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Post-Approval Quality Control Testing of Pharmaceutical Products:

What Constitutes 35 U.S.C. § 271(g) Infringement or Falls Under the 35 U.S.C. § 271(e)(1) Safe Harbor?

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The Federal Circuit recently affirmed that a generic pharmaceutical company's use of post-approval quality control testing was not "making" under 35 U.S.C. § 271(g). *See Momenta Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA Inc.*, Nos. 14-1274, -1277, slip op. (Fed. Cir. Nov. 10, 2015). But, the Federal Circuit also held that the same post-approval quality control testing within the United States, even though reported to the FDA, did not fall within the safe harbor provision of § 271(e)(1).

"Made," as Recited in 35 U.S.C. § 271(g), Still Means "Manufacture"

Momenta alleged infringement of U.S. Patent No. 7,575,886 (the '886 patent) under 35 U.S.C. § 271(g) arguing that the post-approval quality control testing employed by Teva and Amphastar ANDA during production of their products caused them to be "made by a process patented in the United States." *Id.* at 6 (*quoting* 35 U.S.C. § 271(g)). On appeal, the Federal Circuit considered "whether Teva's and Amphastar's enoxaparin products are 'made by' Momenta's patented process within the meaning of § 271(g)." *Id.* at 6-7. While the Federal Circuit noted that Momenta's arguments were not without merit, the court regarded the language of the statute and its own precedent as instructive: "it is more consonant with the language of the statute, as well as with this court's precedent, to limit § 271(g) to the actual 'ma[king]' of a product, rather than extend its reach to method of testing a final product or intermediate substance to ensure that the intended product of substance has in fact been made." *Id.* at 7. Indeed, the Federal Circuit held that "ma[king]" does not extend to testing to determine whether an already-synthesized drug substance possesses existing qualities or properties. *See id.* at 8-9.

Teva's and Amphastar's enoxaparin samples are subjected to testing to assist in determining whether the samples *may* be selected for incorporation into the finished drug product. *See id.* at 9. "No assertion is made, however, that the enoxaparin samples on which tests are performed are themselves incorporated into the finished product or imported into the United States, nor do the tests create or give new properties to the enoxaparin substance in batches that are selected for further processing." *Id.* at 9-10. Thus, no infringement under § 271(g) could be found where the process (*i.e.*, the testing) is too far removed from the actual making of the drug product. *Id.* at 11.

§ 271(e)(1) Safe Harbor Does Not Apply to Routine Activities

The district court also had found that both Teva and Amphastar did not infringe the '886 patent because the alleged post-approval quality control testing activities were for the purposes of obtaining FDA approval of their ANDA products. *Id.* at 4. However, on appeal, while the Federal Circuit did not disrupt the non-infringement holding as to Teva, whose testing was done outside the U.S, the Federal Circuit did find that Amphastar's testing done within the U.S. did not fall within the safe harbor provision. *Id.* at 13, 17-18. Interestingly, this represented a reversal of the Federal Circuit's decision during the preliminary injunction stage of the proceedings. *See id.* at 5, 14-15.

The Federal Circuit explained that "[t]he routine quality control testing of each batch of generic enoxaparin as part of the post-approval, commercial production process is not reasonably related to the development and submission of information to the FDA" and found that Amphastar's activities were "routine." *Id.* at 16-17 (internal quotations omitted). Notably, Amphastar made

"no claim that its accused, post-approval use of the patented method is related to obtaining FDA approval" but were instead directed to commercial manufacture of its product. *Id.* at 17. Accordingly, despite the "sufficiently broad" language of § 271(e)(1), Amphastar's activities were found to be outside the safe harbor protection. *See id.* at 17-18.

The *Momenta* decision is instructive on two points: (1) what activities are non-infringing under 35 U.S.C. § 271(g); and (2) what activities are shielded by the safe harbor provision. Generic pharmaceutical manufacturers faced with patents that may cover post-approval quality control testing, particularly those with ex-U.S. manufacturing facilities, should conduct significant analyses to determine whether conducting such testing can be undertaken in the ex-U.S. facilities. In addition, before conducting post-approval activities within the United States, generic pharmaceutical manufacturers should assess whether a Court would consider such activities as (1) "routine" post-approval activities, including testing commercial batches, as such "routine" activities may not reap the benefit of the safe harbor shield, or (2) related to obtaining FDA approval, which could fall within the safe harbor.

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