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Rambus Redux? – Standards, Patents and Non-Disclosure in the Pharmaceutical Sector (Momenta v. Amphastar)

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Rambus Redux? – Standards, Patents and Non-Disclosure in the Pharmaceutical Sector (*Momenta V. Amphastar*)

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Abstract

Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc. *(D.Mass 2018) involves the alleged deception of a standards-development organization (SDO) by the holder of a patent essential to a standard relating to the manufacture of the drug enoxaparin. The SDO's rules regarding disclosure of standards-essential patents (SEPs) were found to be ambiguous, yet, as in* Qualcomm v. Broadcom *(Fed. Cir. 2008), the district court held that participant expectations created an affirmative obligation to disclose SEPs to the SDO. Following the SEP holder's assertion of the undisclosed patent against a competing generic manufacturer of enoxaparin, the alleged infringer successfully raised defenses of waiver and estoppel against enforcement of the patent. The alleged infringer also brought antitrust claims against the SEP holder, alleging monopolization in violation of the Sherman Act. The case is interesting because it raises issues that were seemingly settled in the information and communication technology (ICT) sector a decade ago, but in the new setting of pharmaceuticals manufacturing. As such, it may give courts an unexpected opportunity to revisit the DC Circuit's controversial decision in* Rambus v. FTC *(D.C. Cir. 2008), which found no antitrust liability for an allegedly deceptive failure to disclose SEPs to an SDO.*

Introduction

During the dozen years demarcated by the FTC's 1996 consent decree with Dell Computer[2] and the D.C. Circuit's 2008 decision in *Rambus, Inc. v. FTC*,[3] the U.S. saw a spate of cases in which participants in voluntary standards-development organizations (SDOs) were alleged to have violated an SDO's rules by failing to disclose patents essential to the SDO's standards. In addition to *Dell* and *Rambus*, highly-publicized deception cases such as *Broadcom v. Qualcomm*[4] explored what SDO policies actually required of their participants and what penalties could be imposed for their breach, whether under contract, equity, patent or antitrust law. These questions, and the large sums at stake, generated a cottage industry of legal and economics scholarship around the law and lore of standardization. But by the early 2010s, the information and communications technology (ICT) sector seems to have learned the lessons of *Dell*, *Rambus* and *Qualcomm*: SDOs improved the clarity of their internal processes, SDO participants adopted a policy of "disclose, disclose, disclose" (on the theory that it can never hurt to disclose too *many* patents), and the cases turned to other pressing questions like the meaning of SDO commitments to license patents

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[2] 121 FTC 616 (1996).

[3] 522 F.3d 456 (D.C. Cir. 2008).

[4] 548 F.3d 1004 (Fed. Cir. 2008).

on terms that are "fair, reasonable and nondiscriminatory" (FRAND), which continues to bedevil courts today. I was thus intrigued to see a case that harkens back to the heyday of the old SDO deception cases in a pair of recent decisions in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc*.[5] Surprisingly, this non-ICT case may give courts an unexpected opportunity to revisit the DC Circuit's controversial decision in *Rambus v. FTC*, which found no antitrust liability for an allegedly deceptive failure to disclose patents to an SDO.

Background: the '886 Patent Dispute

The long-running dispute in *Momenta* is between two generic producers of the blockbuster anticoagulant drug enoxaparin, which Sanofi-Aventis first marketed in 1993 under the brand name Lovenox (2009 U.S. sales $2.7 billion)[6]. In July 2010, Momenta Pharmaceuticals, in conjunction with Novartis's Sandoz division, received FDA approval for a biosimilar version of enoxaparin. Amphastar Pharmaceuticals, another generics manufacturer, received FDA approval for its own biosimilar version of enoxaparin on September 19, 2011. Two days later, Momenta sued Amphastar for infringement of U.S. Patent No. 7,575,886 (the '886 Patent), which claims a quality control process used in the manufacture of enoxaparin. Momenta applied for the '886 Patent in 2003; it was issued in 2009 listing five inventors including Dr. Zachary Shriver. After a lengthy set of proceedings, including two separate appeals to the Federal Circuit, a jury found in 2017 that Amphastar infringed the claims of the '886 patent, but that the claims were invalid due to lack of enablement and inadequate written description.[7]

Dispute Over Method 207

The United States Pharmacopeial Convention (USP) is an SDO that develops standards for testing the quality and purity of foods and drugs.[8] In 2006, with the encouragement of Sanofi-Aventis, USP began to consider a standard for testing enoxaparin. Beginning in 2008, Momenta's employee Dr. Shriver participated in the USP advisory panel that developed what came to be known as USP Method 207 pertaining to enoxaparin manufacture, which USP eventually approved and adopted as a standard in 2009. Amphastar alleges that the claims of the '886 patent cover key portions of Method 207.

USP has a number of written policies that are binding on individuals and firms participating in its standardization work. Amphastar argues that USP's written policies required Dr. Shriver to disclose the existence of Momenta's application for the '886 patent to USP prior to approval of the standard, which he did not. Due to this failure, Amphastar alleges that Momenta intentionally violated USP's policies. In consequence, Amphasrar argues that (1) Momenta has waived its right to enforce the '886 patent, (2) Momenta is estopped from enforcing the '886 patent, and (3) Momenta and Sandoz violated Section 2 of the Sherman Act, as well as various state antitrust and competition statutes by "wrongfully acquiring monopoly power by deceiving the USP into adopting a standard which they later claimed was covered by" the '886 Patent.[9] These allegations reflect the classic SDO deception scenario, akin to those alleged in

[5] D. Mass., Memorandum and Order, No. 11-cv-11681, Feb. 7, 2018 (patent case) and Memorandum and Order, No. 16-10112-NMG, Mar. 19, 2018 (antitrust case).
[6] Dana A. Elfin, *Momenta Battle Over Amphastar Generic Continues*, Bloomberg, Jun. 20, 2017.
[7] *Momenta*, Feb. 7, 2018, slip op. at 1.
[8] *See* U.S. Pharmacopeial Convention, About USP, http://www.usp.org/about (visited June 27, 2018).
[9] *Momenta*, Mar. 19, 2018, slip op. at 9

cases like *Dell*, *Rambus* and *Qualcomm*. In each of these cases the central issue is "the consequence of silence in the face of a duty to disclose patents in a standards-setting organization".[10]

The USP Policies

In assessing Momenta's obligation to disclose the '886 patent, Judge Nathaniel Gordon of the District Court for the District of Massachusetts considered three of USP's written policies. First, Section 2.05 of the Rules and Procedures of the USP Council of Experts (the "Expert Rules") states that no advisory panel member with a "financial or other interest that may conflict, or may appear to conflict, with his or her duties and responsibilities with respect to a particular matter, shall vote on such matter." Dr. Shriver abstained from voting on the Method 207 standard.[11]

Second, Section 2.06(a) of the Expert Rules requires that each advisory panel member submit to USP a written statement disclosing his or her employer, sources of research funding, and "other professional or financial interests, *including intellectual property rights*, that may result in a conflict of interest or the appearance of a conflict of interest".[12] Dr. Shriver submitted such a statement and identified Momenta as his employer.

Third, under a separate document known as the USP Guidelines, all "Sponsors" of USP technical proposals are requested to disclose "whether any portion of the methods or procedures submitted are subject to patent or other IP rights".[13] Momenta made no disclosure responsive to this provision.

Amphastar argued that these three provisions, individually and collectively, required Momenta, through Dr. Shriver, to disclose the existence of the '886 patent and its relevance to Method 207 while it was under consideration at USP. Judge Gordon, however, disagreed. With respect to Section 2.05 of the Expert Rules, Dr. Shriver's abstention from the vote on Method 207 was in compliance with the Rules. As for the Guidelines, Momenta was not formally a "Sponsor" of Method 207 (the only official Sponsor being Sanofi-Aventis), making the patent disclosure request inapplicable to Momenta. Finally, Dr. Shriver's conflict of interest form correctly identified Momenta as his employer. At most, the catch-all provision requiring disclosure of "other professional or financial interests" was ambiguous in its requirements. Accordingly, Judge Gordon found the USP policies to be ambiguous regarding Momenta's obligation to disclose the '886 patent.[14]

Participant Understanding of the Disclosure Requirement

Notwithstanding the ambiguity of USP's policies, Judge Gordon, citing *Qualcomm*,[15] went on to consider whether USP participants may have "understood the policies to include a duty to disclose" patents essential to USP standards.[16] A former USP employee testified that there was a "common understanding" among USP participants that patent disclosures were required.[17] In addition, the witness described a 2008

[10] *Qualcomm*, 548 F.3d at 1008.
[11] *Momenta*, Feb. 7, 2018, slip op. at 10.
[12] *Id*. at 9, emphasis added.
[13] *Id*. at 10.
[14] *Id*. at 11.
[15] 548 F.3d at 1012
[16] *Momenta*, Feb. 7, 2018, slip op. at 11-12
[17] *Id*. at 15.

advisory panel meeting at which USP noted that Sanofi-Aventis, the Sponsor of Method 207, had disclosed a relevant patent. According to the witness, a representative from Momenta then requested that Sanofi-Aventis be requested to abandon the patent before the standard was approved, which it ultimately did.[18] These factors, taken together, the court reasoned, "indicate[d] that Momenta itself, a participant in the USP, acknowledged its own obligation to disclose and abandon like patents".[19] Thus, as in both *Qualcomm* and *Rambus, Inc. v. Infineon Techs. AG*,[20] the court found that, notwithstanding the absence of an express requirement that patents essential to an SDO's standards be disclosed by SDO participants, such an obligation existed on the basis of unwritten participant expectations (a good example of private ordering influencing legal determinations).[21]

Interestingly, Momenta argued that it should not be deemed to have an obligation to disclose the '886 patent because it *opposed* the approval of Method 207 at USP, principally because it used a different method for testing enoxaparin. What's more, Method 207 was not a compulsory standard, meaning that even if Momenta held a patent covering the standard, it could not hold the industry "hostage".[22] The court did not find these arguments persuasive, noting in particular Amphastar's claim that the FDA *did* require it to use Method 207 in order to secure approval of its biosimilar version of enoxaparin.

Waiver

Amphastar argued that Momenta's breach of its obligation to disclose the '886 patent to USP should result in a waiver of Momenta's right to enforce the patent. The unenforceability remedy in patent law is a harsh one, usually extending not only to the infringer, but to the entire world.[23] In both *Dell* and *Qualcomm*, the unenforceability remedy was limited to implementations of the standards in question and, in theory, the patents could have been enforced against products that did not comply with those standards. The court in this case likewise limited unenforceability of the '886 patent to Method 207. Judge Gordon carefully analyzed the precise manufacturing processes used by Amphastar to determine which the processes the unenforceability remedy should apply to. Momenta alleged that three different manufacturing control processes used by Amphastar, referred to as the "15-25%" procedure (both original and revised) and the "DBB" procedure, infringed the '886 patent.[24] But the court concluded that the DBB procedure did not conform to Method 207. Accordingly, the '886 patent was held to be unenforceable as to the 15-25% procedures, which conformed to the standard, but not to DBB, which did not.[25]

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[18] *Id*. at 13.
[19] *Id*.
[20] 318 F.3d 1081, 1098 (Fed. Cir. 2003).
[21] See Jorge L. Contreras, *From Private Ordering to Public Law: The Legal Framework Governing Standards-Essential Patents*, 30 HARV. J.L. & TECH. 211 (2017).
[22] *Momenta*, Feb. 7, 2018, slip op. at 15.
[23] *See Qualcomm*, 548 F.3d at 1024. *See also* Jorge L. Contreras, *Equity, Antitrust and the Reemergence of the Patent Unenforceability Remedy*, ANTITRUST SOURCE (Oct. 2011) (discussing remedy of patent unenforceability and other equitable remedies).
[24] The "15-25%" procedures "use an equation that determines whether 15-25% of the sugar chains in an enoxaparin sample end up in 1,6-anhydro rings". The "DBB" procedure "examines the 23 building blocks of enoxaparin. For 13 of those building blocks, it measures the peaks of the substances in the enoxaparin. For the other 10, including 1,6-anydro rings, it simply establishes that the substance is present in the batch". *Momenta*, Feb. 7, 2018, slip op. at 16-18.
[25] *Momenta*, Feb. 7, 2018, slip op. at 16-17.

Equitable Estoppel

Amphastar also argued that because it reasonably relied on Momenta's misleading conduct (i.e., failing to disclose the existence of the '886 patent) and made investments in manufacturing capacity for enoxaparin on that basis, Momenta should be estopped[26] from enforcing the patent against it. Judge Gordon agreed, citing *Hynix Semiconductor Inc. v. Rambus, Inc*.[27] But as with waiver, the remedy was applied only to the 15-25% procedures, but not to the DBB procedure that did not conform to Method 207.

Antitrust Claims

In addition to the waiver and estoppel defenses raised by Amphastar, Amphastar brought a separate action charging Momenta and Sandoz with violations of the Sherman Act and California antitrust and competition law based on Momenta's failure to disclose the '886 patent to USP. Amphastar argues that Momenta "wrongfully acquir[ed] monopoly power by deceiving the USP into adopting" the Method 207 standard. This conduct, Amphastar alleges, both improperly excluded Amphastar from the market for generic enoxaparin and drove up the price of generic enoxaparin by billions of dollars over the years.[28]

In denying Momenta's motion to dismiss,[29] Judge Gordon looked to *Broadcom Corp. v. Qualcomm, Inc.*,[30] which explains that "[d]eception in a consensus-driven private standard-setting environment harms the competitive process by obscuring the costs of including proprietary technology in a standard and increasing the likelihood that patent rights will confer market power on the patent holder". Accordingly, he held that Amphastar had articulated a cognizable claim for monopolization under the Sherman Act.

A jury trial in the antitrust case is currently scheduled to begin in September 2019. While there appears to be ample basis in the record supporting Amphastar's claims regarding Momenta's deceptive conduct toward USP, Amphastar's greatest challenge at trial will likely be proving the existence of an antitrust injury, particularly in view of the FTC's case against *Rambus*, which faltered on this very point. As the DC Circuit explained in *Rambus, Inc. v. FTC*, "an otherwise lawful monopolist's end-run around price constraints, even when deceptive or fraudulent, does not alone present a harm to competition in the monopolized market."[31] Rather, antitrust injury – harm to competition, rather than to a competitor – cannot be said to exist if an SDO, "in the world that would have existed but for [the patent holder's] deception, would have standardized the very same technologies".[32] Thus, will Amphastar be able to show that *but for* Momenta's allegedly deceptive conduct, the Method 207 standard would *not* have been approved by USP?

The result will be interesting, both at trial and, if appealed, at the First Circuit, which is not strictly bound to follow the DC Circuit's precedent in *Rambus v. FTC*. There are certainly many, including Commissioners at the FTC, who felt the DC Circuit's decision in *Rambus* was excessively forgiving of deceptive conduct within SDOs. *Momenta*, which unexpectedly raises a fact pattern that has all but disappeared from the

[26] *See* Robert P. Merges & Jeffrey M. Kuhn, *An Estoppel Doctrine for Patented Standards*, 97 CALIF. L. REV. 1 (2009).
[27] 645 F.3d 1336, 1348 (Fed. Cir. 2011).
[28] *Momenta*, Mar. 19, 2018, slip op. at 6.
[29] *Id.* at 1.
[30] 501 F.3d 297, 314 (3rd Cir. 2007).
[31] 522 F.3d at 466.
[32] *Id*.

ICT litigation landscape, may give courts an opportunity to revisit this controversial decision in a new context.