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Jorge L. Contreras

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IS BIOPHARMA READY FOR THE STANDARDS WARS?

Jorge L. Contreras¹

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ABSTRACT

This symposium contribution sheds new light on Momenta v. Amphastar, a recent federal case in which issues relating to standardization and patent disclosure that have previously been observed in the semiconductor, computing and telecommunications sectors found their way into a dispute between two biosimilar manufacturers. One such manufacturer, Momenta, participated in the development of a standard for testing the purity of generic enoxaparin under the auspices of the United States Pharmacopeial Convention, but failed to disclose that it had applied for a patent on the testing method. When Momenta later sued Amphastar for infringement based on its use of that testing method, Amphastar raised defenses of waiver and equitable estoppel, then brought antitrust claims against Momenta and its distribution partner Sandoz. Amphastar prevailed at the district court on all three theories before the case was settled prior to disposition on appeal. This case demonstrates that issues surrounding the acquisition and disclosure of patents on standardized technologies have more salience in the biopharma sector than commonly believed. As such, standards organizations operating in this sector should ensure that their policies and procedures are robust enough to delineate clearly the obligations of participants with respect to patents covering standardized technologies, and organizations that participate in biopharma standards-development should heed the valuable lessons offered by more than three decades of litigation and policy making in the technology sector.

¹ Presidential Scholar and Professor of Law, University of Utah S.J. Quinney College of Law, Adjunct Professor, Department of Human Genetics, University of Utah School of Medicine. This research was made possible in part through generous support from the Huntsman Cancer Institute. This paper has benefitted from discussion and feedback at the Texas A&M School of Law Symposium on Pharmaceutical Innovation, Patent Protection and Regulatory Exclusivities (Oct. 2019). Research assistance by Sydney Hecimovich is greatly appreciated.

INTRODUCTION

In 2011, Momenta Pharmaceuticals, the manufacturer of a generic biosimilar version of the best-selling anticoagulant drug enoxaparin, sued another generic enoxaparin manufacturer, Amphastar Pharmaceuticals, for patent infringement. The asserted patent (U.S. Patent No. 7,575,886 (the ‘886 Patent)) covered not any chemical structure or attribute of the drug, but a quality control method used in its manufacture. According to Amphastar, it was required by the Food and Drug Administration (FDA) to use the allegedly infringing Method 207 for the production of generic enoxaparin.² And because at least one Momenta researcher was involved in the development of Method 207 at the United States Pharmacopeial Convention (USP), and because Momenta failed to disclose the resulting ‘866 Patent prior to adoption of Method 207 as an official USP standard, a federal district court held that Momenta waived its right to enforce the patent against Amphastar, was estopped from doing so, and that any such enforcement constituted a violation of Section 2 of the Sherman Act.

Contentions such as these have been made for decades in the computing, networking, telecommunications and semiconductor industries (generally lumped together as “information and communications technology” or ICT), which depend heavily on industry standards.³ Litigation over the disclosure and non-disclosure of patents essential to industry standards (standards-essential patents or SEPs) has included both private claims and enforcement actions by governmental agencies, both in the U.S. and abroad. The aggregate of these disputes has colloquially been termed the global “standards wars”.⁴ But while a range of industry standards have been developed for biotechnology and pharmaceutical applications,⁵ few of them have resulted in disputes relating to patents. *Momenta v. Amphastar* is notable, if not unique, in that it brings to the biopharmaceutical sector a type of dispute most frequently encountered in the ICT industry. The *Momenta* case is also distinctive among biopharma patent disputes in that it involved not a branded pharmaceutical manufacturer suing a generic manufacturer for patent infringement (a relatively common occurrence) or vice versa, but a patent dispute between two generic biosimilar producers.

Part I of this essay provides an overview of the recent law and policy that has evolved around the disclosure and non-disclosure of patents within the context of industry standard-setting, primarily in the ICT sector. Part II describes the background and facts of *Momenta v. Amphastar*, then discusses the district court’s holding regarding Momenta’s alleged failure to disclose the ‘866 patent. This essay concludes with some observations regarding the implications of this case, and

² Complaint for Plaintiff at 9, *Amphastar Pharm., Inc. et. al. v. Momenta Pharm., Inc.*, No. 5:15-cv-01914 (C.D. Cal. filed Sep 17, 2015).

³ There are a few notable exceptions, including the FTC’s case against Unocal with respect to a standard for gasoline additives. See discussion in Part III.A, *infra*.

⁴ See, e.g., Jorge L. Contreras, *The Global Standards Wars: Patent and Competition Disputes in North America, Europe and Asia*, University of Utah College of Law Research Paper No. 353 (Apr. 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3106090.

⁵ See, e.g., Jorge L. Contreras, *Technical Standards and Bioinformatics*, in *BIOINFORMATICS LAW: LEGAL ISSUES FOR COMPUTATIONAL BIOLOGY IN THE POST-GENOME ERA* (Jorge L. Contreras & A. James Cuticchia eds., 2013) (describing a range of standards in the fields of genetics, genomics and computational biology).

the growing importance of collaboratively developed industry standards, for the biopharmaceutical sector more broadly.

I. STANDARDS AND PATENTS

A. Policies of Standards Development Organizations

Most of the technical interoperability standards used today were developed by market participants collaborating within trade associations known as standards-development organizations (SDOs). SDOs range from governmentally recognized bodies that address a diverse range of standardization projects (e.g., the International Organization for Standardization (ISO)), to large, well-established private sector groups that address the standardization needs of major industry segments (e.g., the European Telecommunications Standards Institute (ETSI), Internet Engineering Task Force (IETF), and Institute for Electrical and Electronics Engineers (IEEE)) to smaller groups often referred to as “consortia” that focus on one or a handful of related standards (e.g., the HDMI Forum, Bluetooth Special Interest Group and USB Forum). Because of the significant market benefits that arise from the broad adoption of technical standards,⁶ a high degree of cooperation among competitors has long been tolerated by antitrust and competition law authorities, which might otherwise discourage such large-scale coordination by competitors.

Many of the technological features included in standards can be patented. Such patents are typically obtained by those SDO participants that make technical contributions to the standard. However, to the extent that patents cover technologies that are “essential” to the implementation of a standard (“standards-essential patents” or “SEPs”), concerns can arise. Specifically, there is a risk that the holder of a SEP could emerge after the broad deployment of a standard, and then demand excessive rent from all implementers of the standard. Because those implementers may have invested significant amounts in the design and production of standardized products, they may incur high, if not prohibitive, costs if they are forced to switch to a new, noninfringing (and non-standardized) technology. As a result, they may be willing to pay an excessive price to the SEP holder to avoid having to incur even higher switching costs. This phenomenon has been termed patent or standards “hold-up” and is discussed extensively in the literature.⁷ In addition to harming potential competitors, patent hold-up can have other undesirable market effects, including raising prices for consumers and hindering technological innovation.⁸

⁶ See U.S. Dep’t of Justice & Fed. Trade Comm’n, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation And Competition* 33-37 (2007) [hereinafter DOJ-FTC Antitrust & IPR].

⁷ See Norman V. Siebrasse, *Holdup, Holdout and Royalty Stacking: A Review of the Literature*, in PATENT REMEDIES AND COMPLEX PRODUCTS: TOWARD A GLOBAL CONSENSUS (C. Bradford Biddle et al. eds., (2019)); Jorge L. Contreras, *Technical Standards, Standards-Setting Organizations and Intellectual Property: A Survey of the Literature (With an Emphasis on Empirical Approaches)*, in RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW, VOL. II – ANALYTICAL METHODS 185, 199-200 (Peter S. Menell & David Schwartz eds., 2019); DOJ-FTC Antitrust & IPR, *supra* note 6, at 35–40.

⁸ DOJ-FTC Antitrust & IPR, *supra* note 6, at 35-40; Renata B. Hesse & Frances Marshall, *U.S. Antitrust Aspects of FRAND Disputes*, in CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: COMPETITION, ANTITRUST AND PATENTS 263, 265 (Jorge L. Contreras ed., 2018).

In order to ensure broad access to the standards that they develop, and to avoid patent hold-up, many SDOs have adopted policies that fall into two general categories: disclosure policies and licensing policies.⁹ Disclosure policies require SDO participants to disclose SEPs that they hold to the SDO, generally prior to the approval of a standard. Early disclosure of SEPs enables standards developers to decide whether or not to approve a design that is covered by these SEPS, to choose an alternative, non-infringing technology, to modify a draft standard before it is approved to eliminate the infringing feature, or to seek licenses to the patented technology.¹⁰

Licensing policies, on the other hand, require SEP holders to grant manufacturers of standardized products the right to use their SEPs on terms that are either royalty-free (RF) or that bear royalties that are “fair, reasonable and nondiscriminatory” (FRAND). These commitments are intended to assure product manufacturers that they will be able to obtain all licenses necessary to manufacture a standardized product. FRAND or RF licensing commitments are required of all SDOs accredited by the American National Standards Institute (ANSI) and are also utilized widely among other SDOs around the world.¹¹

B. Standards Deception as a Defense to Infringement of SEPs

When a SEP holder violates the patent disclosure requirements of an SDO and subsequently seeks to enforce patents against implementers of a standard, the infringing implementer may raise one or more equitable defenses. These defenses include fraud, estoppel, laches, waiver, unclean hands, and implied license.¹² Each of these defenses is based on the failure of the SEP holder to disclose a SEP necessary for implementation of the collaboratively-developed standard. For example, in *Stambler v. Diebold*, the patent holder (Diebold) was found to have known for ten years that a proposed standard concerning the activation of automated teller machines infringed its patent, yet remained silent “while an entire industry adopted the proposed standard.”¹³ The court concluded that Diebold’s silence was “intentionally misleading” and granted summary judgment for the defendant based on the equitable doctrines of laches and estoppel.

In *Wang v. Mitsubishi*,¹⁴ Wang Laboratories proposed a memory chip standard to an SDO known as the Joint Electron Device Engineering Council (“JEDEC”).¹⁵ During the three years that the standard was deliberated at JEDEC, Wang did not disclose that it was seeking patent protection for the chip design. After the standard was approved by JEDEC and manufacturers like Mitsubishi

⁹ See DOJ-FTC Antitrust & IPR, *supra* note 6, at 42. These policies are generally considered to be binding on participants in the SDO’s activities, though the legal effect of such policies is not always clear. See Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, 2015(2) UTAH L. REV 479, 501–17 (2015).

¹⁰ See Gil Ohana & C. Bradford Biddle, *The Disclosure of Patents and Licensing Terms in Standards Development*, in CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: COMPETITION, ANTITRUST AND PATENTS 244, 245 (Jorge L. Contreras ed., 2018); DOJ-FTC Antitrust & IPR, *supra* note 6, at 42–45.

¹¹ Justus Baron, et al., *Making the Rules: The Governance of Standard Development Organizations and their Policies on Intellectual Property Rights*, JRC SCIENCE FOR POLICY REPORT EUR 29655 (Nikolaus Thumm ed., Mar. 2019). [hereinafter JRC Report].

¹² See generally, Daryl Lim, *Unilateral Conduct and Standards*, in CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: COMPETITION, ANTITRUST AND PATENTS 47, 56–60 (Jorge L. Contreras ed., 2018).

¹³ *Stambler v. Diebold, Inc.*, No. 85 CV 3014, 1988 WL 95479 at 6 (E.D.N.Y. 1988).

¹⁴ *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571 (Fed. Cir. 1997).

¹⁵ JEDEC also makes an appearance in the *Rambus* disputes, discussed below.

began to manufacture chips conforming to the standard, Wang began to enforce its patent against them. Mitsubishi argued that Wang’s conduct over a six-year period gave rise to an implied license under the patent. A jury agreed with Mitsubishi, and both the district court and the Federal Circuit affirmed, pointing to the large amount of evidence that Wang’s conduct created an implied license.

In *Qualcomm I*,¹⁶ the Federal Circuit held that Qualcomm’s intentional failure to disclose essential patents covering the H.264 video compression standard to the Joint Video Team (JVT) SDO supported the district court’s finding that Qualcomm ceded its right to enforce those patents under the doctrine of implied waiver.¹⁷ The district court applied the remedy of unenforceability to the patents that Qualcomm failed to disclose. It analogized Qualcomm’s inaction to inequitable conduct before the PTO and patent misuse -- other forms of conduct resulting in the unenforceability of the relevant patents.¹⁸ The Federal Circuit approved the district court’s reasoning, recognizing its authority to “give a fair, just, and equitable response reflective of the offending conduct.”¹⁹

In each of these cases, the remedy for the SEP holder’s failure to disclose patents in violation of an SDO’s written or unwritten policies was to render the undisclosed SEPs unenforceable against products implementing the relevant standards. This remedy is sweeping, as it is generally interpreted to cover not only the particular product manufacturer that raised the defense, but all implementers of the relevant standard.²⁰

C. Antitrust Remedies for Standards Deception

In addition to defenses that can be raised by the infringing implementer of a standard, standards deception by a SEP holder can give rise to antitrust claims under the Sherman Act. Section 2 of the Sherman Act makes it unlawful to “monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States.”²¹ To prevail on a claim for monopolization or attempted monopolization, the plaintiff must prove that the defendant had power in the relevant market and willfully sought, acquired, or maintained that power in an unlawful manner. Monopolization claims also require that the defendant have “market power”, or the ability to distort competition in a particular product or technology market. Some have argued that standards, once adopted broadly in the marketplace, can confer market power on the holders of patents that are essential to the use of those standards.²² The abuse of such market power could thus constitute unlawful monopolization or attempted monopolization.

¹⁶ *Qualcomm Corp. v. Broadcom Inc.*, 548 F.3d 1004 (Fed. Cir. 2008) [*Qualcomm I*].

¹⁷ *Id.* at 1022. The Federal Circuit also spoke favorably about the doctrine of estoppel, though because of the court’s finding regarding waiver, did not need to reach the issue. *Id.* at 1024.

¹⁸ *Id.* at 1025–26.

¹⁹ *Id.* at 1026.

²⁰ See 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).

²¹ 15 U.S.C. § 2.

²² Daniel G. Swanson & William J. Baumol, *Reasonable and Nondiscriminatory (RAND) Royalties, Standards Selection, and Control of Market Power*, 73 ANTITRUST L.J. 1, 3-4 (2005); AM. BAR ASSN., HANDBOOK ON ANTITRUST ASPECTS OF STANDARD SETTING 115–17 (2d ed., 2011); Herbert Hovenkamp, *FRAND and Antitrust*, PENN LAW:

The Federal Trade Commission (FTC) has taken the view that a SEP holder’s failure to disclose patents essential to industry standards can thus constitute a violation of Section 2. As explained by the FTC, “Exclusionary conduct such as deception may distort the selection of technologies and evade protections designed by [SDOs] to constrain the exercise of monopoly power, with substantial and lasting harm to competition”.²³

The FTC has brought claims based on deceptive conduct within an SDO principally under its authority to enforce Section 5 of the FTC Act, which prohibits unfair methods of competition.²⁴ These cases have included actions against Dell Computer²⁵ and Unocal²⁶, both of which involved allegations that an SDO participant deceptively withheld information about patents essential to the practice of a standard, and later sought to assert those patents. In each case, this deception was claimed to constitute exclusionary conduct giving rise to a claim for monopolization. The FTC settled its cases against Dell and Unocal, in each instance entering a consent order effectively rendering the asserted patents unenforceable.²⁷

Perhaps the best-known case of alleged deception within a standards body involved semiconductor memory designer Rambus, Inc. The FTC investigated Rambus for a pattern of allegedly deceptive conduct within JEDEC, including the amendment of its undisclosed patent applications to cover current discussions within the SDO. The FTC found that Rambus had engaged in deceptive practices amounting to unfair methods of competition that violated Section 5 of the FTC Act, as well as violations of Section 2 of the Sherman Act.²⁸

This theory also received support from the Court of Appeals for the Third Circuit in *Qualcomm II*,²⁹ a private antitrust action brought by Broadcom in response to Qualcomm’s assertion of previously undisclosed SEPs against it.³⁰ Broadcom argued that Qualcomm’s intentionally false representations to an SDO known as the Joint Video Group (JVG) violated Section 2 of the Sherman Act, and the court agreed. It noted that such deception “harms the competitive process by obscuring the costs of including proprietary technology in a standard and increasing the likelihood that patent rights will confer monopoly power on the patent holder.”³¹ Despite the specter of such liability, however, the court found that Broadcom lacked standing to bring a claim for monopolization (as it did not yet compete in the relevant market), and that it failed to allege a

LEGAL SCHOLARSHIP REPOSITORY 19–20 (Aug. 2019)
https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=3095&context=faculty_scholarship.

²³ In re. Rambus, Inc., No. 9302, 2006 WL 2330117, at *18 (F.T.C Aug. 2, 2006), rev’d, 522 F.3d 456 (D.C. Cir. 2008).

²⁴ 15 U.S.C. § 45.

²⁵ In re Dell Computer Corp., 121 F.T.C. 616 (1996).

²⁶ In re. Union Oil Co. of Cal., F.T.C. Docket No. 9305 (F.T.C. Jul. 27, 2005).

²⁷ See Lim, *supra* note 12, at 54–56; Hesse & Marshall, *supra* note 8, at 271–72.

²⁸ In re. Rambus, Inc., Docket No. 9302 (F.T.C. 2006). The FTC’s judgment against Rambus was reversed by the DC Circuit due to the FTC’s failure to prove an antitrust injury (harm to competition) (*Rambus, Inc. v. FTC*, 522 F.3d 456 (D.C. Cir. 2008)). See, generally, Lim, *supra* note 12, at 51–54; Hesse & Marshall, *supra* note 8, at 272–73.

²⁹ *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297 (3d Cir. 2007) [*Qualcomm II*]. See also Hesse & Marshall, *supra* note 8, at 274–75.

³⁰ *Qualcomm II*, 501 F.3d at 314. Note that this action was brought roughly in parallel with the action that resulted in the Federal Circuit’s 2008 ruling in *Qualcomm I*, discussed above.

³¹ *Id.*

cognizable antitrust injury.³² Thus, the court did not ultimately apply the Sherman Act to Qualcomm’s alleged misconduct.

II. THE ENOXAPARIN CONTROVERSY: A BIOPHARMA STANDARDS DISPUTE

A. *Enoxaparin – Approval and Market Entry*

The anticoagulant properties of the heparin molecule were first described in 1916.³³ It soon became a common antidote for thrombosis, myocardial infarction and other clotting disorders. In the 1970s, researchers began to experiment with shorter chemical chains derived from the heparin molecule – low molecular weight heparins – which appeared to offer similar efficacy with fewer side effects.³⁴ The first such low molecular weight heparin to be approved for use in humans was enoxaparin. Sanofi-Aventis filed a U.S. patent application covering enoxaparin in 1991, resulting in the issuance of U.S. Pat. No. 5,389,618 in 1995.³⁵ Shortly thereafter, Sanofi-Aventis introduced enoxaparin to the U.S. market under the brand name Lovenox.³⁶ Lovenox became a blockbuster drug, achieving \$2.7 billion in sales during 2009 alone.³⁷

In March 2003, Amphastar Pharmaceuticals, a specialty pharmaceutical manufacturer based in Rancho Cucamonga, California, filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA), seeking clearance to market a generic or biosimilar version of enoxaparin.³⁸ Amphastar’s ANDA contained a declaration challenging Sanofi-Aventis’s ‘618 patent.³⁹ As a result, in August, 2003, Sanofi-Aventis sued Amphastar for infringement of the ‘618 patent.⁴⁰ That litigation continued for five years and was appealed twice to the Federal Circuit. In May 2008, the Federal Circuit affirmed a district court’s decision that the ‘618 patent was unenforceable due to Sanofi-Aventis’s inequitable conduct before the PTO.⁴¹ The invalidation of Sanofi-Aventis’s ‘618 patent cleared the way for generic entry of competitors into the market for enoxaparin, pending FDA approval.

³² *Id.*

³³ JIE JACK LI & E.J. COREY, *DRUG DISCOVERY: PRACTICES, PROCESSES, AND PERSPECTIVES* 189 (2013).

³⁴ *Id.*

³⁵ U.S. Pat. No. 5,389,618 (Feb. 14, 1995). The ‘618 patent was reissued on June 14, 2005 as U.S. Patent No. RE 38,743.

³⁶ Complaint at 4, *Amphastar Pharm., Inc. et. al. v. Momenta Pharm., Inc.*, No. 5:15-cv-01914 (C.D. Cal. filed Sep 17, 2015).

³⁷ Dana A. Elfin, *Momenta Battle Over Amphastar Generic Continues*, BLOOMBERG (Jun. 20, 2017).

³⁸ Ctr. for Drug Evaluation and Research, *Application Number: ANDA 076684, Chemistry Reviews*, 3 (July 25, 2011).

³⁹ The ANDA process includes what is known as a “Paragraph IV” certification. This regulatory pathway allows a generic drug maker to declare that the patent(s) protecting a brand-name drug are invalid or otherwise unenforceable. The certification immediately forces the issue to litigation in federal court, without requiring the generic manufacturer to enter the market and risk being held liable for patent infringement. *See* 21 U.S.C. §355.

⁴⁰ *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008). Sanofi-Aventis also sued Teva Pharmaceuticals of Israel, which had also submitted an NDA for the marketing of generic enoxaparin. [cite]

⁴¹ 525 F.3d at 1349.

In 2003, the Sandoz division of Novartis entered into a collaboration agreement with Momenta Pharmaceuticals of Cambridge, Massachusetts relating to the development, manufacture and commercialization of a generic version of enoxaparin.⁴² Based on characterization work conducted by Momenta, Sandoz filed its own ANDA relating to enoxaparin in August, 2005.⁴³

Enoxaparin, a broken-down form of the polymer heparin, is a complex biologic pharmaceutical that is manufactured using an organic process rather than traditional chemistry. As a result, it is difficult to determine definitively whether a particular generic version of enoxaparin is truly “bioequivalent” to the FDA-approved Lovenox. During the pendency of the ANDAs for generic enoxaparin, Sanofi-Aventis contended that enoxaparin could be manufactured only using Sanofi-Aventis’s proprietary manufacturing process, and that without it, a generic manufacturer could not guaranty that what it produced was biologically equivalent to enoxaparin.⁴⁴ Researchers at Momenta, however, identified a unique chemical signature for enoxaparin. On this basis, Momenta contended that one could reliably determine whether a manufactured compound was enoxaparin. As such, Momenta and Sandoz claimed to overcome Sanofi-Aventis’s objection that manufacture of enoxaparin would not be possible without using Sanofi-Aventis’s proprietary manufacturing process. In 2003, Momenta filed a patent application claiming several methods of characterizing enoxaparin. The patent was issued in 2009, listing five inventors including Dr. Zachary Shriver, a senior director of research analytics at Momenta.

In July 2010, the FDA approved the Sandoz-Momenta ANDA for generic enoxaparin.⁴⁵ Sandoz began sales of enoxaparin in the U.S. shortly thereafter.

B. *The USP and Method 207*

The United States Pharmacopeial Convention (USP) is a non-profit organization founded in 1820. USP produces a substance and preparation monograph for each FDA-approved drug, including biologics such as enoxaparin.⁴⁶ The FDA relies heavily on USP monographs in approving drugs for marketing, and the Federal Food, Drug and Cosmetic Act provides that approved drugs must meet the strength, quality and purity requirements set forth by the USP.⁴⁷

In 2006, at the urging of Sanofi-Aventis, USP began to develop a standard for testing the purity of enoxaparin during the manufacturing process.⁴⁸ The standard was based on the presence of a

⁴² Complaint at 6–7, *Amphastar Pharm., Inc. et. al. v. Momenta Pharm.*, No. 5:15-cv-01914 (C.D. Cal. filed Sep 17, 2015).

⁴³ Ctr. for Drug Evaluation and Research, *Approval Package for: Application Number: ANDA 77-857*, 4 (July 23, 2010).

⁴⁴ See Transcript of Record: Dr. Kaundinya at 13039, 13041, *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, No. 18-1740 (Fed. Cir. appeal docketed March 29, 2018); *Larry Bell & Peter O. Safir, Citizens Petition 1–26*, 24 (Feb. 19, 2003).

⁴⁵ Ctr. for Drug Evaluation and Research, *Approval Package for: Application Number: ANDA 77-857*, 1 (July 23, 2010).

⁴⁶ See U.S. Pharmacopial Convention, *Legal Recognition – Standards Categories*, <https://www.usp.org/about/legal-recognition/standard-categories#biologics> (last visited Feb. 13, 2020).

⁴⁷ 21 U.S.C. § 351(b), § 321(j).

⁴⁸ Presumably, Sanofi-Aventis wished to ensure that any generic version of enoxaparin on the market was in fact equivalent to Lovenox.

particular “1,6 anhydro ring” (AR) structure in 15-25% of enoxaparin carbohydrate chains.⁴⁹ Sanofi-Aventis proposed to USP a method (which Sanofi-Aventis had allegedly sought to patent) for determining whether the AR structure was present using high performance liquid chromatography (HPLC).⁵⁰ Sanofi-Aventis urged USP to adopt its method as an official standard for the manufacture of enoxaparin. This eventually became known as Method 207.⁵¹

Momenta participated in the deliberations at USP and opposed making the use of Method 207 mandatory for determining the presence of the AR structure. According to Momenta, it developed a superior method for testing for the AR structure using nuclear magnetic resonance.⁵² During a USP meeting in 2008, USP announced that Sanofi-Aventis had allowed its patent application covering its method of detecting the AR structure to lapse.⁵³ As there were no other known patents or patent applications covering the proposed method, USP approved Method 207 in 2009.⁵⁴ Yet while the USP monograph for enoxaparin, which became effective in December 2009, contained a requirement that at least 20% of manufactured enoxaparin contain the AR structure, it did not require that a particular method be used to make that determination.

During its evaluation of Amphastar’s ANDA for generic enoxaparin, the FDA issued a Quality Deficiency letter in September 2009, requesting Amphastar to confirm that its manufactured enoxaparin would comply with the requirements of the USP monograph, including presence of the AR structure.⁵⁵ In its response, Amphastar committed that it would ensure that its manufactured enoxaparin would comply with the USP monograph requirements, including the presence of the AR structure in the required amounts.⁵⁶ However, neither FDA nor Amphastar discussed the specific method that would be used to detect the AR structure in Amphastar’s manufactured enoxaparin. The FDA approved Amphastar’s ANDA in September 2011, after which it began sales in the U.S.⁵⁷

Two days later, Momenta brought suit against Amphastar for infringement of the ‘886 patent in the Federal District Court for the District of Massachusetts.⁵⁸ Specifically, Momenta alleged that Amphastar’s method of testing manufactured enoxaparin for the AR structure infringed the

⁴⁹ Brief for Plaintiffs-Appellants at 17, *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, Fed. Cir. Case No. 18-1740 (filed July 30, 2018) [hereinafter *Momenta Appeal Brief*].

⁵⁰ *Id.* at 17–18.

⁵¹ USP, <207> Test for 1,6-anhydro Derivative for Enoxaparin Sodium.

⁵² *Momenta Appeal Brief*, *supra* note 49, at 18.

⁵³ U.S. Pharmacopeia, Heparin Ad Hoc Advisory Panel, Meeting #14, Nov. 14, 2008 – Meeting Minutes, Item 2.b (“USP has had successful correspondence with the company that may have patents that may pertain to the test or related tests. The company has reported that it will allow the one patent that may cover the method to lapse. As such USP is not aware of any patent issues that may cover the test. The [Advisory Panel] may proceed with the use of the test as planned.”)

⁵⁴ Complaint at 12, *Amphastar Pharm., Inc. et. al. v. Momenta Pharm.*, No. 5:15-cv-01914 (C.D. Cal. filed Sep 17, 2015).

⁵⁵ FDA Off. Generic Drugs, Deficiency Letter for ANDA 76-684, Dated Sept. 4, 2009 (Deficiency A2).

⁵⁶ Amphastar, Quality Amendment for ANDA 76-684 – Enoxaparin Sodium Injection, Sept. 18, 2009 (response to Deficiency A2).

⁵⁷ U.S. Food & Drug Admin., *Drugs@FDA: FDA-Approved Drugs* <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=076684> (last visited Feb. 25, 2020).

⁵⁸ *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 882 F. Supp. 2d 184, 188 (D. Mass. 2011)

claims of the patent, which covered numerous testing methods.⁵⁹ After a lengthy set of proceedings, including two separate appeals to the Federal Circuit,⁶⁰ 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.⁶¹ The District Court affirmed the jury's verdict.

In addition, Amphastar raised the equitable defenses of waiver and estoppel, as to which the jury rendered an advisory verdict in favor of Amphastar.⁶² The District Court adopted the jury's advisory verdict.⁶³ The basis for Amphastar's waiver and estoppel was Momenta's failure to disclose the '886 patent, allegedly in violation of USP's rules and policies. In 2015, Amphastar brought an antitrust action against Momenta and Sandoz, alleging that they violated the Sherman Act and state antitrust laws as a result of the same failure.⁶⁴

C. The USP Policies

USP has a number of written policies that are binding on individuals and firms participating in its standardization work. First is a set of Rules and Procedures that govern the conduct of USP's various expert bodies.⁶⁵ Second is a written set of Guidelines governing the submission of proposals for the creation of a new USP monograph.⁶⁶

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 alleged that Momenta intentionally violated USP's policies.⁶⁷

⁵⁹ There are numerous methods that can be used to test enoxaparin for the presence of the AR structure. As noted above, Sanofi-Aventis developed a method based on HPLC which eventually was adopted as USP's Method 207. Momenta Appeal Brief, *supra* note 49, at 17–18. Momenta first used capillary electrophoresis, and then switched to a superior method based on nuclear magnetic resonance. Mom. Momenta Appeal Brief, *supra* note 49, at 18. And Amphastar developed a disaccharide building block (DBB) procedure for testing enoxaparin, which the FDA approved in 2006 and 2007. Stephen A. Campbell, *Telephone Amendment: RE: ANDA 76-684, Enoxaparin Sodium Injection*, AMPHASTAR PHARM., (Nov. 2, 2006). Stephen A. Campbell, *Telephone Amendment: RE: ANDA 76-684, Enoxaparin Sodium Injection*, AMPHASTAR PHARM., (March 29, 2007). At some point after it began to produce generic enoxaparin in September 2011, Amphastar switched from the DBB procedure to Method 207 for testing its product. Momenta alleges that Amphastar strategically switched from the DBB procedure to Method 207 in order to argue that because it was using a method required by the FDA (a requirement that Momenta disputes), it was immunized from suit under 35 U.S.C. § 271(e)(1) (“It shall not be an act of infringement to make, use, offer to sell, or sell within 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...”).

⁶⁰ See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 457 F. App'x. 929 (Fed. Cir. 2011).

⁶¹ *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 289 F. Supp. 3d 258 (D. Mass. Feb. 7, 2018) (*Momenta I*).

⁶² The applicability of equitable defenses is typically a question reserved to the court. However, courts may put such questions to a jury to render an advisory verdict, which the court may or may not adopt. J.E. Macy, *Nature and Effect of Jury's Verdict in Equity*, 15 A.L.R. 1147 (originally pub. 1945).

⁶³ *Momenta I*, 289 F. Supp. 3d at 265.

⁶⁴ *Amphastar Pharm., Inc. v. Momenta Pharm., Inc.*, 297 F. Supp. 3d 222 (D. Mass. 2018) (*Momenta II*).

⁶⁵ USP, USP Rules and Procedures of the 2005-2010 Council of Experts (Effective Jan. 1, 2008) [hereinafter USP Rules and Procedures].

⁶⁶ USP, USP Guideline for Submitting Requests for Revision to USP-NF V4 July 2009 [hereinafter USP Guidelines].

⁶⁷ Complaint at 10–11, *Amphastar Pharm., Inc. et. al. v. Momenta Pharm.*, No. 5:15-cv-01914 (C.D. Cal. filed Sep 17, 2015).

In consequence, Amphastar argued that (1) Momenta waived its right to enforce the ‘886 patent, (2) Momenta was 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. These allegations reflect a typical SDO deception scenario, akin to the facts alleged in cases like *Dell, Rambus* and *Broadcom v. 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”.⁶⁸

In assessing Momenta’s failure to disclose the ‘886 patent, the court considered Momenta’s and Dr. Shriver’s obligations under USP’s written policies. First, Section 2.05 of the USP Rules and Procedures 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.”⁶⁹ Dr. Shriver was a member of USP’s Heparin Ad Hoc Advisory Panel, and as such was subject to the Rules and Procedures. Accordingly, Dr. Shriver abstained from voting on the Method 207 standard.⁷⁰

Second, Section 2.06(a) of the Rules and Procedures 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”.⁷¹ Dr. Shriver submitted such a statement and accurately identified Momenta as his employer.⁷²

Third, under 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 Sponsor-held intellectual property rights”.⁷³ Momenta made no disclosure responsive to this provision.⁷⁴

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. The court, however, disagreed. First, Dr. Shriver’s abstention from the vote on Method 207 was in compliance with Section 2.05 of the Rules and Procedures.

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”

⁶⁸ *Qualcomm I*, 548 F.3d at 1008.

⁶⁹ USP Rules and Procedures, *supra* note 65, at § 2.05.

⁷⁰ *Momenta I*, 289 F. Supp. 3d at 266.

⁷¹ USP Rules and Procedures, *supra* note 65, at § 2.06(a).

⁷² Zachary Shriver, USP Council of Experts, Expert Committee, and Ad Hoc Advisory Panel Member Conflict of Interest Statement (Feb. 26, 2008) (reproduced in *Momenta Appeal Brief*, *supra* note 49, at 16).

⁷³ USP Guidelines, *supra* note 66, at 5.

⁷⁴ *Momenta I*, 289 F. Supp. 3d at 265.

was ambiguous in its requirements. Accordingly, the court found that, at worst, the USP policies were ambiguous regarding an affirmative obligation to disclose patents.⁷⁵

D. Participant Understanding of USP’s Disclosure Requirement

In at least two well-known standards deception cases in the ICT industry, the court has looked beyond the ambiguous language of the relevant SDO’s policies to find an affirmative obligation to disclose SEPs. In *Rambus v. Infineon*,⁷⁶ semiconductor designer Rambus, Inc. was accused, among other things, of committing fraud based on its alleged concealment of patents that were essential to the implementation of a standard developed at JEDEC. The district court found that no such duty of disclosure was created by JEDEC’s written policies. But the court also found, based on the testimony of various JEDEC participants, that even without a written disclosure requirement, SDO participants shared a common understanding that they *should* disclose patents necessary to practice JEDEC standards.⁷⁷ As such, the court recognized a legal duty to disclose arising from the norms and practices of JEDEC participants.⁷⁸

The Federal Circuit in *Qualcomm II* also upheld a lower court’s recognition of a duty to disclose based on informal expectations and practices of SDO participants, where such a duty was not clearly delineated in the SDO’s written policies.⁷⁹ The court in *Qualcomm II* recognized that “[a] duty to speak can arise from a group relationship in which the working policy of disclosure of related intellectual property rights (‘IPR’) is treated by the group as a whole as imposing an obligation to disclose information in order to support and advance the purposes of the group.”⁸⁰

Accordingly, the district court in *Momenta I* considered whether USP participants may have “understood the policies to include a duty to disclose” patents essential to USP standards, notwithstanding the ambiguity of USP’s written policies.⁸¹ In support of this proposition, Amphastar introduced testimony from at least one former USP employee, who testified that there was a “common understanding” among USP participants that patent disclosures were required.⁸² This witness described a 2008 advisory panel meeting at which a USP employee observed that Sanofi-Aventis, the Sponsor of Method 207, had disclosed a relevant patent. According to the witness, a representative from Momenta then asked USP to request Sanofi-Aventis to abandon the patent before the standard was approved, which it ultimately did.⁸³ Amphastar argued that all of these facts indicated both an informal expectation among USP participants to disclose patents covering USP standards, and that Momenta was aware of this expectation. The court agreed, finding that notwithstanding the absence of an express requirement to disclose patents essential to

⁷⁵ *Id.*

⁷⁶ *Rambus, Inc. v. Infineon Techs. AG*, 318 F.3d 1081 (Fed. Cir. 2003).

⁷⁷ *Id.* at 1098.

⁷⁸ Notwithstanding the existence of such a duty, Rambus was found not to have violated its obligation to disclose patent applications to JEDEC. *Id.* at 1105. See also *Broadcom I* (finding similar duty to disclose patents based on informal norms and expectations of SDO participants).

⁷⁹ *Broadcom I*.

⁸⁰ *Qualcomm I*, 548 F.3d at 1022.

⁸¹ *Momenta I*, 289 F. Supp. 3d at 265–70.

⁸² *Id.* at 268.

⁸³ *Id.* at 267.

USP’s standards, such an obligation should be implied on the basis of unwritten participant expectations.⁸⁴

E. Waiver

As noted in Part I, both courts and the FTC have found that a patent holder’s deceptive failure to disclose a SEP in violation of an SDO’s rules can result in a waiver of the right to enforce the SEP. Given that Momenta had an implicit duty to disclose patents essential to its standards, Amphastar argued that Momenta breached that duty by failing to disclose the ‘886 patent. As a result, Amphastar argued that Momenta should be deemed to have waived its right to enforce the ‘886 patent against Amphastar and other implementers of Method 207. The district court agreed.

Citing *Hynix v. Rambus*, the court explained that “implied waiver occurs if the behavior of the patent owner was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished.”⁸⁵ Finding that Momenta had a duty to disclose the ‘886 patent to USP, and that it breached this duty, the court held that Momenta had waived its right to enforce the patent against implementers of Method 207.⁸⁶

F. Equitable Estoppel

Amphastar also argued that it reasonably and detrimentally relied on Momenta’s misleading failure to disclose the ‘886 patent, which induced it to make significant investments in manufacturing enoxaparin using Method 207. As a result, Amphastar argued, Momenta should be estopped from enforcing the ‘886 patent against it with respect to the use of Method 207. The district court agreed. It noted that to succeed on a claim for equitable estoppel, the alleged infringer must prove that the patent owner engaged in misleading conduct that resulted in a reasonable inference that it did not intend to enforce its patent.⁸⁷ The infringer must then show that it relied on the misleading conduct and that it will be materially prejudiced if the patent holder is permitted to enforce the patent against it.⁸⁸ The court acknowledged that a patent holder’s breach of its obligation to disclose a patent to an SDO can constitute misleading conduct in this context, and that an infringer’s subsequent adoption of the relevant standard can demonstrate reliance.⁸⁹

Applying these principles to the facts alleged in this case, the jury found, and the district court affirmed, that Momenta breached its duty to USP through its silence, and that Amphastar detrimentally relied on the Momenta’s silence in practicing Method 207.⁹⁰ Accordingly, it held

⁸⁴ *Id.* at 264.

⁸⁵ *Momenta I*, 289 F. Supp. 3d at 269 (citing *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1348 (Fed. Cir. 2011) (quoting *Qualcomm I*, 548 F.3d at 1020)).

⁸⁶ *Id.* at 265. The court limited the unenforceability of the ‘886 patent to processes implementing USP Method 207 only. Because only two of the processes used by Amphastar conformed to Method 207, and Amphastar’s DBB process did not, the ‘886 patent was held to be unenforceable as to the two procedures that conformed to the standard, but not to DBB.⁸⁶ *Id.* at 270.

⁸⁷ *Id.* at 268.

⁸⁸ *Id.* at 269–70.

⁸⁹ *Id.* at 269.

⁹⁰ *Id.* at 269–70.

that Momenta was estopped from enforcing the ‘886 patent against Amphastar with respect to Method 207.⁹¹

G. Antitrust Claims

In addition to raising its waiver and estoppel defenses in the infringement suit brought against it by Momenta, in September 2015 Amphastar brought a separate action charging Momenta and Sandoz with violations of the Sherman Act and California antitrust and competition law.⁹² These claims were all based on Momenta’s alleged failure to disclose the ‘886 patent to USP in violation of USP’s policies.⁹³ Amphastar argued that Momenta “wrongfully acquir[ed] monopoly power by deceiving the USP into adopting” Method 207. This conduct, Amphastar alleged, both improperly excluded Amphastar from the market for generic enoxaparin and drove up the price of generic enoxaparin by billions of dollars.⁹⁴

In denying Momenta’s motion to dismiss this claim, the court again cited *Qualcomm II*, in which the court explained 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”.⁹⁵ Because Amphastar alleged such conduct, the court held that Amphastar had articulated a cognizable claim for monopolization under the Sherman Act.⁹⁶

In addition, a month after the initiation of Amphastar’s antitrust suit, a group of plaintiffs led by Nashville General Hospital brought an antitrust class action suit against Momenta and Sandoz in the U.S. District Court for the Middle District of Tennessee.⁹⁷ The plaintiffs, consisting of hospitals, HMOs and other healthcare payors, alleged that Momenta’s and Sandoz’s actions delayed Amphastar’s entry into the market for generic enoxaparin, resulting in elevated prices for the drug. They alleged violations of both Sections 1 and 2 of the Sherman Act.

H. Appeal and Settlement

Momenta and Sandoz appealed the district court’s decisions on waiver and estoppel to the Federal Circuit in July 2018.⁹⁸ But in June 2019, prior to oral argument, the parties settled their dispute. Under the terms of a confidential settlement agreement, Momenta and Sandoz paid

⁹¹ *Id.* at 270.

⁹² Amphastar filed this suit in the Central District of California in September 2015. *Amphastar Pharm., Inc. v. Momenta Pharm., Inc.*, 5:15-cv-01914 (D. C.D. Cal. filed Sept. 17, 2015). The case was transferred to the District of Massachusetts in January 2016. *Momenta II*, 297 F. Supp. 3d at 227

⁹³ Complaint at 10–12, *Amphastar Pharm., Inc. v. Momenta Pharm., Inc.*, 5:15-cv-01914 (D. C.D. Cal. filed Sept. 17, 2015).

⁹⁴ *Id.* at 19.

⁹⁵ *Amphastar Pharm., Inc. v. Momenta Pharm., Inc.*, 297 F. Supp. 3d 222, 230 (D. Mass. 2018).

⁹⁶ *Id.* at 230.

⁹⁷ *See* Complaint, *Hosp. Auth. of Metro. Gov’t of Nashville v. Momenta Pharm, Inc.*, 244 F. Supp. 3d 705 (M.D. Tenn. 2017).

⁹⁸ Momenta Appeal Brief, *supra* note 49.

Amphastar \$59.9 million and dismissed all pending litigation among the parties.⁹⁹ The parties separately settled the Tennessee antitrust class action in December 2019, with Momenta agreeing to pay \$35 million, and Sandoz agreeing to pay \$85 million, to the plaintiffs and their counsel.¹⁰⁰

III. IMPLICATIONS OF *MOMENTA V. AMPHASTAR* – HOW WILL BIOPHARMA FARE IN THE STANDARDS WARS ?

The district court decision in *Momenta I* was the first to apply the patent nondisclosure and deception principles established in ICT standardization cases to parties in the biopharmaceuticals sector. While there are notable similarities between the facts alleged in *Momenta* and those in earlier ICT cases like *Wang*, *Stambler*, *Qualcomm* and the series of cases involving Rambus, there are significant differences as well. Several of these differences were raised by Momenta in its briefing to the Federal Circuit, but because the parties settled their dispute prior to consideration of the case by the Federal Circuit, the degree to which these differences might have been persuasive to the court are unknown. Nevertheless, it is worth considering some of these distinctions and the degree to which the patent nondisclosure and deception principles that evolved in the ICT industry are apposite to standardization at USP and in the biopharma sector more broadly.

A. *Is USP an SDO?*

Momenta argued in its appellate brief that USP differs significantly from the ICT-based SDOs around which the principles of standards deception and nondisclosure were first developed.

USP is an independent, scientific organization that sets formulary standards for drugs sold in the United States. It is not a “standard-setting” body like those previously addressed by this Court: USP is not a consortium of industry competitors setting technical requirements needed for different products to interoperate. Rather, USP produces monographs describing the attributes of drugs; the monographs may be incorporated into requirements set by the FDA. USP’s monographs are produced by staff scientists, with input from eminent scientists who volunteer on advisory panels and others, including drug companies.¹⁰¹

In the above description, Momenta points out two principal areas in which USP is unlike ICT-based SDOs: its organizational structure and the nature of its standards. I consider each of these in turn below.

⁹⁹ Amphastar Pharmaceuticals, Inc., *Amphastar Pharmaceuticals, Inc. Announces Settlement in Litigation with Momenta and Sandoz* (July 19, 2019) <http://ir.amphastar.com/news-releases/news-release-details/amphastar-pharmaceuticals-inc-announces-settlement-litigation>.

¹⁰⁰ Mike Leonard, *Momenta, Sandoz Get Preliminary OK for Lovenox Class Settlement*, BLOOMBERG LAW (Jan. 3, 2020) https://www.bloomberglaw.com/product/blaw/document/XC3N55SC000000?criteria_id=baab3ccc4a9ad0615164a068869ca2&searchGuid=fadeb4f9-1872-4f02-8afb-56f337a1825d&bna_news_filter=pharma-and-life-sciences.

¹⁰¹ *Momenta Appeal Brief*, *supra* note 49, at 14. *See also id.* at 4 (“unlike the standard-setting organization in *Qualcomm*, whose members were industry competitors, USP is an independent, scientific organization.”)

1. *SDO Structural Issues*

It is true that the technical work of many ICT-based SDOs is performed largely by volunteer representatives of the SDO’s membership – usually companies interested in the standards under development -- and the SDO’s staff play a predominantly administrative and coordinating role.¹⁰² However, this allocation of responsibility varies from SDO to SDO, and some SDOs in the ICT sector have professional staff numbering in the hundreds.¹⁰³

Moreover, in *Unocal*, the FTC brought an enforcement action against Unocal with respect to its failure to disclose relevant patents to the California Air Resources Board (CARB).¹⁰⁴ CARB, a governmental agency, was involved in developing regulations and standards governing the composition of low-emissions gasoline. Unocal participated in CARB’s public rulemaking proceedings, making various proposals and representations, while at the same time withholding information about several patent applications that it had filed on gasoline technologies under consideration by CARB. The fact that CARB was not an industry association typical of the ICT sector did not appear to deter the FTC from condemning Unocal’s allegedly deceptive conduct. Rather, the FTC’s focus was on Unocal’s “anticompetitive and exclusionary acts and practices” which constituted “unfair methods of competition” in violation of Section 5 of the FTC Act.¹⁰⁵ That conduct, the FTC alleged, caused substantial harm to competition and consumers.¹⁰⁶ The organizational structure of CARB, on the other hand, seems to have had little relevance to the analysis of Unocal’s conduct.

The same can be said for those cases involving SDOs in the ICT sector. In each of *Wang*, *Stambler*, *Dell*, *Qualcomm* and *Rambus*, the nature of the SDO had little bearing on the alleged conduct of the patent holder, and was scarcely discussed. Rather, the emphasis of the courts and agencies adjudicating these cases, whether under equitable defenses to infringement or affirmative theories of antitrust liability, was on the unilateral conduct of the patent holder in the face of a commitment to disclose SEPs to the SDO.¹⁰⁷ Accordingly, it does not seem that structural differences between USP and ICT-based SDOs should play much, if any, role in analyzing Momenta’s conduct with respect to non-disclosure of its patents.

2. *Nature of the Standards*

Momenta also points out that the standards developed by USP are “monographs describing the attributes of drugs”, rather than “technical requirements needed for different products to interoperate”.¹⁰⁸ While this description is itself somewhat inaccurate, as USP’s Method 207

¹⁰² See generally, JRC Report, *supra* note 11, at 91-92.

¹⁰³ *Id.*

¹⁰⁴ Decision and Order, In re. Union Oil Co. of Cal., F.T.C. Docket No. 9305 (F.T.C., Jul. 27, 2005).

¹⁰⁵ Complaint at 19–20, In re. Union Oil Co. of Cal., F.T.C. Docket No. 9305 (Mar. 4, 2003).

¹⁰⁶ *Id.* at 19.

¹⁰⁷ Of course, the character of ICT-based SDOs as associations of competitors is highly relevant in cases charging the SDO or its members with collusion or other concerted action. See, e.g., George S. Cary & Daniel P. Culley, *Concerted Action in Standard-Setting*, in CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: COMPETITION, ANTITRUST AND PATENTS 61 (Jorge L. Contreras ed., 2018). But allegations of collusion at the SDO level played no part in *Momenta*.

¹⁰⁸ Momenta Appeal Brief, *supra* note 49, at 14.

described a *method* for testing the purity of a compound, rather than any particular *attribute* of the compound, Momenta is correct that USP’s standards differ from ICT-based standards that seek to enable product interoperability. Yet this distinction does not seem meaningful in the context of Momenta’s alleged failure to disclose its patent. If Momenta’s actions harmed competitors like Amphastar (by inducing them to use an infringing method when testing the purity of enoxaparin) or hospitals and healthcare payors (by reducing competition and thus raising the price of generic enoxaparin), then the fact that the standard related to a testing method rather than product interoperability is largely irrelevant. This conclusion is supported by the FTC’s reasoning in *Unocal*, in which the relevant CARB standard related to the chemical composition of reduced emission gasoline. The standard did not pertain to product interoperability, yet Unocal’s deceptive concealment of its patents nevertheless resulted in competitive and consumer harm. Accordingly, the nature of USP’s standards does not seem particularly relevant to the analysis of Momenta’s conduct.

B. Was Method 207 Mandatory?

In its appellate briefing, Momenta also places great weight on its conclusion that Method 207 was not “mandatory”. There is clearly some debate regarding whether Amphastar’s use of USP Method 207 was required by the FDA. According to the district court, “the jury apparently found credible the testimony of Amphastar’s witnesses ... that Amphastar used the revised [AR testing] procedure in reliance on [Method 207] and was required by the FDA to do so.”¹⁰⁹ Amphastar emphasizes this point in its appellate brief, arguing that “The FDA required Amphastar to use Method [207] and following the FDA’s requirements is not optional.”¹¹⁰

Yet it is not clear from the record that this was actually the case. As Momenta points out, the USP monograph on enoxaparin specified the required AR structure to identify the compound, but did not specify a particular testing methodology to detect this structure. The FDA, in an *amicus* brief that it filed in an earlier phase of this case, explained that “to satisfy the [FDA] batch-testing requirement, a manufacturer has considerable latitude to employ any test protocol that meets the requirements specific to FDA’s approval of that drug, provided that the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm are established and documented.”¹¹¹

USP’s Method 207 does describe a particular testing process for detecting the AR structure in manufactured enoxaparin, but this was not the only known testing process, and the testing process was not part of the USP enoxaparin monograph. In fact, Momenta and Sandoz used a different testing process for their manufactured enoxaparin, and even Amphastar used a process that differed from Method 207 in some cases.¹¹² Momenta argues that while the FDA required that Amphastar

¹⁰⁹ *Momenta I*, 289 F. Supp. 3d at 270.

¹¹⁰ Brief for Defendants-Appellants at 55, *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, Fed. Cir. Case No. 18–1740 (filed Sept. 21, 2018)

¹¹¹ Corrected Brief for the United States as Amicus Curiae at 6, *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, (Filed Jul. 17, 2015) (quoting 21 C.F.R. § 211.165(e)).

¹¹² *Momenta Appeal Brief*, *supra* note 49, at 53–54.

comply with the USP monograph on enoxaparin, and thus to test for the AR structure, the monograph did not specify how that testing was to be accomplished.¹¹³

While the FDA was not explicit about the method for testing generic enoxaparin, there is some ambiguity regarding the degree to which USP requires the use of Method 207. Method 207 itself states that

The following procedure is used to determine the levels of [AR structures] in enoxaparin sodium. [NOTE - The test ... is conducted only where specified in the individual monograph.]¹¹⁴

This language implies that Method 207 is *the* way to test for the AR structure in enoxaparin (as testing is required by the enoxaparin monograph), not merely *a* way to test it. Moreover, Method 207 is included as part of USP’s National Formulary,¹¹⁵ and the Food, Drug, and Cosmetics Act explicitly requires that the strength, quality and purity of approved drugs be tested “in accordance with the tests or methods of assay set forth in [the relevant] compendium” (in this case, the USP National Formulary).¹¹⁶ Thus, Amphastar’s argument that the use of Method 207 was mandatory is not wholly without merit, even though it appears that Amphastar did not itself fully adhere to this requirement.

But even if the use of Method 207 were *not* mandatory, it is not clear that this relieves Momenta of liability under relevant doctrines pertaining to patent disclosure in standard-setting. Admittedly, some technical standards that have been subject to disputes regarding patent disclosure are mandated by governmental edict. One example is the standard for low emissions gasoline adopted by CARB which was at issue in *Unocal*. However, in the ICT sector, most technical standards are voluntary. That is, firms are not required, either by government regulation or SDO rules, to use them.¹¹⁷ The success or failure of interoperability standards is thus dictated largely by market forces rather than governmental edict, and the landscape is littered with abandoned standards that never achieved market success (e.g., who remembers WIMAX, Firewire or HD-DVD?). In fact, the voluntary nature of collaboratively developed standards is one of the principal safety mechanisms that ensure that SDOs do not exert anticompetitive market power by forcing participants to adopt their standards.¹¹⁸

Nevertheless, Momenta attempts to recharacterize the voluntary nature of most ICT standards by reasoning that they are “effectively mandatory” – an industry participant must practice them in order to compete effectively.¹¹⁹ It argues that the threat of patent hold-up, and the accompanying anticompetitive effects, occur only when the adoption of a standard is mandatory (or “effectively”

¹¹³ *Id.* at 53–54.

¹¹⁴ Method 207, *supra* note 51, at 10.

¹¹⁵ *Id.*

¹¹⁶ 21 U.S.C. § 351(b), § 321(j).

¹¹⁷ See David J. Teece & Edward F. Sherry, *Standards Setting and Antitrust*, 87 MINN. L. REV. 1913, 1919-20 (2003); ABA COMM. ON TECH. STANDARDIZATION, STANDARDS DEVELOPMENT PATENT POLICY MANUAL ix (Jorge L. Contreras ed., 2007) [hereinafter ABA Standards Manual].

¹¹⁸ See Raymond T. Nimmer, *Technical Standards Setting Organizations & Competition: A Case For Deference To Markets*, Washington Legal Foundation Critical Legal Issues Working Paper Series No.155, at 9-10 (2008).

¹¹⁹ Momenta Appeal Brief, *supra* note 49, at 52.

mandatory). But because Method 207 was *not* mandatory, it argues, Momenta could not hold the industry “hostage” as Qualcomm and others did in the ICT standards deception cases. Failing to disclose patents covering optional standards, Momenta argues, “creates no trap because industry participants can choose alternate technology.”¹²⁰

Momenta’s arguments here are worth considering in some detail, as they address the fundamental rationale behind liability for standards deception. Clearly, when a technology is not standardized, a patent holder is free (subject to generally-applicable antitrust laws) to assert its patents covering that technology in any manner, whether to extract whatever royalties the market will bear, or to prevent others from competing with respect to patented features. If a product manufacturer does not wish to pay the required royalty, or fears an injunction from the patent holder, then it is free to use an alternate, noninfringing technology.

When the patented technology is standardized, however, different considerations come into play. A standard is intended to be broadly adopted, and an SDO that imposes a patent disclosure policy does so in order to promote the broad adoption of its standards. Market participants are encouraged to adopt such standards with the expectation that all SEPs have been disclosed. On that basis, they can make investments in manufacturing, design, marketing and the like, all based on the standardized technology, whether or not it is formally mandated by law or SDO rules. When a patent holder emerges later with a previously undisclosed SEP, these investments can be upset.

In the case of enoxaparin, it appears that several methods of conducting AR structure testing were available, and several non-infringing alternatives were in use both by Momenta/Sandoz and Amphastar. If it were truly the case that Amphastar was under no compulsion to use Method 207, then the only harm suffered by Amphastar from Momenta’s late disclosure of the ‘886 patent would have been its cost of switching to an alternate, noninfringing testing method. Nevertheless, those switching costs may have been non-negligible. In addition, in October 2011 Momenta obtained a preliminary injunction preventing Amphastar from selling generic enoxaparin on the basis of the ‘886 patent.¹²¹ Though the injunction was stayed by the Federal Circuit in January 2012, four months later, Amphastar’s sales of generic enoxaparin were limited thereafter given the ongoing litigation.¹²² The class action plaintiffs claimed that Momenta and Sandoz were able to reap hundreds of millions of dollars in wrongful overcharges as a result of Momenta’s concealment of its patent.¹²³ These considerations all point to some monetary remedy that may have been available to Momenta and the class action plaintiffs, which may have been borne out by the multi-million dollar settlements that Momenta reached with each of them.

However, the district court’s ruling in *Momenta I* did not award monetary relief to Amphastar, but rather rendered Momenta’s ‘886 patent unenforceable against the practice of Method 207 (i.e., Momenta’s waiver of its right to enforce the patent and its estoppel from doing so). And, presumably, this ruling would extend not only to Amphastar, but also to other producers of generic enoxaparin (e.g., Teva), and most likely stands even after the parties’ settlement of their various

¹²⁰ *Id.* at 53.

¹²¹ *Momenta I*, 289 F. Supp. 3d at 263.

¹²² See Amended Complaint at 21–22, *Hosp. Auth. of Metro. Gov’t of Nashville v. Momenta Pharm, Inc.*, 244 F. Supp. 3d 705 (M.D. Tenn. 2017).

¹²³ *Id.* at 2.

suits. As such, the unenforceability remedy can be seen as even more potent than monetary relief. And it is distinctly unrelated to the harm suffered by implementers of the relevant standard. Rather, it addresses deceptive conduct by the patent holder in violating the SDO’s policies and is imposed to safeguard the integrity of the SDO standardization process, whether or not particular harm can be shown in a given instance. That is, even if Amphastar and the class action plaintiffs were unable to prove any monetary injury arising from Momenta’s concealment of the ‘886 patent, the unenforceability remedy would still be available to punish Momenta for its deceptive conduct. The next sections explore the contours of this liability.

C. Intent to Trap the Industry

Amphastar argues that even if it was required to disclose the ‘886 patent to USP and failed to do so, the district court should not have imposed the remedy of patent unenforceability because Momenta did not intend to “trap” the industry in a standard that it had patented.¹²⁴ On the contrary, Momenta actively opposed the adoption of Method 207 at USP. It argues that “Momenta sought to prevent USP from locking Momenta and anyone else into using Method 207 so that industry would be free to use newer, more accurate methods.”¹²⁵ Momenta contrasts its behavior with that of Qualcomm in *Qualcomm I*, observing that “Qualcomm had engaged in a carefully orchestrated plan with the deadly determination of holding hostage the entire industry desiring to practice the ... standard...”¹²⁶ Momenta’s behavior, on the other hand, was “the very opposite of a patent holder intentionally trapping an industry into using its patent.”¹²⁷

Momenta’s argument are worth considering here. In most standards deception cases of which I am aware, the allegedly deceptive patent holder urged the SDO to adopt the standard, portions of which it had surreptitiously patented. If Momenta’s assertions are taken at face value, then its opposition to Method 207 would indeed suggest a less devious pattern of conduct than that challenged in cases such as *Qualcomm I*.¹²⁸

Nevertheless, Method 207 was ultimately adopted by USP as a standard, and Momenta did fail to disclose the ‘886 patent. If there is no penalty for such failures, then the effectiveness of SDO rules requiring disclosure would be severely limited.

It is perhaps for this reason that the FTC, in its case against Dell Computer, adopted what could be termed a strict liability standard for failure to disclose SEPs to an SDO.¹²⁹ In her dissenting statement, Commissioner Mary L. Azcuenaga outlines the relative blamelessness of Dell in dealing with the Video Electronics Standards Association (“VESA”):

¹²⁴ Momenta Appeal Brief, *supra* note 49, at 55–56.

¹²⁵ *Id.* at 56. As the attentive reader will note, this argument could be viewed as at odds with Momenta’s prior argument that Method 207 was not mandatory.

¹²⁶ *Id.* at 50 (quoting *Qualcomm I*, 548 F.3d at 1009-10) (internal quotation marks omitted).

¹²⁷ *Id.*

¹²⁸ Even Qualcomm disputed the characterization of its behavior, arguing that “[e]ven if a duty to disclose had been breached, this breach is best explained as negligence, oversight, or thoughtlessness, which does not create a waiver.” *Qualcomm I*, 548 F.3d at 1020.

¹²⁹ See *In re. Dell Computer Corp.*, Dissenting Statement Of Commissioner Mary L. Azcuenaga, 121 F.T.C. 627, 630 (1996).

Nothing in the limited information available to the Commission suggests that Dell had any greater role in the development and promulgation of the VESA VL-bus standard than that described in the minimal factual allegations in the complaint. For example, the complaint does not allege that Dell proposed or sponsored the standard, that Dell urged others to vote for the standard, that Dell employees participated in drafting the standard, that Dell employees were present, in person or online, during the committee drafting sessions, that Dell steered the VESA committee toward adopting a standard that incorporated Dell technology, or that Dell had any hand whatsoever in shaping the standard.

The sole act for which Dell is charged with a violation of law is that Dell's voting representative, in voting to adopt the standard, signed a certification that to the best of his knowledge, the proposed standard did not infringe on any relevant intellectual property.¹³⁰

Nevertheless, the FTC held that because Dell, as an entity, must have been aware of its patent covering the VL-Bus standard, and because it did not disclose that patent to the SDO, it lost the ability to enforce that patent against others. “[W]here Dell failed to act in good faith to identify and disclose patent conflicts -- enforcement action is appropriate to prevent harm to competition and consumers.”¹³¹

Momenta, for its part, appears to have had even greater awareness of its relevant SEP than the Dell engineer who certified that he was unaware of Dell’s pending patents covering the VL-bus standard. At least Dr. Shriver, who made representations to USP, was an inventor on the ‘886 patent and could hardly claim to have been unaware of it. Accordingly, the district court’s holding that the ‘886 patent was unenforceable does not go even so far as the FTC did in *Dell*.

Likewise, there is little basis for Momenta’s argument that only intentional scheming to trap the industry is required to warrant a remedy of patent unenforceability. Without this remedy, the incentives to comply with SDO disclosure policies would be significantly weakened.

D. Reliance

The district court in *Momenta I* adopted the jury’s advisory verdict finding that Momenta should be equitably estopped from enforcing the ‘886 patent against Amphastar.¹³² In analyzing this claim, the court first recited the three general elements required for equitable estoppel: 1) misleading conduct that resulted in a reasonable inference of non-enforcement, 2) reliance and 3) that the infringer will be materially prejudiced if the patent owner’s claim is allowed.¹³³ A finding of misleading conduct on the part of Momenta is supported by the findings, discussed above, that Momenta failed to disclose the ‘886 patent as required by USP’s informal rules. Likewise, material

¹³⁰ *Id.* at 628.

¹³¹ Dell Computer Corp., 121 F.T.C. 616, 624 (1996). The FTC declined to address the prospect of liability for truly “inadvertent” failures to disclose patent rights. *Id.* at 625.

¹³² *Momenta I*, 289 F. Supp. 3d at 270.

¹³³ *Id.* at 269 (citing *Radio Sys. Corp. v. Lator*, 709 F.3d 1124, 1130 (Fed. Cir. 2013)).

prejudice is not difficult to find based on Amphastar’s alleged investment in the performance of Method 207.¹³⁴

Proving reliance, however, was “a closer question that was vigorously disputed at trial.”¹³⁵ Ultimately, the district court deferred to the jury’s evaluation of witness credibility in making this determination.¹³⁶ In its appeal brief, Momenta refuted Amphastar’s reliance arguments on several grounds. First, it noted that Amphastar could not have relied on any statement or action of Momenta, as the parties had no dealings until this litigation.¹³⁷ Second, Momenta objected to the district court’s “substituting Amphastar’s supposed reliance on USP in place of any reliance on statements or conduct by Momenta”.¹³⁸ Even if such reliance could estop Momenta from asserting its patent, Momenta argued that Amphastar had no relationship or communication with USP either. Finally, Momenta points out that Amphastar did not start using Method 207 until 2011, *after* Momenta had sued Amphastar for patent infringement. Accordingly, Amphastar could not have relied on Momenta’s alleged deception in deciding to use Method 207.¹³⁹

Clearly, the facts of Momenta are complex and the district court may have been justified in leaving this fraught factual determination to the jury. Yet the difficulty of proving reliance in equitable estoppel cases has raised doubts regarding the general effectiveness of this doctrine in the standards-setting context.¹⁴⁰ To address the potential mismatch between equitable estoppel and the misfeasance that can arise from deception in the standards-development context, I have previously proposed that courts consider adopting a modified form of promissory estoppel in which the implementer of a standardized product need not prove actual reliance on any statement or action of the defaulting patent holder, but only that the patent holder participated in an industry-wide standardization activity intended to produce a broadly adopted standard (what I have termed “market reliance”).¹⁴¹ An approach such as this would alleviate many of the evidentiary challenges presented by cases such as *Momenta*.

¹³⁴ *Id.* at 270.

¹³⁵ *Id.* at 269.

¹³⁶ *Id.* at 270.

¹³⁷ Momenta Appeal Brief, *supra* note 49, at 69.

¹³⁸ *Id.*

¹³⁹ *Id.* at 69–71.

¹⁴⁰ See Contreras, *Market Reliance*, *supra* note 9, at 521–22 (“equitable estoppel is not an ideal theoretical framework for the general enforcement of [standards-related patent commitments]”); George S. Cary et al., *The Case for Antitrust Law to Police the Patent Holdup Problem in Standard Setting*, 77 ANTITRUST L.J. 913, 939 (2011) (both the reliance and material prejudice elements of equitable estoppel may be difficult to prove in the standards context); Robert P. Merges & Jeffrey M. Kuhn, *An Estoppel Doctrine for Patented Standards*, 97 CALIF. L. REV. 1, 39 (2009) (“equitable estoppel has inherent limitations that preclude its effectiveness against snake-in-the-grass and bait-and-switch tactics. The primary defects are its requirements of: (1) misrepresentation by the patentee to the infringer; (2) reasonable reliance on those promises by the infringer; and (3) material reliance”). *But see* Henry E. Smith, *Property as Platform: Coordinating Standards for Technological Innovation*, 9 J. COMPETITION L. & ECON. 1057, 1086 (2013) (describing equitable estoppel as a viable “anti-opportunism safety valve” for standard setting).

¹⁴¹ Contreras, *Market Reliance*, *supra* note 9, at 542–43.

E. The Need for Clarity in Biopharma SDO Policies

Perhaps the most unusual aspect of the *Momenta* cases is the uncertain foundation upon which the obligation to disclose patents at USP was built. The district court acknowledged that no disclosure obligation was created by the Guidelines (which applied only to Sponsors) and that *Momenta*'s Dr. Shriver complied with the conflict of interest abstention rule set out in USP's Rules and Procedures.¹⁴² The only source of a disclosure obligation binding on *Momenta* arose from the conflict of interest form that Dr. Shriver submitted, which asked him to list "other professional or financial interests".¹⁴³ His failure to list the '886 patent in response to this question gave rise to the "ambiguity" identified by the court and to the subsequent introduction of evidence of the common understanding of participants regarding patent disclosure.

The district court in *Momenta* followed the lead of the Federal Circuit in *Rambus v. Infineon* and *Qualcomm I* by looking to such common understandings when confronted with ambiguous policy language. In particular, the court focused on USP's insistence that Sanofi-Aventis abandon its own patent covering purity testing for enoxaparin.¹⁴⁴ That, together with other witness testimony, gave rise to the obligation that the court found for all other expert panel members to disclose patents held by their own companies.

Such a disclosure obligation may, indeed, have existed at USP. However, it was far from clear. Preferable would have been a written policy document that clearly described what patent disclosure obligations, if any, bound the members of USP expert panels. The FTC's 1996 ruling against Dell and the Federal Circuit's 2003 holding in *Rambus v. Infineon* served as wake-up calls to SDOs in the ICT sector. In particular, the Federal Circuit's sharp critique of the JEDEC patent policy -- which the court characterized as suffering from "a staggering lack of defining details" that left SDO participants with only "vaguely defined expectations as to what they believe the policy requires"¹⁴⁵ -- motivated many SDOs to clarify their own policies in this regard.¹⁴⁶ The result is that the patent policies of many SDOs in the ICT sector have increased in length and complexity, but also define the obligations of SDO participants with a reasonable degree of specificity.

Unfortunately, the same degree of evolution has not occurred in the policies of SDOs that operate in the biopharma sector.¹⁴⁷ USP's Rules and Procedures, as they are described in *Momenta*,

¹⁴² See Section II.C, *supra*.

¹⁴³ Shriver, *supra* note 72.

¹⁴⁴ *Momenta I*, 289 F. Supp. 3d at 267.

¹⁴⁵ *Rambus, Inc. v. Infineon Techs. AG*, 318 F.3d 1081 (Fed. Cir. 2003).

¹⁴⁶ See, e.g., Contreras – *Literature Review*, *supra* note 7, at 27; Jorge L. Contreras & Andrew Updegrave, *A Practical Guide to Patent Policies of Standards Development Organizations*, 67(6) STANDARDS ENGINEERING, Issue 1, 1, 3 (Nov/Dec 2015). Shortly after the *Infineon* decision was released, the American Bar Association initiated a three-year long project to provide drafting guidance to the industry regarding the terms of SDO patent policies. ABA Standards Manual, *supra* note 117.

¹⁴⁷ I tried to warn the biopharmaceutical industry about the need to pay closer attention to standardization issues in 2008. See Jorge L. Contreras, *Correspondence: Legal Issues in the Development of Biological Research Standards*, 26 NATURE BIOTECH. 498, 499 (2008):

To date, the biological sciences have been blissfully free of the standards litigation battles that have plagued the ICT industry. With the increasing adoption of standards by biological researchers, however, these issues

resemble the conflict of interest policies of scientific journals and conferences more than patent policies of technical standards bodies. In order to avoid the degree of uncertainty and dispute evidenced by the *Momenta* cases, USP and other SDOs in the biopharma sector should carefully review their existing patent policies and make any needed clarifications and amendments to ensure that these policies clearly and unambiguously define the obligations of their participants.¹⁴⁸ The added clarity that such an exercise can produce will facilitate the standardization process, avoid unintentional breaches of policy, and, hopefully, thwart those who deliberately wish to abuse the standardization process to their own ends.

CONCLUSION

Momenta v. Amphastar demonstrates that issues surrounding the acquisition and disclosure of patents claiming standardized technologies have more salience in the biopharma sector than commonly believed. While significant factual uncertainty continues to exist with regard to the intentions and obligations of the parties in *Momenta*, the lack of clarity inherent in USP's policies echoes the ambiguities that plagued SDO policies in the ICT sector two decades ago. As such, standards organizations operating in the biopharma sector should ensure that their policies and procedures are robust enough to delineate clearly the obligations of participants with respect to patents covering standardized technologies, and organizations that participate in biopharma standards-development should heed the valuable lessons offered by more than three decades of litigation in the technology sector.

will become increasingly relevant. Thus, participants in the biological research field should take care to organize their standards-development efforts carefully and with adequate legal consideration.

¹⁴⁸ Such a process is currently under way, for example, at the Global Alliance for Genomics and Health (GA4GH), a group that develops standards for genomic data exchange and storage. See Global Alliance for Genomics & Health, Constitution of the Global Alliance for Genomics and Health, § 7 (v2, Jan. 22, 2018) (“It is a guiding principle of the GA4GH that work products developed as part of the GA4GH Steering Committee and Work Stream processes will be openly shared for the benefit of humanity. Appropriate intellectual property policies will be developed and promulgated.”)