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Post-Approval Conduct and the Hatch-Waxman Safe Harbor

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After the Federal Circuit's decision in Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012), one might conclude that post-approval conduct is immune under the Hatch-Waxman safe harbor as long as the accused conduct is "for uses reasonably related to the development and submission of information to the FDA." 35 U.S.C. § 271(e)(1). This result would most certainly be true if the conduct under consideration occurred before FDA-approval. But the case law, including Momenta itself, suggests that a more stringent test may be applied in analyzing whether post-approval conduct is protected by section 271(e)(1).

The earliest decision addressing the interplay between the safe harbor and post-approval conduct is Wesley Jensen Corp. v. Bausch & Lomb, Inc., 235 F. Supp. 2d 370 (D. Del. 2002). There, Wesley Jensen charged B&L with infringement of a patent covering contact lenses. An injunction prohibiting B&L from making, using or selling the accused lenses had been entered, and B&L sought to modify that injunction.

Prior to suit, FDA had granted B&L approval to market its PureVision contact lenses for, inter alia, 30-day extended wear. But "[t]he FDA's approval was conditioned on defendant's conducting a post-approval study to collect follow-up data on the adverse effects associated with using the PureVision product for up to 30 days." The study would last one year. Significantly, "[d]efendant's failure to perform the study and submit the data to the FDA would result in the withdrawal of the approval."

The defendant contended that the ongoing study should not be enjoined as it was protected by section 271(e)(2). Plaintiff argued that the safe harbor did not cover post-approval conduct. In holding that the accused conduct was protected by section 271(e)(1), Chief Judge Robinson relied heavily on the FDA's "conditional approval," noting that "defendant's post-approval study is narrowly tailored and directly related to the development and submission of information to the FDA." In holding that the study was protected by section 271(e)(1), the court explicitly rejected plaintiff's argument that section 271(e)(1) is limited to pre-approval activities. It further noted that the safe harbor was intended to allow a drug maker to prepare for commercial activity after a patent expires and "that is exactly what defendant is doing."

A Closer Look at Cases Provides Insight

Classen Immunotherapies, Inc. v. Biogen Idec, 659 F.3d 1057 (Fed. Cir. 2011), directly addressed post-approval conduct and the safe harbor. The case involved three related patents covering the scheduling of vaccinations to prevent complications. Defendants argued that their post-approval safety studies were protected by section 271(e)(1) and the district court agreed, holding that defendants' conduct in providing vaccines, in advising on immunization schedules, and in reporting adverse effects to the FDA was protected because the information, once obtained, was required to be submitted to the FDA. In reversing the district court and rejecting this defense, the Federal Circuit majority stated: "The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." As such, defendant's activities were "not a 'phase of research' possibly leading to market approval," because such approval had already been obtained.

Judge Moore dissented, stating that "[n]o where does the statute limit the safe harbor to pre-approval activities," and reasoned that this specific conduct was protected by section 271(e)(1) because defendants were required to report the results of their tests to the FDA. In Judge Moore's opinion, reporting pursuant to 21 C.F.R. § 601.70, which requires annual progress reports of post-approval studies, could be protected by the safe harbor: "I conclude that the safe harbor extends to all uses that are reasonably related to submitting any information under the FDCA, including information regarding post-approval uses."

Defendants, however, were also accused of vaccinating patients according to the patented methods. And although defendants were required to report the results of their studies to the FDA, "they [were] not required by law or regulation to perform such post-approval vaccinations in order to generate data." Judge Moore concluded that these activities were not protected by the safe harbor. Thus, Judge Moore—like Chief Judge Robinson—drew a distinction between conduct required by the FDA and conduct that was not. It would appear that this distinction was not made in cases addressing the applicability of the safe harbor to pre-approval conduct.

In Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012), Judge Moore, writing for the majority, held that the safe harbor was not limited to pre-approval activities. There, the FDA had approved defendant's sales of generic LOVENOX provided that each commercial batch be tested before marketing to insure that it complied with strict product specifications. Defendant used Momenta's patented assay to conduct these tests.

In distinguishing Classen, Judge Moore stated: "The [Classen] studies themselves were not mandated by the FDA," and further, that "the patented methods were not insulated by the safe harbor because the studies did not facilitate marketing a generic drug by 'expedit[ing] development of information for regulatory approval.'" This statement is apparently based on the fact that approval had already been obtained.

The Momenta Court confirmed that "the scope of the safe harbor does not extend to information that may be routinely reported to the FDA, long after marketing approval has been obtained." Indeed, according to Judge Moore, this decision is not inconsistent with Classen because the submitted information "is necessary both to the continued approval of [the] ANDA and to [Momenta's] ability to market the generic drug." As such, the submissions were not "routine," but rather were "required to maintain FDA approval." In summary, the court stated:

Under a proper construction of 35 U.S.C. § 271(e)(1), the fact that Amphastar's testing is carried out to "satisfy the FDA's requirements" means it falls within the scope of the safe harbor, even though the activity is carried out after approval. Unlike Classen, where the allegedly infringing activity "may" have eventually led to an FDA submission, there is no dispute in this case that Amphastar's allegedly infringing activities are carried out to "satisfy the FDA's requirements."

Looking for Consistency

The holdings in all three cases are consistent, and each noted that the post-approval conduct was "required" by the FDA. This may be a mere coincidence, but in view of these decisions, post-approval conduct should be analyzed to determine if it is required by the FDA when considering the applicability of the safe harbor.

However, according to Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc., 981 F. Supp.2d 415 (D. Md. 2013), post-approval studies on the effect of food on a drug's bioavailability that resulted in a change in the drug label were protected by the safe harbor. The court held that "Momenta did not hold that only information that the FDA 'required' could be considered not 'routine' under Classen," but rather that the "safe harbor should be interpreted expansively." Because the studies resulted in changes in the drug approval process for generic applicants, the testing "expedit[ed] development of information for regulatory approval," and therefore, was not "routine," and was protected by the safe harbor. Thus, the use of the results of any pre-approval studies that

are included in the label are certainly within the safe harbor, even though the label is distributed post-approval. Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals, 2:12-cv-06643-GAF-PLA at *6 (C.D. Cal. 2013).

In conclusion, the safe harbor applies when post-approval conduct is “required” by the FDA. Although the definition of “required” is somewhat indefinite, post-Momenta district court holdings have applied the safe harbor “expansively.”