

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

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In *Festo Corp. v. Skoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), the Supreme Court adopted a foreseeability test for assessing whether the doctrine of equivalents should apply in patent infringement cases. However, that test may in some instances have the undesirable side effect of punishing innovation. This side effect is demonstrated by the Federal Circuit's decisions in two companion cases involving the same patent: *Glaxo Wellcome v. Impax Labs*, 356 F.3d 1348 (Fed. Cir. 2004) and *SmithKline Beecham Corp. v. Excel Pharms.*, 356 F.3d 1357 (Fed. Cir. 2004). The patent at issue in both cases claims a sustained-release version of a particular drug using a particular sustained-release carrier, hydroxypropyl methylcellulose (HPMC), the only carrier described in the patent's specification. Impax filed an ANDA to sell a version of sustained-release bupropion using a different carrier, hydroxypropyl cellulose (HPC), that everyone in the art knew could be substituted for the claimed carrier. Excel filed an ANDA to sell a version using polyvinyl alcohol (PVA), which was not formerly known to be useful as a sustained-release carrier. Glaxo sued both companies, asserting infringement under the doctrine of equivalents. The court found that Impax made only an obvious modification that was readily foreseeable, and so it did not infringe under the doctrine of equivalents. Conversely, because PVA was not formerly known as a sustained-release carrier, its use was unforeseeable, and so Excel might be found to infringe under the doctrine of equivalents. Stepping back from the details of the foreseeability test and looking at the big picture, Impax made an obvious modification and is really just free-riding on the patent, while Excel made an innovative new delivery vehicle and thus is an innovator who really created a new product. The foreseeability test is therefore punishing the innovator and not the free-rider. The treatment of Impax under the foreseeability test seems proper, in that Glaxo wrote its specification and drafted its claims the way it did with full knowledge of alternatives. However, that logic should apply even more strongly to an innovator in the position of Excel, and thus the foreseeability test is having a perverse effect. Having identified the problem, I am still working on the solution. One simple reformulation that might work is to shift the focus of the foreseeability test from whether the patentee should have foreseen that it was giving up a particular accused embodiment, to whether the accused embodiment is a member of a class that the patentee should have foreseen it was giving up. Under that test, Glaxo should have known that limiting the claims to HPMC was giving up the class of other sustained-release carriers, and it should not matter whether a particular accused member was known at the time or not.