IP Alert: Subject-Matter Eligibility Swallows Infringement Litigation?

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On October 4, 2017, the U.S. Court of Appeals for the Federal Circuit heard oral arguments in a case that has been running for more than 10 years—Classen Immunotherapies, Inc., v. Elan Pharmaceuticals, Inc. (No. 17-1033). During that time, much has changed in the legal framework for subject-matter eligibility. Claims directed to a business method, such as the ones of Classen at issue, have been at the center of these legal changes. The issue in this appeal is whether the "safe harbor infringement exemption" of 35 U.S.C. § 271(e)(1) applies to acts that allegedly took place after approval by the U.S. Food and Drug Administration. Now, it appears the ultimate outcome of the case may turn on the subject-matter eligibility of Classen's claims or the influence of the new legal framework of subject-matter eligibility on what can be considered infringing acts.

In 2001, Elan conducted a clinical study on the effect of food on the bioavailability of the marketed muscle relaxant Skelaxin® (metaxalone), for which Elan then held an approved New Drug Application (NDA). Elan used the study results in three ways: (1) it submitted the results to the FDA in a citizen petition, requesting that applicants requesting approval of generic metaxalone be required to provide both fed and fasting bioavailability data; (2) it submitted a supplemental New

Drug Application (sNDA) to revise the Skelaxin® product label; and (3) it filed two patent applications.

Classen asserted U.S. Patent 6,584,472 against Elan in 2004, alleging that Elan's clinical studies and three uses of the study results infringed the '472 patent. Classen asserted claims directed to methods for creating and using data associated with a commercially available product; methods of establishing at least one commercial new use for a commercially available product; and kits comprising a product and documentation notifying a user of the product of at least one new adverse event relating to the product, where the new adverse event was obtained by the claimed methods.

The district court granted Elan's motion for summary judgment of non-infringement, finding that Elan's studies and submissions to the FDA fell under the safe harbor exemption provided in the Hatch-Waxman Act, now 35 U.S.C. § 271(e)(1), which states:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products…

Classen Immunotherapies v. King Pharmaceuticals, 466 F.Supp.2d 621, 625 (D. Md. 2006). Classen appealed. The Federal Circuit affirmed the judgment of non-infringement for the pre-sNDA submission acts, but remanded the case to the district court for consideration of Elan's post-submission acts. Classen Immunotherapies v. Elan Pharmaceuticals, Inc. 786 F.3d 892 (Fed. Cir. 2015).

Classen asserted that Elan's use of study results to file patent applications and marketing of Skelaxin with its revised label were post-submission infringing acts not shielded by § 271(e)(1). The district court found that all of the alleged infringing activities fell within the safe harbor and again granted Elan's motion for summary judgment of non-infringement. Classen Immunotherapies v. Elan Pharmaceuticals, 210 F.Supp.3d 772 (D. Md. 2016). The present appeal followed.

During the argument, the parties focused on whether evidence of infringing acts had been submitted during trial and whether the safe harbor of § 271(e)(1) applied to such acts. But the panel did not seem to engage as much on these points as on the notion of applying certain steps of the claimed methods to the alleged infringing activities. The panel expressed concern that these steps seemed to be directed to abstract ideas. "Documenting inventorship? That's an abstract idea. Why does that contribute to infringement of a claim? Analyzing data? How is that infringing?" Thus, the new legal framework of subject-matter eligibility seems to have infected the very idea of what acts can be considered to infringe.

This long-running case, which had been stayed for five years while Classen's patent was under ex parte reexamination, illustrates the pitfalls of a lengthy stay in infringement suits based on patents that issued before the subject-matter eligibility revolution. Claims that were formerly considered subject-matter eligible are now routinely invalidated as directed to laws of nature, abstract ideas, or

natural phenomena. During the oral argument, the Classen panel asked whether the defendant had made any motions attacking patent validity under Section 101. Such motions had been made, the panel was told, but the motions were held in abeyance while the safe harbor issue was appealed.

The court's willingness to engage on the issue of subject-matter eligibility suggests that there may well be some unsolicited dicta on this issue when the court issues its opinion. And if the court eventually reaches the Section 101 motions, Classen and Elan can both add their names to the long list of litigants who went into court thinking they knew what their fight was about, only to have that fight swallowed by standards of subject-matter eligibility that did not exist when the case was filed.

Click here to download a recording of oral arguments in this case.

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