

Prosecution History Estoppel: A Newly Refined Tool For Right-To-Use Analyses

George B. Snyder
and Mary W. Richardson

KRAMER LEVIN NAFTALIS &
FRANKEL LLP

In today's marketplace new technology is one of a business' most valuable assets. However, deployment of new technology is a double-edged sword because it can lead to significant exposure, in particular patent infringement liability. Accordingly, a business must be able to assess beforehand whether its new technology, if deployed, would be covered by another's patent.

How successfully that exercise can be conducted depends on how predictable application of patent infringement law is in respect of any given set of facts. Noninfringement can only be concluded if the new technology (1) is not literally within the language of the patent, and then (2) is also not the equitable equivalent of the patented subject matter. Deciding whether new technology is covered in a literal sense by the patent's language is rather a "cut and dried" proposition. Making an accurate determination as to whether new technology is equivalent to patented subject matter is much more in the nature of a judgment call. Thus, certainty in a noninfringement analysis is increased when the equivalence factor can be eliminated, or at least limited.

One restraint placed on equivalence is the doctrine of "prosecution history estoppel," *i.e.*, a prohibition against extending patent scope via equivalence to encompass subject matter when that extension would be irreconcilable with narrowing concessions made to procure the patent (as evidenced by the file of proceedings in the United States Patent and Trademark Office, commonly known as the "prosecution history"). While self-evidently a valuable resource for predicting whether technology "on the drawing board" might run afoul of another's patent, the doctrine was substantially undermined for many years by decisions of the Court of Appeals for the Federal Circuit ("Federal Circuit"), chief patent court of the land, leading to a crisis of confidence in the doctrine's reliability. The purpose of this article is to explore what effect recent pronouncements of the United States Supreme Court will have to rectify the situation, and thus re-invigorate the business community's ability to steer clear of patent infringement problems when introducing new technology into the marketplace.

Background Fundamentals

Let us begin with a simple illustration. Assume that, like the accused infringer in the well-known case of *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997), your company manufactures dyestuffs from which impurities must be removed. A competitor's patent covers a purification process involving dyestuff ultrafiltration at pH levels between 6.0 and 9.0. Your company's ultrafiltration process coincidentally is the same, including operating at a pH of 8.0. Since pH 8.0 falls within the pH range prescribed in the competitor's patent, it can be predicted that a court will find your company infringes the patent because every element recited in the patent claim language is literally found in the process by which your company's product was produced. ("Literal infringement of a claim exists ... when the

George B. Snyder is a Partner and Mary W. Richardson is an Associate at Kramer Levin Naftalis & Frankel LLP.



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properly construed claim reads on the accused device [alternatively, process or product] exactly." *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996), *cert. denied*, 522 U.S. 812 (1997).)

But now suppose your company's product is manufactured using an ultrafiltration process that operates at pH 5.0. Though the process does not correspond to the literal terms of the patent, infringement could nonetheless be found if there is "equivalence" between the pH for the accused process and the pH range of the patent. This has been the law for at least 150 years. *Winans v. Denmead*, 15 How. 330, 343 (1853). Although contrary to the "public notice" function of patents – that is, the patent's claim language should define the invention and give notice to the public of the patent monopoly's limits – "equivalence" prevents persons from practicing fraud on patents and otherwise assures patent owners a fair scope of protection. See *Warner-Jenkinson*, 520 U.S. at 34. This unfortunately institutionalizes an element of uncertainty.

Enter "prosecution history estoppel." As indicated above, this doctrine prevents a claim scope adjudication that would in effect resurrect subject matter surrendered during application proceedings. Chisum, Donald S., *Chisum On Patents*, Vol. 5A, § 18.05. The doctrine's workings are typified in *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126 (1942), where the Supreme Court indicated that if a patentee abandons or redrafts a claim more narrowly to avoid rejection, "the difference ... thus disclaimed must be regarded as material, and since the amendment operates as a disclaimer of that difference it must be strictly construed against him [the patentee]." 315 U.S. at 137. In 1997 the Supreme Court unequivocally proclaimed the doctrine to mean an amendment made to meet a requirement of patentability (not confined to differentiating over prior art) during prosecution presumptively gives rise to a bar against expansion, subject to limited rebuttal by the patent owner. *Warner-Jenkinson*, 520 U.S. at 33-34.

Prosecution History Estoppel In Crisis

All was historically well until the Federal Circuit began blurring the parameters established by the Supreme Court for determining when prosecution history estoppel would defeat a patent owner's claim of equivalence. For instance, in *Hughes Aircraft Co. v. United States*, 717 F.2d 1351 (Fed. Cir. 1983), the Federal Circuit decided to apply prosecution history estoppel "flexibly," stating that: "Depending on the nature and purpose of an amendment, it may have a limiting effect [on



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the doctrine of equivalents] within a spectrum ranging from great to small to zero. The effect may or may not be fatal to application of a range of equivalents (in respect of the amended language) broad enough to encompass a particular accused product." 717 F.2d at 1363. The Federal Circuit applied this "flexible" approach in at least 50 cases between 1983 and 2000 (see *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 612-15 ("Festo I") (Michel, J., concurring-in-part, dissenting-in-part)). Making things even more unpredictable was a parallel line of cases starting with *Kinzenbaw v. Deere & Co.*, 741 F.2d 383 (Fed. Cir. 1984), which (in contradictory fashion) followed the more traditional stricter view.

Back to our illustration. What would happen if the accused embodiment's pH is 5.0, and the patent is directed to operating at pH 6.0 to 9.0, but this was arrived at by narrowing the originally specified pH range of 2.0 to 9.0 to avoid a prior art teaching of pH 3.0? Under Federal Circuit precedent until 2000 a court might have concluded that the amendment had no limiting effect on applying the doctrine of equivalents to embrace a pH of 5.0 because it was made to avoid prior art specifying a pH of 3.0, not 5.0. On the other hand, a court could have concluded based on the other line of Federal Circuit precedent that the range 6.0 to 9.0 cannot be expanded, thus foreclosing equivalence. This is the antithesis of predictability.

Finally, in November 2000, the Federal Circuit recognized that its "flexible" approach to prosecution history estoppel makes it "virtually impossible to predict before the decision on appeal where the line of surrender [will be] drawn." *Festo I*, 234 F.3d at 578. However, instead of simply embracing the Supreme Court's position that a limiting amendment gives rise to a "rebuttable presumption" of prosecution history estoppel, the court ruled that "[r]egardless of whether the amendment is explained or unexplained, if the amendment narrows the scope of the claim for a reason related to patentability, a complete bar to the doctrine of equivalents provides the public and the patentee with definite notice as to the scope of the claimed invention." *Festo I*, 234 F.3d at 576. Ironically, *Festo I* actually created the unpredictability it sought to reduce because businesses were left to decide whether that case would remain the law, or the Supreme Court would reverse.

Prosecution History Estoppel Rescued

It did not take long for the Supreme Court to do the latter. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722,

(2002) ("*Festo II*"), the Supreme Court rejected *Festo I*, and opted for the more moderate view that narrowing amendments made to satisfy any requirement of patentability (not only to distinguish prior art) presumptively give rise to an estoppel against equivalence, with three exceptions: (1) "the equivalent may have been unforeseeable at the time of the application"; (2) "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question"; and (3) "there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." 535 U.S. at 740-41.

This is clearly a laudable step forward. *Festo II* furnishes a comprehensive framework for determining whether there is an infringement problem with a high degree of predictability. It follows that businesses applying the *Festo II* rationale should be able to make reliable, informed judgments.

Residual Controversy

Some subsidiary issues remain even after *Festo II*. On remand, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) ("*Festo III*"), the Federal Circuit prescribed rules for implementing *Festo II*. Among other things, the Federal Circuit indicated that (i) showing an alleged equivalent would have been "unforeseeable at the time of the amendment" can involve "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" (*Id.* at 1369); (2) "whether the patentee has established a merely tangential reason for a narrowing amendment" is usually but not always determined from the prosecution history record without introduction of additional evidence (*Id.* at 1370); and (3) "some other reason" for countenancing an alleged equivalent may be found in the shortcomings of language, but such is not an exhaustive list of "other" reasons (*Id.* at 1370).

Obviously *Festo III* leaves room for argument. For example, *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126 (D. Mass. 2003), and Dickinson, Q. Todd, "Latest 'Festo' Ruling Affects Drafting, Prosecution," Nat'l L. J. S7 (1/26/04), point up a number of ambiguities and/or inconsistencies. These include questions about when extrinsic evidence (*e.g.*, expert testimony, a notorious "wild card") may or must be introduced, what qualifies as a "tangential" relationship between the narrowing amendment/argument and the alleged equivalent, and how to handle alleged equivalents that become foreseeable between the date of the application and the time of the amendment. Even those collateral factors could introduce uncertainty into infringement analyses, thus detracting from the reliability of such evaluations.

Conclusion

Nevertheless, subsidiary concerns like those discussed above do not materially lessen the beneficial effects of *Festo II*. Precedential obfuscation of the principles for applying the doctrine of prosecution history estoppel had seriously undercut its usefulness to the business community as a planning tool for avoiding patent infringement in the marketplace. But now, the Supreme Court's landmark *Festo II* decision has restored the integrity of the prosecution history estoppel doctrine. While some points of clarification are still necessary, the doctrine is once again a bulwark of predictability.

Please email the authors at gsnyder@kramerlevin.com or mrichardson@kramerlevin.com with questions about this article.