Federal Circuit struggled with what effect, if any, the change in Rule 56 has on the applicable standard for inequitable conduct. The court stated that it “has not decided whether it should adhere to the preexisting standard for inequitable conduct in prosecutions occurring after the effective date of the new [PTO] rule.” The court did note, however, that its power to declare patents unenforceable because of inequitable conduct is founded in equity, not the PTO’s regulations, thus suggesting that the change to Rule 56’s definition of materiality would not effectuate a similar change in the test for inequitable conduct. Ultimately, the *Dayco* court avoided directly answering the question regarding what effect, if any, revised Rule 56 has on the standard for materiality in inequitable conduct cases. Instead, the court held that the result of the appeal would be the same under either materiality standard. The panel’s reluctance to affirmatively restrict the inequitable conduct analysis to revised Rule 56’s definition of materiality is harmonious with an earlier statement by the Federal Circuit that revised Rule 56 “was not intended to constitute a significant substantive break with the previous standard.”

From a practitioner’s perspective, the Federal Circuit’s reluctance to affirmatively endorse any one definition of materiality compels certain precautionary measures. For example, one should make all materiality determinations and arguments, both in prosecution and during litigation, under both pre- and post-1992 materi-

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which the courts recognized long before the adoption of the Rule 56 duty of candor in 1977.”).  
193 329 F.3d 1358 (Fed. Cir. 2003).  
194 Id. at 1364.  
196 *Dayco Prods., Inc.*, 329 F.3d at 1364.  
197 Id. at 1364 n.3 (“The court’s authority to render a patent unenforceable for inequitable conduct is founded in the equitable principle that ‘he who comes into equity must come with clean hands.’” (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945))).  
199 Id. at 1364.  
200 Id.  
201 *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).
alifi standards. Furthermore, should the different definitions of materiality somehow create confusion regarding whether there is a duty to disclose certain information, the applicant should err on the side of disclosure.

E. Practitioner Perspectives: Material Misrepresentations Concerning “Completed” Test Results

In the recent case of Hoffmann-La Roche, Inc. v. Promega Corp., the Federal Circuit affirmed a finding of inequitable conduct based on, inter alia, misrepresentations by the patentees concerning a purification protocol that was never performed, but was described using the past tense, indicating that the experiment had been conducted. The implications of this decision are wide-ranging, especially in the context of biotechnology and pharmaceutical patents, because examples (i.e., experiments) are frequently included in patents in these fields.

In Hoffmann-La Roche, the inventors represented to the PTO that they had (1) performed a certain experimental protocol (Example VI) to purify an enzyme; and (2) obtained certain results as a result of that experiment. In fact, the applicants had not performed that experiment even though it was written in the past tense. Moreover, the inventors argued for patentability in part based on the “results” of this experiment, when, in reality, they lacked sufficient evidence to substantiate their assertion. The district court found inequitable conduct on these facts.

On appeal, the Federal Circuit affirmed this ground on which the district court found inequitable conduct. The court found that such past tense language created a misrepresentation, in that “a reader of the patent would conclude that the . . . [results described] were actually achieved.” In examining the use of the past tense in light of the knowledge that the tests had never actually been conducted as represented, the Federal Circuit concluded

204 323 F.3d 1354, 1363-68 (Fed. Cir. 2003).
205 Id. at 1363.
206 Id. at 1364.
207 Id. at 1364-68.
208 Id. at 1363.
209 Id. at 1372. The Federal Circuit felt compelled to vacate the order of unenforceability and remand the case because the trial judge failed to expressly address the third step of the inequitable conduct analysis. Id.
210 Id. at 1364.
that the patentees' misrepresentations were material and intentional.\textsuperscript{211}

As alluded to above, the implications of this decision are great to those practitioners who frequently include examples or experiments in patent applications. Specifically, a prosecuting attorney must take several steps to avoid providing an accused infringer with an inequitable conduct defense based on "completed" tests. Initially, the attorney must make sure that all of the experiments disclosed in the specification have been performed. If this is not the case, the attorney must make sure that the present tense is used to describe those experiments that have not been performed.\textsuperscript{212} Adherence to the foregoing protocol could be complicated by the fact that inventors are becoming more willing to predict, and rely upon, the results of unperformed (or prophetic) experiments in their applications as technology advances.

CONCLUSION

The preceding discussion hopefully illustrated how the Federal Circuit’s jurisprudence in three areas of patent law impacts how a patent attorney practices law. Although, as discussed earlier, some issues remain to be resolved by that court, the resulting standardization of patent law as a result of the Federal Circuit’s commendable efforts has greatly benefited the quality of legal practice in the field of patent law.

\textsuperscript{211} Id. at 1367-68; see also U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p) (8th ed. 2001) ("Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have been achieved. Paper examples should not be described using the past tense.").

\textsuperscript{212} See U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p) (8th ed. 2001).