Some Good News, Some Bad News for Biotechnology Patent Holders

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On 28 May 2002, the Supreme Court released its decision in Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Company, a case that began 13 years ago (1). We traced the issues and consequences of the Court of Appeals for the Federal Circuit Court decision in the last issue of BioPharm (2,3). Primarily, the concern was that Festo might significantly limit application of an equitable doctrine — the doctrine of equivalents (DOE) — which protects patent holders from those who make minor and insubstantial changes to inventions to escape liability from infringement (4,5).

Good News

The good news is that the Court struck down the Federal Circuit’s “complete bar” decision on applying the DOE, in favor of a “flexible bar.” (A complete bar would offer the public greater certainty over the scope of patent claims, but it would have a disparate effect on biotechnological inventions because to acquire a patent of value on a gene or protein, applicants would need to test, describe, and claim thousands of functional variants.)

A flexible bar means that the act of narrowing a claim during prosecution will not automatically preclude the application of the DOE, but will instead give rise to a presumption that the patentee is disclaiming the subject matter that was removed to create the new narrower claim (prosecution history estoppel, PHE, prevents applicants from taking a different position in the infringement case than they did when they made their initial claim). PHE allows other applicants to claim inventions that lie between the original claim and the new narrower claim, so it often favors those accused of infringing.

The presumption elaborated in Festo can be rebutted with evidence that the amendment was made for reasons unrelated to patentability or with evidence that it could not have been foreseen that by removing the subject matter in question, the applicant was disclaiming alleged equivalents. If the presumption is rebutted, the DOE can be applied (that is, the patent’s scope covers the invention and similar or equivalent inventions) preventing infringements that might otherwise have been allowed under PHE.

Bad News

The bad news is that the Court explicitly allows PHE to be applied to claims amended in response to enablement rejections (broad claims, such as ‘all analogs of a protein,’ can be rejected for failing to adequately describe the invention) not just those amended to avoid prior art (discussion in the literature about the invention before the patent claim, for instance). Applying PHE to enablement rejections is a significant blow to patentees and applicants with biotechnology claims because claims to nucleotide and amino acid sequences are often amended during prosecution in response to enablement rejections.

Forseeability. Even though such amendments no longer invoke a “complete bar” to applying the DOE, the key to rebutting the presumption that PHE should apply will be foreseeability. In other words, if it was foreseeable that potential copyists would make minor, nonfunctional substitutions in the claimed nucleotide or amino acid sequence, and the claim was narrowed during prosecution so that it no longer literally encompasses such minor substitutions, the DOE will not be available for that claim.

Effects of the Decision

In general, the Court’s decision removes some of the rigidity of the Federal Circuit’s “complete bar,” but the new approach is by no means as flexible as patentees wanted. The “flexible bar” requires patentees to show (through expert testimony) that the alleged equivalent (the infringement) was not foreseeable at the time the claim was amended. That process will make patent litigation even more lengthy and costly. More patent appeals are likely in response to rejections to avoid amending claims. Biotechnology applicants appear to be saddled with a significant burden: Literally claim every possible variant of a nucleotide or amino acid sequence or risk a finding that minor, nonfunctional substitutions in the claimed sequence were foreseeable.

Questions remain about applying the “flexible bar” in future patent litigation. Biotechnological patent holders, however, can expect even greater uncertainty in the precise scope of their claims.

References