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TECHNICAL STANDARDS FOR BIOINFORMATICS AND MEDICAL INFORMATICS

Jorge L. Contreras^{} and Adrian Thorogood[†]*

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INTRODUCTION

Standards are ubiquitous in today's technology-driven marketplace. Some standards mandate minimum requirements for product safety, others seek to reduce environmental impact, while others specify minimum levels of information that must be provided to consumers. "Interoperability standards," which dominate the information and communications technology (ICT) sector, specify the manner in which products and services offered by different vendors interface with one another. Many of these standards, including Wi-Fi, USB, Bluetooth, DVD, PDF and HTML, have become household terms, and thousands of others ensure that a vast array of products and services interact seamlessly in a manner that is largely invisible to the consumer.

The explosion of bioinformatics and medical informatics technologies ("informatics") over the past two decades has led to a surge of interest in the development of interoperability and compatibility standards for informatics applications. These standards range from genome annotation and controlled vocabularies (ontologies) to data formats and search engine integration. A variety of standards development organizations (SDOs) are involved in informatics standardization activities. These include large, established bodies such as the International Organisation for Standardisation (ISO), the European Committee for Standardization (CEN), and the Institute for Electrical and Electronics Engineers Standards Association (IEEE-SA) to broad-based informatics industry associations such as the Asia-Pacific Bioinformatics Network, the European Bioinformatics Institute (EBI), and the Global Alliance for Genomics and Health (GA4GH), to narrowly-focused efforts such as the Adaptive Immune Receptor Repertoire (AIRR) Community, Proteomics Standards Initiative (PSI) and the Functional Genomics Investigation Ontology (FuGO) project.¹ Well-known SDOs with a clinical informatics focus include the Clinical Data Interchange Standards Consortium (CDISC), Digital Imaging and Communications in Medicine (DICOM), Health Level 7 International (HL7), and SNOMED International.

Over the past three decades, standardization in the ICT sector has experienced both enormous success as well as major disputes. Litigation has spread around the world, with lawsuits brought by participants in the standards-development process, and by government regulators and affected third parties. SDOs in the ICT sector have responded to these claims by promulgating rules and policies of increasing sophistication, both to specify procedures designed to avoid abusive activity and to accommodate the requirements of their principal participants.

With a few exceptions, the biomedical industry, and the informatics field in particular, have not been affected by the standards litigation that has plagued the ICT industry. But with the increasing adoption of standards by informatics researchers and vendors, the issues faced by ICT standards groups will become increasingly relevant. This chapter summarizes general legal issues associated with standards development, then surveys standardization efforts in the informatics space and reviews the policies and procedures adopted by SDOs operating in the informatics area. It

¹ For a general overview of the international standardization landscape, see Brad Biddle, *No Standard for Standards: Understanding the ICT Standards-Development Ecosystem*, in Cambridge Handbook of Technical Standardization Law: Competition, Antitrust, and Patents 17 (Jorge L. Contreras ed., 2018).

concludes with recommendations regarding prudent policy adoption by SDOs developing standards for informatics applications.

I. STANDARDS AND STANDARD SETTING: A BRIEF OVERVIEW

A. Types of Standards

Standards serve a variety of purposes and functions. Some standards specify requirements intended to protect public health and safety, to preserve the environment, and to prevent fraud and other abuses. These include standards relating to food and drugs, air and water quality, hazardous materials, construction, transportation, handling of personal data, and the like. Other standards signify a specified level of quality, such as the 4C (cut, color, clarity and carat) ratings for diamonds. Most relevant to informatics, however, are interoperability or compatibility standards, which specify design features that enable data, equipment, and services produced by different parties to operate together. Electrical outlets, for example, share a common design in the United States that enables any appliance to be plugged into an outlet anywhere in the country (though, as any frequent traveler knows, these standards vary dramatically from country to country). More complex, but equally illustrative, are the numerous networking (USB, Wi-Fi, Bluetooth), Internet (TCP/IP, HTML, http), telecommunications (GSM, LTE) and digital media (CD, DVD, BluRay) standards that enable devices manufactured by different vendors to interact with one another in a manner that is largely invisible to the consumer.

At the highest level of generality, standards may be categorized as either *mandatory*, meaning that compliance is required by an external body, such as a governmental agency or a professional accreditation organization, or *voluntary*, meaning that compliance is not required, though it may be prudent or even necessary from a commercial standpoint. Mandatory standards are often adopted by governments to protect the health and welfare of their citizens. Most interoperability standards, however, are voluntary.

B. Standards Development Organizations

Standards may be developed in many different environments. Individual companies or institutions may release a technology or format to the industry in the hope that it will become broadly adopted. Such “de facto” standards include Adobe Systems’ Portable Document Format (PDF) and Microsoft’s “.doc” document format. Other standards may be developed by a group of companies and institutions working collaboratively within a standards-development organization (SDO). SDOs vary greatly in size and composition. Some SDOs consist of just a few participants that collaborate on a focused set of technical specifications, sometimes for a single product. These are sometimes referred to as consortia or “special interest groups” (SIGs). Standards for many consumer electronics devices and digital media such as the DVD disc and player were developed by SIGs. Other SDOs are very large and encompass many different standardization activities at any given time. ASTM International, for example, is one of the largest SDOs and regularly develops standards in areas as diverse as electrical wiring, playground equipment, composite materials, unmanned aircraft, and nanotechnology.²

² See ASTM Int’l, www.astm.org.

The work of individual SDOs is sometimes coordinated at the national and international levels. In the United States, SDOs can be accredited by the American National Standards Institute (ANSI) if they meet certain criteria of openness, due process, and transparency (“Essential Requirements”). The standards developed by ANSI-approved SDOs can be designated as American National Standards (ANS), a status that both validates and promotes adoption. More than 200 different SDOs are currently accredited by ANSI.

The International Organization for Standardization (ISO) is a Geneva-based non-governmental organization whose members include 164 national standards institutes from across the globe. ISO coordinates standards-development activities among its members and develops its own consensus standards through numerous committees. In addition, ISO often collaborates with other standards bodies. It observes a common intellectual property policy with the International Telecommunications Union (ITU) and the International Electrotechnical Committee (IEC), and develops healthcare informatics standards with CEN.³

Many governmental agencies also adopt standards, either as part of their regulatory function or for their own use. The U.S. Office of Management and Budget’s (OMB) has promulgated guidelines requiring that U.S. federal agencies adopt suitable “voluntary consensus standards” in their procurement and regulatory activities to the extent not “inconsistent with law or otherwise impractical.”⁴

II. COMPETITION AND ANTITRUST ISSUES IN STANDARDS DEVELOPMENT

One of the principal purposes of antitrust law is to prevent competitors from colluding in ways that are harmful to competition and the market. Such collusive behavior in the U.S. is prohibited under Section 1 of the Sherman Act, which bans agreements in restraint of trade.⁵ Conversely, Section 2 of the Sherman Act prohibits monopolization and attempted monopolization. In recent years, the Federal Trade Commission (FTC) has also exercised its authority under Section 5 of the FTC Act to prosecute unfair methods of competition that arise in the standards-setting context.⁶ Because consensus-based technical standards are generally developed through collaborative processes that involve multiple competitors, a basic understanding of antitrust law principles is critical to effective operation of any SDO. This section summarizes some of the major antitrust and competition issues that can arise in the standards-setting context.

³ CEN has an agreement with ISO to jointly plan and simultaneously approve international and European standards. International standards have primary, but CEN may also need to develop standards meeting European priorities. The preferred route is for standards work to begin at a European level and then be raised to the international level. ISO & CEN “Agreement On Technical Co-Operation Between ISO and CEN (Vienna Agreement) (1991) <https://www.cencenelec.eu/intcoop/StandardizationOrg/Pages/default.aspx> (last visited May 15, 2020).

⁴ Office of Management and Budget, OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, Jan. 22, 2016.

⁵ 15 U.S.C. § 1.

⁶ 15 U.S.C. § 45.

A. Improper Exclusion

SDOs must exercise caution if they wish to limit their membership or to expel a member after it has joined.⁷ The exclusion of parties from the standard-setting process can be viewed as an attempt by the SDO members to gain an unfair advantage over the excluded parties. Accordingly, many SDOs do not restrict their membership and claim to be open to all interested participants.⁸ Being “open,” however, does not mean that an SDO must admit all participants on equal terms. It is not uncommon, for example, for SDOs to vary their membership fees based on a participant’s size, revenue, or industry sector (e.g., producer, customer, government, academic, etc.).⁹ Courts have also held that trade associations may establish reasonable criteria for membership, even if such criteria necessarily exclude some potential participants;¹⁰ many important industry standards, such as the CD and DVD digital storage formats were developed by small, closed groups of industry participants. Although some limitations may be permitted, SDOs can avoid allegations of improper exclusion by opening their membership as broadly as possible. Similar issues regarding exclusion arise when a group wishes to expel a member. In short, expulsion of a member is generally permissible when the member has violated the organization’s rules or otherwise acted in an unlawful or unethical manner, but raises antitrust concerns when effected for competitive purposes.¹¹

Claims of anticompetitive exclusion can arise in connection with technologies as well as participants. Thus, even if a company is not excluded from participation in an SDO, it is possible for other SDO participants to collude to exclude that company’s technology from a standard under consideration. Such claims were raised, for example, in *Addamax Corp. v. Open Software Foundation Inc.*¹² Addamax was a developer of security software for the UNIX operating system. Open Software Foundation (OSF), a consortium of computer and software vendors, developed a version of UNIX that included a security package developed by one of Addamax’s competitors. Addamax alleged, among other things, that OSF’s exclusion of its security software from OSF UNIX amounted to unfair competition and a boycott of Addamax’s products by the members of OSF. The U.S. Court of Appeals for the First Circuit rejected these claims, holding that Addamax failed to show that the eventual decline in sales of its security products was attributable to concerted action by OSF and its members.¹³ Other unsuccessful cases involving claims of exclusion have been brought against SDOs more recently.¹⁴

⁷ See generally, Am. Bar Ass’n, ABA Section of Antitrust Law, Handbook on the Antitrust Aspects of Standards Setting 51-52 (2d ed. 2011) (hereinafter “ABA Antitrust Handbook”).

⁸ *Id.*

⁹ *Id.*

¹⁰ *Nat’l Ass’n of Review Appraisers & Mortg. Underwriters v. Appraisal Found.*, 64 F.3d 1130, 1133 (8th Cir. 1995) (upholding Appraisal Foundation’s membership criteria where there was no evidence of any harm to the overall market for appraisal organizations).

¹¹ See, e.g., *Pretz v. Holstein Friesian Ass’n of Am.*, 698 F. Supp. 1531, 1542 (D. Kan. 1988) (holding that cattle registry association did not commit antitrust violation by expelling a member alleged to be manipulating tests for grading cattle).

¹² 152 F.3d 48 (1st Cir. 1998).

¹³ *Id.* at 53.

¹⁴ See *Golden Bridge Tech. v. Nokia Inc.*, No. 6:06-CV-163, 2007 U.S. Dist. LEXIS 67071, at *25-26 (E.D.Tex. Sept. 10, 2007) (plaintiff unsuccessfully claimed that defendants intentionally excluded its technology from standard relating to wireless telephony); *True Position, Inc. v. LM Ericsson Tel. Co.*, No. 2011-CV-04574-RK, 2012 WL 33075

B. Improper Exchange of Information

If competitors exchange sensitive commercial information during standard-setting meetings, or if they otherwise use the standard-setting process as a vehicle for engaging in illegal collusion, the SDO can be challenged for facilitating this unlawful behavior. The clearest example of behavior exposing SDOs to potential antitrust risk is the sharing of information relating to product pricing or salaries.¹⁵ But less blatant instances of information sharing may also lead to allegations of anticompetitive behavior. For example, a standard could facilitate collusion by making it easier for competitors to monitor and enforce illegal price fixing agreements.¹⁶

C. Compliance Certification

In some cases, the members of an SDO may improperly influence the SDO's decisions regarding whether a competitor's products comply with a standard. The Supreme Court addressed this type of behavior in *American Society of Mechanical Engineers v. Hydrolevel Corp.*¹⁷ In that case, a subcommittee chair of the American Society of Mechanical Engineers (ASME), a professional association with over 90,000 members, misrepresented that Hydrolevel's boiler control valves did not conform to a key provision of ASME's Boiler and Pressure Vessel Code, and were therefore unsafe. The chair allegedly made these misrepresentations because his employer competed with Hydrolevel. When ASME staff propagated this inaccurate portrayal, Hydrolevel alleged that it suffered significant harm in the market. The Supreme Court held that ASME could be liable for these misrepresentations, as the weight of its reputation greatly enhanced the anticompetitive effect of its member's misrepresentation.¹⁸

But not all allegations that an SDO improperly failed to certify a product's compliance with its standards are successful. In *Consolidated Metal Products v. American Petroleum Institute*,¹⁹ the plaintiff alleged that the American Petroleum Institute (API) committed an antitrust violation by intentionally delaying certification of its products. The Fifth Circuit rejected this claim, holding that the plaintiff did not have a claim "simply because others refuse to promote, approve, or buy its products."²⁰

(E.D. Pa. Jan. 6, 2012) (alleging that concerted activity by defendants, including two SDOs, resulted in exclusion of plaintiff's technology from wireless telecommunications standard).

¹⁵ See, e.g., *United States v. Container Corp. of Am.*, 393 U.S. 333, 337 (1969) (holding that exchange of price quotes for sales of corrugated containers was a price fixing agreement that violated the Sherman Act since the product was fungible and demand was inelastic); *Todd v. Exxon Corp.*, 275 F.3d 191, 214-15 (2nd Cir. 2001) (holding that employees have a claim against employers to examine employers' habit of sharing information regarding non-managerial, non-union workers to determine if it was a collusion to keep wages down in violation of the Sherman Act).

¹⁶ See Harry S. Gerla, *Federal Antitrust Law and Trade and Professional Association Standards and Certification*, 19 Dayton L. Rev. 471, 486 (1994).

¹⁷ 456 U.S. 556 (1982).

¹⁸ *Id.* at 577.

¹⁹ *Consol. Metal Prod., Inc. v. Am. Petroleum Inst.*, 846 F.2d 284 (5th Cir. 1988).

²⁰ *Id.* at 293; see generally ABA Antitrust Handbook, *supra* note 7, at 55-59.

D. Abuse of Process

Perhaps the most frequent antitrust charge against SDOs is the claim that one or more participants abused the process by which standards are set within the SDO, either to secure approval of a standard that they backed or to exclude the technology of their competitors from a standard. The Supreme Court addressed this type of abuse in *Allied Tube & Conduit v. Indian Head*.²¹ In that case, the plaintiff, a manufacturer of polyvinyl chloride (PVC) products, requested that the National Fire Protection Association (NFPA) approve an amendment to the National Electrical Code that would have allowed the use of PVC in electrical wiring conduits. The defendant, a manufacturer of steel conduit, recruited 230 people to join NFPA for the sole purpose of voting against the amendment, which was ultimately defeated by a vote of 394 to 390. The jury found that the steel conduit manufacturers defeated the PVC standard solely for anticompetitive purposes, subverting the standards-development process and violating the antitrust laws. The Supreme Court agreed, stating that a participant in private standards-setting activities should not bias the process in a manner designed to restrain competition.²²

E. Policies and Precautions

In order to avoid the types of antitrust claims discussed above, and to deter unlawful conduct by their participants, SDOs have increasingly adopted rules and policies that expressly prohibit anticompetitive behavior within the SDO context. Such policies typically seek to accomplish the following general objectives:

- a. to ensure that the standards-development process is open, fair and transparent;
- b. to ensure that membership in the SDO is open to all interested parties on a non-discriminatory basis;
- c. to prohibit the sharing of competitive information within the context of SDO activities; and
- d. to provide that compliance with standards is voluntary, and that participation in the SDO is not conditioned on use of the SDO's output.

While policies implementing these objectives cannot themselves prevent collusion or improper behavior, they can serve to raise awareness of antitrust issues within an SDO. More importantly, such policies can demonstrate (whether to potential plaintiffs or finders of fact) that the SDO has actively sought to curtail activity that could be construed as anticompetitive.

III. INTELLECTUAL PROPERTY AND STANDARDS DEVELOPMENT

Standards often implicate and are affected by intellectual property. Indeed, standards themselves may specify patentable inventions, and the written embodiments of standards are generally protectable by copyright. Furthermore, the more complicated the technology that a standard

²¹ *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492 (1988).

²² For a more detailed discussion of the *Allied Tube* case and other cases relating to due process within SDOs, see Jorge L. Contreras, *Understanding 'Balance' Requirements for Standards Development Organizations*, CPI Antitrust Chronicle, Sept. 2019.

specifies, the more likely the standard is to implicate patents owned by members of the SDO or by third parties. SDOs and implementers of technical standards are therefore likely to encounter numerous intellectual property issues outlined in this section.

A. Copyright in Standards

Technical standards typically take the form of written descriptions of how products or services should be designed, built, or operated. Like other written documents, standards are typically protected by copyright, meaning that they cannot be reproduced, displayed, or modified without permission of the copyright owner (often the SDO).²³ Many SDOs earn significant revenue from the sale of standards (some of which extend to hundreds of pages) and therefore warn against illegal copying and distribution, though a number of major SDOs such as IETF and W3C allow their standards to be downloaded and copied without charge.

The tension between copyright protection and the social utility of standards becomes particularly acute when a proprietary standard is adopted and referenced by a governmental agency (incorporated by reference), thereby becoming “the law.”²⁴ Under longstanding principles of democratic governance, citizens are entitled to know the law. Yet if a copyrighted standard, such as a building or electrical code, is incorporated by reference into law, the copyright holder can theoretically control access to that standard. Some commentators have argued that standards, as purely utilitarian documents, should not be entitled to copyright protection at all.²⁵ Others have argued that reproduction of such copyrighted documents should be permitted as “fair use” under copyright law.²⁶ These issues are currently being litigated in *Am. Soc’y for Testing & Materials v. Public.Resource.org*.²⁷

B. Patenting and Standards

(1) Patents Covering Standardized Technology

As noted above, standards are written descriptions of particular attributes of specified products and processes. Assuming that statutory requirements of utility, novelty, and non-obviousness are met, patents may be obtained on products and processes that conform with particular standards. Such patents would ordinarily not be obtained by the SDO in which the standard was developed, as SDOs seldom develop complete products and almost never seek to patent their work. Rather, if such a patent were obtained, it would be obtained by a participant in the SDO or an outsider, and sometimes both. Thus, two general patent-related issues arise in the context of technology standardization: “patent stacking” and “patent hold-up.”

²³ See Pamela Samuelson and Kathryn Hashimoto, *Questioning Copyrights in Standards* in *The Cambridge Handbook of Technical Standardization Law: Further Intersections of Public and Private Law* 91 (Jorge L. Contreras, ed., 2019).

²⁴ See Daniel J. Sheffner, *Integrating Technical Standards into Federal Regulations: Incorporation by Reference* in *The Cambridge Handbook of Technical Standardization Law: Further Intersections of Public and Private Law* 108 (Jorge L. Contreras, ed., 2019).

²⁵ See Samuelson and Hashimoto, *supra* note 23.

²⁶ See Sheffner, *supra* note 24, at 119.

²⁷ *Am. Soc’y for Testing & Materials v. Public.Resource.org*, 896 F.3d 437 (D.C. Cir. 2018) (remanded to district court).

(2) Patent Stacking and Patent Pools

Patent or royalty “stacking,” also referred to as a patent “thicket” or anti-commons, occurs when multiple entities each hold patents claiming aspects of a single standardized technology.²⁸ In order for a producer to implement the standardized technology in a product, it must obtain licenses from multiple parties, each acting independently and each seeking to maximize its gains. The risk of stacking is that the sum of individual royalty demands may be excessive in relation to the overall value of the product, making the standardized product uncompetitive in comparison to products that do not conform with the standard.²⁹

One method of addressing patent stacking is through the creation of a patent pool. In a patent pool, multiple patent owners contribute or license patents that are essential to the implementation of the standard to a common agent (sometimes one of the patent holders and sometimes a newly-formed entity). Licensees are charged a single royalty to practice the entire group of patents, and net revenues are allocated among the pool participants in accordance with a pre-determined formula. Such pools have been used effectively in consumer electronics standards such as the MPEG audio compression format,³⁰ the DVD video compression format,³¹ and third generation wireless communications standards.³² In each of these instances the U.S. Department of Justice approved the proposed patent pool, so long as it possessed certain features that would reduce potentially anticompetitive effects.³³ For example, pools must contain only patents “essential” to the implementation of the standard (as the inclusion of patents on substitute technologies could lessen competition among technical alternatives). Furthermore, licensees must have the freedom to obtain licenses to the patents independently from the pool, and licensing of the pooled patents must be conducted on a non-discriminatory basis. To the extent that the patent pool owners require licensees to “grant back” licenses to them, such grantback licenses must only cover patents that are, themselves, essential to implementation of the standard.

It is important to note that the usefulness of a patent pool may be limited if fewer than all holders of essential patents participate. This situation arose in connection with the Federal Communication Commission’s (FCC) mandatory ATSC digital television standard.³⁴ Though several holders of patents essential to the ATSC standard formed a patent pool, one patent holder, Japan’s Funai Electric Company, did not join. Instead, Funai sought to charge royalties for a single patent at a rate allegedly equal to the rate charged by the entire ATSC pool. Vizio, Inc., a U.S. television manufacturer, refused to pay this royalty, causing Vizio to seek relief from the FCC. Though the matter was ultimately rendered moot when the Federal Circuit held that Vizio did not infringe the

²⁸ The economic and legal literature exploring this phenomenon, both within and outside the context of technical standards, is extensive and varied. See 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 (Peter S. Menell & David Schwartz eds., 2019).

²⁹ U.S. Dep’t of Justice & U.S. Fed. Trade Comm’n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition 76-84 (2007) (hereinafter “2007 DOJ/FTC Report”).

³⁰ Letter from Joel I. Klein, Assistant Attorney Gen., U.S. Dep’t of Justice, to Garrard R. Beene (June 26, 1997).

³¹ Letter from Joel I. Klein, Assistant Attorney Gen., U.S. Dep’t of Justice, to Garrard R. Beene (Dec. 16, 1998); Letter from Joel I. Klein, Assistant Attorney Gen., U.S. Dep’t of Justice, to Carey R. Ramos (June 10, 1999).

³² Letter from Charles A. James, Assistant Attorney Gen., U.S. Dep’t of Justice, to Ky P. Ewing (Nov. 12, 2002).

³³ 2007 DOJ/FTC Report, *supra* note 29, at 68-71.

³⁴ Vizio, Inc. v. Funai Elec. Co. Ltd., 24 F.C.C.R. 2880 (2009).

asserted patent,³⁵ the dispute highlights the limited benefits of patent pooling arrangements that do not include all holders of standards-essential patents.

(3) Patent Ambush

The second major patent issue that can arise in the standards context is patent ambush. Patent ambush occurs when a patent holder seeks to assert a previously unidentified patent against implementers of a standard after the standard has been adopted (either by an SDO or a governmental agency).³⁶ If patent ambush occurs after the industry has devoted significant resources to production, marketing, and training with respect to standardized products (in economic terms, after the standard has become “locked-in”), unexpected royalty demands from patent holders can have an extremely disruptive effect on the market. This phenomenon is commonly referred to as “hold-up” and results in an increase in the cost of standardized products, sometimes to levels that are inefficient and uncompetitive with alternative technologies.³⁷

Patent ambush has been alleged in several cases within the ITC industry. The first of these cases to gain significant attention involved Dell Computer, which allegedly failed to disclose patents covering the voluntary VL-bus standard that it helped to develop at the Video Electronics Standards Association (VESA).³⁸ Following approval of the standard, Dell sought to enforce its patents against other computer manufacturers. Responding to complaints by these potential infringers, the Federal Trade Commission (FTC) sought to enjoin Dell’s enforcement activity on the ground that Dell’s violation of the VESA disclosure rule effectively rendered its patents unenforceable. The FTC action resulted in the entry of a 1996 consent order that permanently prohibited Dell from enforcing its VL-bus patents against any third party.

Perhaps the best-known disclosure failure within an SDO involved Rambus, Inc., a developer of semiconductor memory technology. Volumes have been written about the decade-long legal battles in which Rambus sought to assert its patents against implementers of dynamic random access memory (DRAM) technology standardized by the Joint Electron Device Engineering Council (JEDEC), a voluntary SDO in which Rambus participated in the early 1990s.³⁹ Despite

³⁵ *Vizio, Inc. v. Int’l Trade Comm’n*, 605 F.3d 1330 (Fed. Cir. 2010).

³⁶ See U.S. Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011) (hereinafter “FTC 2011 Report”); Mark A. Lemley, *Ten Things to Do About Patent Holdup of Standards (and One Not to)*, 48 B.C. L. Rev., 149 (2007); Sean M. Royall, et al., *Deterring “Patent Ambush” in Standard Setting: Lessons Learned from Rambus and Qualcomm*, Antitrust, Summer 2009, at 34.

³⁷ See FTC 2011 Report at 5 (“[a]t the time a manufacturer faces an infringement allegation, switching to an alternative technology may be very expensive if it has sunk costs in production using the patented technology. ... If so, the patentee can use the threat of an injunction to obtain royalties covering not only the market value of the patented invention, but also a portion of the costs that the infringer would incur if it were enjoined and had to switch. This higher royalty based on switching costs is called the “hold-up” value of the patent. Patent hold-up can over-compensate patentees, raise prices to consumers who lose the benefits of competition among technologies, and deter innovation by manufacturers facing the risk of hold-up”).

³⁸ *In re Dell Computer Corp.*, 121 F.T.C. 616 (1996).

³⁹ See, e.g., Am. Bar Ass’n, Comm. on Technical Standardization, Section of Science & Tech. Law, *Standards Development Patent Policy Manual* vii-viii (Jorge L. Contreras, ed., 2007) (hereinafter “ABA Patent Policy Manual”); Lemley & Shapiro, *supra* note 28, at 1929-30; Joel M. Wallace, *Rambus v. F.T.C. in the Context of Standard-Setting Organizations, Antitrust, and the Patent Hold-Up Problem*, 24 Berkeley Tech. L.J. 661 (2009); Robert A. Skitol and

conduct that was condemned by both the Court of Appeals for the Federal Circuit and the FTC, Rambus was largely exonerated on the basis that the poorly-worded JEDEC patent policy was simply too imprecise an instrument to support liability. The court criticized the JEDEC policy as suffering from “a staggering lack of defining details” that left SDO participants with “vaguely defined expectations as to what they believe the policy requires.”⁴⁰

In a subsequent action, the FTC found Rambus liable for, among other things, attempted monopolization in violation of Section 2 of the Sherman Act and deceptive conduct under Section 5 of the FTC Act.⁴¹ The FTC’s decision, however, was reversed by the Court of Appeals for the D.C. Circuit, which held that Rambus’s attempt to increase prices following adoption of a standard could not amount to anticompetitive conduct unless such conduct also resulted in adoption of the standard, which was not shown.⁴² This decision has been criticized, both on the basis of its antitrust analysis and as a matter of public policy, inasmuch as it failed to sanction conduct that was widely condemned as deceptive.⁴³

Notably, standards ambush and deception cases have not been limited to the ICT sector. In *Momenta v. Amphastar*,⁴⁴ the manufacturer of a generic version of a top-selling anticoagulant was accused of failing to disclose its patent covering a quality-control test for the drug that had been sanctioned by the Food and Drug Administration, leading to many of the same arguments raised in cases such as *Rambus* and *Qualcomm*.⁴⁵

C. SDO Patent Policies

(1) Policy Measures to Address Patent Issues

The *Dell* and *Rambus* cases demonstrated to the standards-development community both that patent ambush was a real possibility, and that existing SDO policies might lack adequate force to prevent such conduct. In response, many SDOs adopted or enhanced their formal policies to address ambush issues more clearly. They did so by imposing one or both of the following obligations on SDO participants: (1) an obligation to disclose patents essential to implementation of a standard, and/or (2) an obligation to license patents essential to implementation of a standard, either on a royalty-free basis or on terms that are “reasonable and nondiscriminatory.”⁴⁶ These obligations are intended to ensure that standards developers have sufficient information to assess the relative costs and risks of technologies under consideration for standardization. That is, disclosure obligations ensure that standards developers know whether and which patents cover

Kenneth M. Vorrasi, *Patent Holdup in Standards Development: Life After Rambus v. FTC*, Antitrust, Summer 2009, at 26.

⁴⁰ *Rambus, Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1102 (Fed. Cir. 2003), cert. denied, 540 U.S. 874 (2003).

⁴¹ Opinion of the Commission, *In re Rambus, Inc.*, Docket No. 9302, Slip op. at 3 (F.T.C. Aug. 2, 2006) (Public Record Version), available at <http://www.ftc.gov/os/adjpro/d9302/060802commissionopinion.pdf>.

⁴² *Rambus, Inc. v. F.T.C.*, 522 F.3d 456, 463 (D.C. Cir. 2008), cert. denied 129 S.Ct. 1318 (2009).

⁴³ See, e.g., Wallace, *supra* note 39, at 683-90; Wilson D. Mudge & Marni B. Karlin, *The District of Columbia Circuit Court’s Decision in Rambus Overturns the FTC Finding of Monopolization*, Intell. Prop. & Tech. L.J. 11, (2008).

⁴⁴ *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 298 F. Supp. 3d 258 (D. Mass. Feb. 7, 2018) and *Amphastar Pharm., Inc. v. Momenta Pharm., Inc.*, 297 F. Supp. 3d 222 (D. Mass. 2018).

⁴⁵ See Jorge L. Contreras, *Is Biopharma Ready For The Standards Wars?* 6 Tex. A&M J. Prop. L. (forthcoming, 2020).

⁴⁶ See 2007 DOJ/FTC Report, *supra* note 29, at 42-48; ABA Patent Policy Manual, *supra* note 39, xiii-xiv.

technologies under consideration, giving them the opportunity to “design around” such patents if they so wish.⁴⁷ Likewise, licensing obligations are intended to ensure that such patents will be licensed to implementers of the standard on terms that are, at least roughly, understood.⁴⁸

(2) *Royalties for Standards-Essential Patents*

Many SDO policies require that participants license patents essential to their standards on terms that are “reasonable and non-discriminatory” (RAND) or “fair, reasonable and non-discriminatory” (FRAND).⁴⁹ This requirement is built into ANSI’s “Essential Requirements” for all ANSI-accredited SDOs and is equally pervasive in Europe and other jurisdictions. Despite the intuitive appeal of these requirements, however, a consistent and practical definition of FRAND terms has failed to emerge. In several recent cases, parties have disputed whether the terms under which licenses have been proffered violate or conform with FRAND requirements.⁵⁰

FRAND licensing commitments can lead to disputes because there is no universal, objective standard by which “reasonableness” (or “nondiscrimination”) can be measured. In order to make a FRAND determination, the specific facts of each situation must be evaluated. These facts include not only relevant market norms for royalties, but also customary practices relating to non-royalty terms such as reciprocity, grantback licenses, defensive suspension, confidentiality, and the like. Also, given that a patent holder’s FRAND licensing terms are generally not revealed until negotiations that occur *after* a standard has been adopted (i.e., “locked-in”), parties involved in standards setting can experience uncertainty regarding the ultimate cost of adopting a standard encumbered by patents. Put another way, the uncertainty of FRAND licensing may simply substitute the risk of patent hold-up arising from unknown patents with hold-up arising from unknown FRAND licensing terms.⁵¹

A few SDOs have taken steps to clarify the meaning of their FRAND commitments. In 2006, the VMEbus International Trade Association (VITA) amended its patent policy to require that participants disclose in advance the “most restrictive” licensing terms in their RAND licenses.⁵² Around the same time, the IEEE proposed a similar, but voluntary, arrangement. The U.S. Department of Justice indicated that it would not take enforcement action against either SDO, explaining that such disclosures would promote, rather than hinder, competition among patent holders.⁵³ The European Commission has also expressed a general level of comfort with *ex ante*

⁴⁷ ABA Patent Policy Manual, *supra* note 39, at xiv.

⁴⁸ *Id.*

⁴⁹ For purposes of this chapter, we will treat RAND and FRAND requirements as identical.

⁵⁰ See generally Chrysoula Pentheroudakis & Justus A. Baron, *Licensing Terms of Standard Essential Patents: A Comprehensive Analysis of Cases*. JRC Science for Policy Report EUR 28302 (2017) (cataloging FRAND litigation around the world).

⁵¹ 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)).

⁵² Letter from Thomas O. Barnett, Assistant Attorney General, U.S. Dep’t of Justice, to Robert A. Skitol on behalf of VMEbus International Trade Association (Oct. 30, 2006), *available at* <http://www.justice.gov/atr/public/busreview/219380.htm> [hereinafter VITA Letter].

⁵³ See VITA Letter, *supra* note 52, and Letter from Thomas O. Barnett, Assistant Attorney General, U.S. Dep’t of Justice, to Michael A. Lindsay on behalf of Institute of Electrical and Electronics Engineers (Apr. 30, 2007), *available at* <http://www.justice.gov/atr/public/busreview/222978.htm>.

licensing disclosures in its guidelines relating to horizontal competition.⁵⁴ In 2015, the IEEE again amended its patent policy to clarify various aspects of its FRAND commitment, including the basis on which royalties should be charged, imposing a requirement that licenses be made available to all applicants, and prohibiting the seeking of injunctive relief from willing licensees.⁵⁵ These amendments were also approved by the Department of Justice,⁵⁶ although they have been notably unpopular with companies that earn substantial revenue from patent royalties.⁵⁷

IV. THE INFORMATICS STANDARDS LANDSCAPE

Informatics research utilizes a broad range of technologies including experimental apparatus such as microarrays, data analysis tools, and databases that store and allow sharing of experimental and analytic data. Standards are required within each of these broad technology categories to enable data sharing, analysis, and the interoperability of different experimental platforms. To date, hundreds of standards relevant to informatics applications have been developed in three broad categories: terminological artifacts, reporting requirements, and exchange formats.⁵⁸ Below is a brief description of these categories and a summary of some of the more prominent standardization efforts being undertaken in each.

A. Terminological Artifacts

A consistent and unambiguous vocabulary is required in order for different groups and applications to communicate about a wide array of organisms, experimental conditions, and study designs.⁵⁹ A “controlled vocabulary” offers a single set of terms with explicitly-defined meanings within a particular field. An “ontology” creates relationships among these terms, often in hierarchical form, such as the familiar taxonomic classification for biological entities (kingdom, phylum, class, etc.).

In genomics, the Human Genome Organization supports a Gene Nomenclature, while the Human Genomic Variation Society supports a Human Genetic Variant Nomenclature. Similarly, SNOMED CT is a global standard of healthcare terms. One of the earliest and most mature informatics ontologies is the Gene Ontology (GO), which has produced “a structured, precisely defined, common, controlled vocabulary for describing the role of genes and gene products in any organism.”⁶⁰ The Gene Ontology Consortium, which developed the GO, began its work in 1998

⁵⁴ European Commission, Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements, ¶299 (2011).

⁵⁵ IEEE Standards Board Bylaws § 6 (2015).

⁵⁶ Letter from Renata B. Hesse, Acting Assistant Attorney Gen., to Michael A. Lindsay, Dorsey & Whitney LLP (Feb. 2, 2015).

⁵⁷ See Jorge L. Contreras, *Taking it to the Limit: Shifting U.S. Antitrust Policy Toward Standards Development*, 103 Minn. L. Rev. Headnotes 66, 73-75 (Fall 2018).

⁵⁸ This classification system was developed by Biosharing.org, which catalogs and provides information regarding most of the standards discussed below. See *A Catalogue of Standards*, biosharing, <http://www.biosharing.org/standards> (last visited October 28, 2011). A list of the standards compiled by biosharing.org can be found at http://www.biosharing.org/standards_view.

⁵⁹ Thomas R. Gruber, *Toward Principles for the Design of Ontologies Used for Knowledge Sharing?*, 43 Int'l Journal of Human-Computer Studies 907, 908 (1995).

⁶⁰ See Michael Ashburner et al., *Gene Ontology: Tool for the Unification of Biology*, 25 Nature Genetics 25 (2000).

as a joint project of research groups studying three different organisms (the fruit fly, budding yeast, and mouse). As of 2020, the GO included more than 1.4 million annotated gene products.⁶¹

Numerous other ontology projects have arisen following the success of the GO.⁶² These include the Systems Biology Ontology (SBO) originated by EBI,⁶³ the Open Biological and Biomedical Ontologies (OBO Foundry),⁶⁴ and FuGO project.⁶⁵

B. Reporting Requirements

The advent of microarray technology in the 1990s quickly led to the realization by the research community that standardized methods of reporting experimental data generated by microarray studies would be required. The Microarray Gene Expression Data (MGED) Society (now the Functional Genomics Data Society) was formed in 1999 by EBI to develop “Minimum Information About A Microarray Experiment” (MIAME), a checklist specifying the information about every microarray experiment that should be reported in order to enable its proper validation, reproduction, and interpretation.⁶⁶

Many other minimum information standards development efforts have followed the early success of MIAME.⁶⁷ Among others, these include specifications for minimum information in hybridization and immunohistochemistry experiments (MISFISHIE),⁶⁸ proteomics experiments (MIAPE),⁶⁹ molecular interactions (MIMIx),⁷⁰ and (meta)genome sequences (MIGS/MIMS).⁷¹ The Minimum Information for Biological and Biomedical Investigations (MIBBI) Project collects and publishes information about various minimum information standards.⁷² The Adaptive Immune Receptor Repertoire (AIRR) Community has developed a Minimal information about Adaptive

⁶¹ See Gene Ontology Consortium, *The Gene Ontology (GO) Project in 2006*, 34 *Nucleic Acid Research* D322, D323 (2006); Gene Ontology Resource, Statistics, <http://geneontology.org/stats.html> (last visited May 21, 2020).

⁶² A more comprehensive list of ontology projects can be found in Chris F. Taylor, *Standards for Reporting Bioscience Data: A Forward Look*, 12 *Drug Discovery Today* 527, 529 (2007).

⁶³ See *Systems Biology Ontology*, European Molecular Biology Lab.-European Bioinformatics Inst., <http://www.ebi.ac.uk/sbo/main> (last visited Oct. 28, 2011).

⁶⁴ See Barry Smith, *The OBO Foundry: Coordinated Evolution of Ontologies to Support Biomedical Data Integration*, 25 *Nature Biotechnology* 1251 (2007).

⁶⁵ See Patricia L. Whetzel et al., *Development of FuGO: An Ontology for Functional Genomics Investigations*, 10 *OMICS* 199 (2006).

⁶⁶ See Catherine A. Ball & Alvis Brazma, *MGED Standards: Work in Progress*, 10 *OMICS* 138, 139-140 (2006).

⁶⁷ There are more comprehensive lists of minimum information standards projects available: Taylor, *supra* note 62, at 528; Lyle D. Burgoon, *Clearing the Standards Landscape: the Semantics of Terminology and their Impact on Toxicogenomics*, 99 *Toxicological Sciences* 403, 408-10 (2007).

⁶⁸ See Inst. for Sys. Biology, MISFISHIE, <http://scgap.systemsbiology.net/standards/misfishie/> (last visited Oct. 28, 2011).

⁶⁹ See Sandra Orchard & Henning Hermjakob, *The HUPO Proteomics Standards Initiative – Easing Communication and Minimizing Data Loss in a Changing World*, 9 *Briefings in Bioinformatics* 166, 167 (2008).

⁷⁰ See *id.* at 170-71.

⁷¹ See Pelin Yilmaz, *The Genomic Standards Consortium: Bringing Standards to Life for Microbial Ecology*, 5 *ISME J.* 1565 (2011).

⁷² See Chris F. Taylor, *Promoting Coherent Minimum Reporting Guidelines for Biological and Biomedical Investigations: the MIBBI Project*, 26 *Nature Biotechnology* 889, 889 (2008).

Immune Receptor Repertoire datasets (MiAIRR).⁷³ In the field of neuroscience, the Brain Imaging Data Structure (BIDS) supports the reporting of data from neuroimaging experiments.

C. Exchange Formats

A recent compilation of molecular biology databases lists 1330 different data sources across the world.⁷⁴ In order for researchers to make use of data beyond their own laboratories, they require the ability to access and utilize data from disparate sources. The exchange of data among different software applications and databases has become commonplace in today's data-driven economy. Much of this exchange is accomplished using markup languages, or schema that enable the annotation of digital text in a manner that can be interpreted by a computer.⁷⁵ The most common markup language, Hypertext Markup Language (HTML), is the dominant language for encoding web pages.⁷⁶ Markup languages work through the use of "tags" that delimit characteristics of the text they designate. For example, in HTML, the tags and cause the text between the tags to be displayed in boldface type. Extensible Markup Language (XML), developed by the Worldwide Web Consortium (W3C), is a flexible data format that enables users to create customized tags based on the specific types of data in which they are interested.⁷⁷ Hundreds of XML-based languages exist today, many of which are optimized for informatics applications.⁷⁸ Among the best-known XML-based bio-focused languages are the Systems Biology Markup Language (SBML),⁷⁹ CellML for computational cell biology,⁸⁰ MAGE-ML, for the exchange of microarray data,⁸¹ and BioPAX, for the exchange of biological pathway data.⁸²

Despite the widespread adoption of XML as the preferred standard for data exchange in the biosciences, some commentators have criticized XML as too limited and imprecise for the robust exchange of scientific data.⁸³ An alternative data exchange standard is the Reference Data Format (RDF), also developed by W3C, which takes advantage of the so-called "semantic web" and offers developers greater freedom to define data relationships.⁸⁴ The Bio2RDF Project led by W3C has

⁷³ Jacob S. Sherkow, [AIRR working paper]

⁷⁴ Michael Y. Galperin & Guy R. Cochrane, *The 2011 Nucleic Acids Research Database Issue and the Online Molecular Biology Database Collection*, 39 *Nucleic Acids Res.* D1, D1 (2011).

⁷⁵ James H. Coombs et al., *Markup Systems and the Future of Scholarly Text Processing*, 30 *Comm. ACM* 933 (1987).

⁷⁶ *Introduction to HTML 4*, W3C, <http://www.w3.org/TR/html4/intro/intro.html> (last visited Jan. 30, 2012).

⁷⁷ *Extensible Markup Language Introduction*, W3C, <http://www.w3.org/XML/> (last visited Jan. 30, 2012).

⁷⁸ More comprehensive lists of bioinformatics markup languages can be found in Burgoon, *supra* note 67, at 409; Luciano Milanesi, *Trends in Modeling Biomedical Complex Systems*, 10 *BMC Bioinformatics*, 12 (Supp. 2009).

⁷⁹ See M. Hucka, *The Systems Biology Markup Language (SBML): A Medium for Representation and Exchange of Biochemical Network Models*, 19 *Bioinformatics* 524 (2003).

⁸⁰ See Catherine M. Lloyd et al., *CellML: Its Future, Present and Past*, 85 *Progress in Biophysics & Molecular Biology* 433, 436 (2004).

⁸¹ See Ball & Brazma, *supra* note 66, at 140-41.

⁸² See Christoph Wierling et al., *Resources, Standards and Tools for Systems Biology*, 6 *Briefings Functional Genomics & Proteomics* 240, 245-46 (2007).

⁸³ See, e.g., John Quackenbush, *Standardizing the Standards*, 2 *Molecular Systems Biology* 1, 1-2 (2006); Xiaoshu Wang et al., *From XML to RDF: how semantic web technologies will change the design of 'omic' standards*, 23 *Nature Biotechnology* 1099 (2005).

⁸⁴ Wang et al., *supra* note 83, at 1099.

recently developed software and a website for accessing data from different public informatics databases in RDF format.⁸⁵

Closely related to markup languages are object models. Object models describe the relationships among computer programming “objects” of interest within a given discipline and can thus act as blueprints for the development of specialized markup languages.⁸⁶ Of particular interest in informatics are the Microarray and Gene Expression Object Model (MAGE-OM),⁸⁷ the SysBio-OM developed by the National Institute of Environmental Health Sciences (NIEHS),⁸⁸ and the Functional Genomics Experiment Object Model (FuGE-OM).⁸⁹

The object models and markup languages discussed above are essential for the exchange of data among disparate data sources and databases. Yet data exchange tools alone are not enough, and commentators find that the proliferation of incompatible data sources has led to increasing duplication of effort, poor interoperability, and loss of data.⁹⁰ To address these problems, an international consortium of database users and developers has begun work on a uniform set of defining attributes for biological databases called BioDBCore.⁹¹

Technology is allowing more sophisticated and granular exchange of bioinformatics data. Increasingly, data exchange standards are coupled with associated application programming interfaces (APIs), which enable access to targeted components of a database or a data file. The GA4GH Beacon API standard, for example, allows for researchers to query a whole genome sequence or database of sequences to ask if it contains a particular variant of interest.⁹² This can allow researchers to find genomes of interest without having to first request access to or download an entire database. From an IP perspective, APIs are most reliably protected by copyright.⁹³

D. Other

As the bioinformatics field matures, the range of related standards continues to diversify. The Global Alliance for Genomics and Health (GA4GH) and the Moving Picture Experts Group (MPEG), a working group of ISO (ISO/IEC JTC 1/SC 29/WG 11) have both released compression standards for genomic data, respectively CRAM and MPEG_G. The GA4GH has also developed

⁸⁵ See Francois Bellau et al., *Bio2RDF: Towards a Mashup to Build Bioinformatics Knowledge Systems*, 41 J. Biomedical Informatics 706 (2008).

⁸⁶ Philippe LeHegaret et al., *What is Document Object Model?*, W3C, Apr. 7, 2004, <http://www.w3.org/TR/DOM-Level-3-Core/introduction.html> (last visited Feb. 1, 2012).

⁸⁷ *Microarray Gene Experiment – Object Model*, Functional Genomics Data Society, <http://www.mged.org/Workgroups/MAGE/mage.html> (last visited Oct. 29, 2011).

⁸⁸ Burgoon, *supra* note 67, at 409.

⁸⁹ *Functional Genomics Experiment Object Model*, Functional Genomics Experiment, <http://fuge.sourceforge.net/index.php> (last visited Oct. 29, 2011).

⁹⁰ See Pascale Gaudet, et al., *Towards BioDBCore: A Community-Defined Information Specification for Biological Databases*, 39 Nucleic Acids Res. D7 (2011).

⁹¹ *Id.*

⁹² Global Alliance for Genomics and Health, Beacon Project, <https://beacon-project.io/> (last visited May 21, 2020). The API accepts “queries in the form “Do you have any genomes with an ‘A’ at position 100735 on chromosome 3” and responds with “Yes” or “No.” ”

⁹³ Parth Sagdeo, *Application Programming Interfaces and the Standardization-Value Appropriation Problem*, 32 Harvard Journal of Law & Technology (2018), p 241-43.

an encryption standard for genomic data, CRYPT4GH. These areas appear to be more susceptible to patenting, raising patent considerations for SDOs.⁹⁴

V. INFORMATICS STANDARDS POLICIES TODAY: ASSESSMENT AND RECOMMENDATIONS

A. Summary of Informatics SDO Policies

Technical standards are likely to play an increasingly prominent role in the development, adoption, and regulation of informatics research and technologies. Whether such standards relate to minimum information requirements, controlled vocabularies, or data exchange formats, the legal and policy considerations described in this section will play a key role in determining which of these standards are broadly adopted, and at what price.⁹⁵

Given the importance of legal issues to standards development in other sectors of the economy, we conducted a review of the publicly-available policies and rules of a number of major informatics standards initiatives. The results, summarized in *Appendix 1* below, indicate that few standardization efforts in informatics address these issues in detail, and a significant number omit any legal guidelines in their public documentation. In many cases the organizations responsible for bioinformatics standards development either lack written policies entirely or have adopted vague, aspirational statements regarding a desire that materials produced be “open” and publicly-available. This informality generally reflects the academic and open science context of most bioinformatics standards development and implementation. Furthermore, some bioinformatics SDOs focus on specific standard types with limited IP implications (e.g., terminologies). This informal and minimalist approach to IP may become increasingly problematic with greater commercial and healthcare involvement in bioinformatics standardization. It not only invites opportunistic behavior, but also leaves aggrieved participants with little legal recourse after abuse has occurred.

Nevertheless, the data collected in *Appendix 1* does reveal a number of recurring themes. These include a general preference that informatics standards be “open” and “not restricted” by intellectual property rights. Stated more precisely, these preferences can be expressed in terms of the following two maxims: (a) informatics standards should be freely available, and (b) the implementation of informatics standards should not be impeded by patents.

By contrast, health informatics standards development envisaging implementation in healthcare contexts is characterized by formal intellectual property policies (see Table 1). Healthcare terminologies like SNOMED, CT and LOINC are protected by copyright and trademark. Health

⁹⁴ See e.g., Sterling Thomas, Nate Dellinger & Mychal Ivancich, *Compression and transmission of genomic information* (2016), <https://patents.google.com/patent/US20160344849/en?q=genomic+compression> (last visited May 21, 2020).

⁹⁵ Admittedly, intellectual property considerations may play a smaller role in standards devoted to the definition of controlled vocabularies and minimum information guidelines (which are themselves less amenable to patent protection) than they do in standards relating to data exchange formats, database structures, and scientific apparatus. This distinction may be less pronounced with respect to the impact and importance of antitrust issues.

informatics SDOs also have a more diverse range of business models, with some making standards freely available, and others using IP to protect standards made available only through member licenses. As bioinformatics matures, bioinformatics and associated standards will increasingly also need to be implemented in clinical research and healthcare contexts.⁹⁶ Traditional health informatics SDOs will play a greater lead or partnership role with respect to clinical bioinformatics. An example of a bioinformatics standard with a clinical focus is ISO/TS 20428:2017, which describes data and metadata structures for clinical genomic sequence information in electronic health records. These bioinformatics standards will need to be coupled with greater clarity around IP rights.

B. Policy Recommendations

As discussed above, it is important for SDOs to establish clear policies regarding compliance with antitrust law and the disposition of intellectual property rights in a manner that is aligned with the expectations and wishes of their participants. This is especially true for generalist SDOs adopting an open-ended range of standard types. At a minimum, such policies should include provisions addressing the antitrust considerations described in Section IV.E above, as well minimum provisions relating to copyrights and patents. Among the more critical issues to include in such policies are the following:

Copyrights

- What rights do SDO participants grant to the SDO and to one another with respect to their copyrights in documents (e.g., specifications), text and code that are “contributed” to a standard?
- Is the standard available free of charge, or must those wishing to implement it purchase copies from the SDO or others? If the latter, do SDO participants gain access at a discounted rate?
- What rights does the SDO grant to the world under its copyrights, if any, in a standard (e.g., can the standard be reproduced, modified, translated, excerpted, re-distributed, or otherwise manipulated outside of the SDO that developed it)?

Patents

- May SDO participants obtain patents covering the implementation of the SDO’s standards?
- If so, must these participants commit to license such patents to all implementers of the standards?
- If so, must these licenses be royalty-free, or may royalties be charged (and if so, are there any limitations on royalty-rates, FRAND or otherwise)?
- Must participants disclose these patents and, if so, when?

⁹⁶ Ewan Birney, *The convergence of research and clinical genomics*, 104 *American Journal of Human Genetics* 781–783 (2019).

While at first blush it might appear that the above issues can be addressed in a relatively straightforward and concise manner, SDO antitrust and intellectual property policies have become increasingly complex and lengthy over the years. This trend can generally be attributed to the desire of SDO participants, and their legal counsel, to anticipate a growing range of legal contingencies and to accommodate the diverse interests and business models of those participants. For example, in a typical SDO that focuses on the development of next-generation wireless telephony standards, participants might include handset manufacturers, chip designers, service providers (carriers), software developers, and businesses that do no more than acquire and assert patents, not to mention academics, consumer advocates, and government agencies. It is not surprising that developing a policy that accommodates the requirements of each of these groups can be difficult, time-consuming, and expensive and can result in a complex policy that reflects myriad compromises required to appease these differing interests and business models.

In contrast to the world of mobile telephony, participants in informatics standards development activities currently appear to consist primarily of academics, industrial scientists, and a handful of product vendors. This observation, coupled with the general consensus around the simple intellectual property-related maxims described in Section VI.A above, suggests that informatics SDOs might be able to adopt legally-prudent policies while avoiding the complexity, effort, and rancor often experienced in ICT-focused SDOs.

To this end, *Appendix 2* contains a brief example of an SDO policy reflecting the two maxims noted above and other key provisions. While it is not intended that this exemplar be adopted verbatim by all SDOs, it is hoped that it might be useful as a starting point for consideration, and that it might provide scaffolding atop which an SDO may build more specialized provisions to address the particularized needs of its participants.⁹⁷ Additional examples can be found on the websites of the SDOs listed in *Appendix 1*.

C. Making Policies Binding

Even the most artfully-drafted SDO policy is of little value unless it binds its participants and possibly other implementers and users of its standards. Simply announcing the SDO's policy on the SDO website, without affirmative assent by those parties that the SDO intends to bind, will make the policy more difficult to enforce.⁹⁸ Thus, SDOs have adopted a variety of approaches to ensure (or at least improve the chances) that their policies will legally bind their participants. These approaches include the incorporation of such policies into the SDO's by-laws and other constitutional documents, the use of signed participation agreements, and the issuance of frequent reminders of the existence and effect of such policies.⁹⁹

⁹⁷ The ABA Patent Policy Manual, *supra* note 39, contains a large collection of annotated sample clauses that appear in SDO patent policies. The exemplar presented in *Appendix 1* is intentionally brief and does not delve into most of the complexities addressed by the Manual. For example, the exemplar policy does not address issues associated with the inclusion of software code in a standard, nor the licensing of patents on royalty-bearing terms.

⁹⁸ See Jorge L. Contreras, *Enforcing FRAND and Other SDO Licensing Commitments* in Cambridge Handbook of Technical Standardization Law: Competition, Antitrust, and Patents 178 (Jorge L. Contreras ed., 2018).

⁹⁹ See ABA Standards Manual, *supra* note 39, at 27.

Many informatics standardization efforts are carried out in semi-academic settings without formal participation or membership structures. Groups of this nature would do well to consider formalizing their participation at least to the extent of requiring that participants expressly acknowledge (or, better still, agree to comply with) the SDO's written policies.

CONCLUSIONS

Though informatics SDOs have demonstrated a consistent preference for standards that are open and unencumbered by intellectual property rights, few of them have adopted explicit policies ensuring that these preferences will be respected by their participants. As evidenced by the increasing number of disputes and litigation in other fields that are heavily dependent on interoperability standards, it is important for organizations to adopt clear and binding policies governing the conduct of their participants. Accordingly, informatics SDOs should carefully review their existing policies and procedures. To the extent that they fail to address key points regarding process and intellectual property, these policies and procedures should be revised to reflect the intentions and expectations of participants in the standardization process.

APPENDIX 1

Selected Bioinformatics and Health Informatics Standards Development Organizations and Standards

Types

R = Reporting

X = Exchange

T = Terminology

E = Encryption

SDO	Year Started	Notable Standards	Type	Policies	Website
BIOINFORMATICS STANDARDS					
Adaptive Immune Receptor Repertoire (AIRR) Community of The Antibody Society	2015	Minimal information about Adaptive Immune Receptor Repertoire datasets (MiAIRR)	R	None	https://docs.airr-community.org/en/latest/index.html
		AIRR Data Representation Standard	X		
		AIRR Data Commons API	X		
Asia-Pacific Bioinformatics Network	1998	Minimum Information About a Bioinformatics Investigation	R	None	http://www.apbionet.org
BioPAX.org	2002	BioPAX	X	Open source licenses that are academic and corporate friendly are used for all work	http://www.biopax.org
Brain Imaging Data Structure (BIDS) Community	2014	Brain Imaging Data Structure (BIDS)	R	Creative Commons Attribution (CC-BY) License	https://bids.neuroimaging.io
European Molecular Biology Laboratory, European Bioinformatics Inst. (EMBL-EBI)	1992	Systems Biology Ontology (SBO)	T	No restrictions on use or redistribution of data. Some original data may be subject to patent, copyright, or other IP rights, and users must ensure that their exploitation of the data does not infringe the rights of third parties	http://www.ebi.ac.uk
		Experimental Factor Ontology (EFO)	T		

SDO	Year Started	Notable Standards	Type	Policies	Website
Functional Genomics Data Socy. (FGED) [formerly Microarray Gene Expression Data (MGED) Socy.]	1999	MGED Ontology	T	No funding sources have IP rights over FGED's output; FGED currently owns no patents or copyrights, and advocates free use of data, tools, and publications	http://www.mged.org
		Minimum Information About a Microarray Experiment (MIAME)	R		
		Minimum Information Specification for <i>In Situ</i> Hybridization and Immunohistochemistry Experiments (MISFISHIE)	R		
		The development of the Minimum Information about a high-throughput SEQuencing Experiment standard for Ultra High-Throughput Sequencing experiments. (MINSEQE)	R		
		MAGE-ML	X		
Gene Ontology Consortium	1998	Gene Ontology	T	Creative Commons Attribution (CC-BY) License. Unrestricted use if user acknowledges GO as source, displays the version number, and does not alter files	http://geneontology.org
Genomic Standards Consortium	2005	MiXS standards	R	Common Public License Version 1.0 (CPL). The license generally provides that any contributor grants a royalty-free license to use any copyrighted or patented materials	http://gensc.org/gc_wiki/index.php/Main_Page
		Minimum Information about a MARKer gene Sequence standard (MIMARKS)	R		
		Genomic Contextual Data Markup Language (GCDML)	X		
Global Alliance for Genomics and Health (GA4GH)	2014	SAM/BAM next-generation sequencing file formats	X	Open source licenses for specifications and software, that are academic and corporate friendly, are used for all work created.	https://www.ga4gh.org/
		VCF/BCF variant call file formats	X		
		CRAM File Format	C		
		Beacon API	X		
		htsget API	X		
Human Genome Organization	1988	Crypt4GH	E	Nomenclature and information are freely available to all, with request for attribution.	http://www.hugo-international.org
		HUGO Gene Nomenclature	T		

SDO	Year Started	Notable Standards	Type	Policies	Website
Human Genome Variation Society	2001	Human Genome Variant Nomenclature	T	None	http://www.hgvs.org
Intl. Socy. Biocuration	N/A	BioDBCore	R	None	http://biocurator.org
International Organization for Standardization (ISO) - Health Informatics (ISO/TC 215) - Genomics Informatics (SC 1)	1947	ISO 25720:2009 Genomic Sequence Variation Markup Language (GSVML)	X	ISO/IEC/ITU Common Patent policy: a patent embodied fully or partly in an ISO document must be accessible to everybody without undue constraints. Any party participating in ISO work should draw the attention of the Director to any known patent or pending patent application pertaining to that work. The patent holder may negotiate licenses with other parties either free of charge or on reasonable and non-discriminatory terms and conditions. If it is not willing to do so, the document shall not include provisions depending on the patent.	https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/committee/75/46/7546903.html
		ISO/TS 20428:2017 Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records	X		
Moving Picture Experts Group (MPEG) - ISO TC 276	1988	MPEG-G	C	Follows ISO rules	https://mpeg-g.org/about/
Ontology for Biomedical Investigations Consortium	2016	Ontology for Biomedical Investigations	R	Creative Commons Attribution (CC-BY) License	http://obi-ontology.org/
Open Biological and Biomedical Ontologies (OBO) Foundry	2001	Does not create its own, but endorses ontologies that meet its principles and standards	T	OBO will not endorse ontology unless it allows for free use to all	http://obofoundry.org
Proteomics Standards Initiative (PSI) [HUPO]	2002	Minimum Information about a Proteomics Experiment (MIAPE)	R	PSI takes no position regarding validity or scope of any IP or other rights pertaining to the implementation or use of technology or the extent to which any license under such rights might or might not be available; neither does it represent that it has made any effort to identify any such rights	http://www.psdev.info
		Min. Information about a Molecular Interaction Experiment (MIMIx)	R		
		Min. Information about a Protein Affinity Reagent (MIAPAR)	R		
		Proteomics Standards Initiative-Molecular Interaction (PSI-MI) XML	X		
		mzML	X		
SBML.org	2000	Systems Biology Markup Language	X	The organization considers SBML to be free and open to the community, such that no one owns rights to it	http://sbml.org/Main_Page

SDO	Year Started	Notable Standards	Type	Policies	Website
University of Auckland	2004 ¹⁰⁰	CellML	X	Individuals may freely use, publish and redistribute CellML, write and sell applications which create, load, or write CellML-valid XML files; distribute or sell their own CellML-valid XML files; and transmit verbatim copies of the CellML format to any person without restriction	https://www.cellml.org
Worldwide Web Consortium (W3C)	1994	Bio2RDF	X	GPL v. 2.0; W3C will not approve a recommendation if it is aware that essential patent claims are not available on royalty-free terms	http://www.w3.org/
HEALTH INFORMATICS STANDARDS					
Clinical Data Interchange Standards Consortium (CDISC)	1997	Operational Data Model (ODM)	X	Participants in Working Groups must grant a non-exclusive copyright license in contributions and must make royalty-free licensing commitment for patents. Final standards are openly available.	www.cdisc.org
Digital Imaging and Communications in Medicine (DICOM) Committee (ISO 12052)	1983 ¹⁰¹	Digital Imaging and Communications in Medicine (DICOM)	X	Standard is available for free and without intellectual property constraints	https://www.dicomstandards.org/
European Committee for Standardization CEN/TC 251 – Health Informatics	1961	Standards are usually jointly planned and simultaneously approved in partnership with ISO (see above and below)		Permits inclusion of patented technologies made under royalty-free or fair, reasonable and non-discriminatory licensing commitments, and encourages early disclosure of related patents. Assignment of copyrights in contributions.	https://standards.cen.eu/dyn/www/f?p=204:7:0:::FSP_ORG_ID:6232&cs=18CA078392807EDD402B798AAEF1644E1

¹⁰⁰ Work on CellML began in 2004. The University itself is much older.

¹⁰¹ This committee was started within the National Electrical Manufacturers Association, founded in 1926.

SDO	Year Started	Notable Standards	Type	Policies	Website
Health Level 7 International (HL7)	1987	Fast Healthcare Interoperability Resources	X	Standards are protected by copyright and trademark and are available through membership licenses. Participants must disclose patents, and must make a non-assertion commitment, or a royalty-free or reasonable and non-discriminatory licensing commitment.	https://www.hl7.org/
International Organization for Standardization (ISO) - Health Informatics (ISO/TC 215)	1947	ISO 13606-1:2019 Electronic health record communication — Part 1: Reference model (See also ISO genomics standards above)	X	See above	https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/committee/05/49/54960.html
Regenstreif Institute	1969	Logical Observation Identifiers Names and Codes (LOINC)	T	Standard is protected by copyright and trademark and is available through a member license.	https://loinc.org
SNOMED International	2007	SNOMED CT	T	Standard is protected by trademark and is available through an affiliate license.	https://www.snomed.org

APPENDIX 2

Sample Informatics “Open” Standards Development Policy

[*Insert name of standards development organization*] (SDO) is committed to the open and transparent development and dissemination of technical standards relating to [*subject matter*]. Accordingly, all physical and online meetings, working groups, mailing lists, correspondence, and other activities conducted under the auspices of SDO (“SDO Activities”) will be subject to the following rules.

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- b. condition or discuss conditioning the implementation of an SDO standard on the implementer’s use of products or services offered by a particular party; or
- c. agree with others to refuse to do business with a particular party.

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¹⁰² The term “SDO Participant” should be defined to include all members, organizers, promoters, and other participants in SDO Activities, together with their corporate affiliates.

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c. SDO Participant agrees and acknowledges that other SDO participants working within SDO may, individually or collectively, seek to modify draft SDO standards so as to avoid one or more Necessary Patents, and such activity does not, without more, constitute a violation of any antitrust or competition law.

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