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Federal Circuit Patent Bulletin: *Danisco US Inc. v. Novozymes A/S*

March 11, 2014

"[For purposes of declaratory judgment jurisdiction, the Federal Circuit has] never held that 'pre-issuance conduct' cannot constitute an affirmative act, [nor] that the only affirmative acts sufficient to create justiciable controversies are 'implied or express enforcement threat[s].'"

On March 11, 2014, in *Danisco US Inc. v. Novozymes A/S*, the U.S. Court of Appeals for the Federal Circuit (Lourie,* Prost, O'Malley) reversed and remanded the district court's dismissal of Danisco's suit seeking a declaration of noninfringement of U.S. Patent No. 8,252,573, which related to a truncated Geobacillus stearothermophilus (BSG) alpha-amylase variant polypeptide with a substitution from glutamic acid (E) to proline (P) at sequence position 188 (E188P substitution) that exhibits increased viscosity reduction in a starch liquefaction assay compared to the parental alpha-amylase polypeptide. The Federal Circuit stated:

Article III does not mandate that the declaratory judgment defendant have threatened litigation or otherwise taken action to enforce its rights before a justiciable controversy can arise, and the Supreme Court has repeatedly found the existence of an actual case or controversy even in situations in which there was no indication that the declaratory judgment defendant was preparing to enforce its legal rights. The Court has instead only "required that the dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" "'Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" That standard is satisfied here.

The record demonstrates that a definite and concrete patent dispute exists between the parties. Novozymes's E188P alpha-amylase variant claim issued as the sole claim of its '573 patent and is the same claim that Novozymes described as interfering with the claim in Danisco's [U.S. Patent No. 8,804,240]. Novozymes has insisted on multiple occasions that its '573 patent claim reads on the BSG alpha-amylase with an E188P

mutation, which is the active compound in Danisco's [Rapid Starch Liquefaction] products and is claimed in Novozymes's patent. The record shows that Novozymes sought its patent because it believed that Danisco's products would infringe once the claim issued. Novozymes twice asserted that Danisco's '240 patent was invalid and that Novozymes, not Danisco, is entitled to a patent on the claimed BSG E188P alpha-amylase invention. Danisco has taken a legal position that is entirely opposed to the position taken by Novozymes, viz., that Danisco successfully prosecuted and obtained the '240 patent, that it is the rightful owner of the claimed invention, and that its RSL products do not infringe the claim of Novozymes's '573 patent. Novozymes has twice sued Danisco or its predecessors in interest for patent infringement regarding related liquefaction products. The parties have plainly been at war over patents involving genetically modified alpha-amylase enzymes and are likely to be for the foreseeable future. They thus have adverse legal interests over a dispute of sufficient reality that is capable of conclusive resolution through a declaratory judgment.

Novozymes has never withdrawn its allegation that Danisco's alpha-amylase variant is encompassed by and would infringe the claim that issued in Novozymes's '573 patent. Nor has Novozymes offered any assurance, such as with a covenant not to sue, that it will not accuse Danisco's RSL products of infringement, which could potentially moot a controversy between the parties. . . . We see no reason why we should not similarly consider a pattern of administrative challenges in analyzing the totality of the circumstances.

The district court's categorical distinction between pre-and post-issuance conduct is therefore irreconcilable with the Supreme Court's insistence on applying a flexible totality of the circumstances test, its rejection of technical bright line rules in the context of justiciability, and our own precedent. Contrary to the district court's stated view, we have never held that "pre-issuance conduct" cannot constitute an affirmative act, nor have we held that the only affirmative acts sufficient to create justiciable controversies are "implied or express enforcement threat[s]." Even the district court itself acknowledged that Danisco showed that it was "reasonable to infer that Novozymes obtained the '573patent with the hopes of asserting it against Danisco's products, and there may even be a probability that it will someday do so." The court also determined that the facts plausibly "support a reasonable inference that Novozymes pursued the E188P claim in the '573 patent with the hopes of wielding it against [Danisco's] RSL products, and even that Novozymes may still be harboring the intent to pursue infringement claims at the time of its own choosing." The court likewise recognized that "the prosecution history may strongly support an inference that Novozymes sought to obtain this patent for the purpose of potentially asserting it against Danisco's products . . . ." Thus, applying a mechanical distinction to the totality of the circumstances inquiry between pre-and post-issuance events is unsound. . . .

Taken together, Novozymes's activities thus demonstrate that it has "engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights." That is enough to establish subject matter jurisdiction. Novozymes's behavior validates that Danisco, quite reasonably, is more than a "nervous . . . possible infringer," even if Novozymes is not currently "poised on the courthouse steps" to sue Danisco for infringement of the '573 patent. At bottom, Danisco is in the position of either abandoning its RSL products or running the risk of being sued for infringement, which is precisely the type of situation that the Declaratory Judgment Act was intended to remedy. Accordingly, because a totality of the circumstances shows that Novozymes's posturing put Danisco in a position of either pursuing arguably illegal behavior, i.e., infringement, or abandoning that which it claims a right to do, i.e., make and sell the RSL products that are the embodiments of its '240 patent, we conclude that the district court erred as a matter of law in dismissing Counts 1 and 2 of Danisco's complaint for lack of subject matter jurisdiction.