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Standards and the Law

By Cary Coglianese

The world of standards is typically viewed as separate from the world of laws. Standards, after all, are often described using adjectives such as “voluntary” and “consensus.” Standards-development organizations are not in the business of producing mandatory or legally binding standards; that business is the responsibility of legislatures, agencies, and courts. But even though the world of standards and the world of laws seem separate, they are actually more closely intertwined than many professionals working with laws or standards realize.

Standards intersect with and affect the law in numerous ways. They serve as benchmarks to determine liability and as frames of reference to facilitate domestic and international transactions handled by lawyers. They prompt legal negotiations over the licensing of patented technologies needed to conform to standards—and when these negotiations break down, they spill over into court battles.

Standards can also sometimes be incorporated into laws and regulations, thereby becoming binding. They can even govern the processing of evidence in the judicial system, affecting highly consequential decisions about criminal liability.

This article explains how standards come into play in six major domains of law: product liability, patent law, contracts, administrative law, international trade, and criminal law. Although examples are provided from

the United States, similar intersections between standards and the law apply in other jurisdictions. Seeing the connections between standards and the law can help legal professionals better appreciate the important role that standards play in the economy; equally, it can help standards professionals better understand how their work affects the legal system.

PRODUCT LIABILITY

When standards specify how products should be designed, especially for reasons of safety and health, they can determine the applicable standard of care in product liability cases. Because the overarching standard of care for proving negligence is generally an open-ended one of “reasonable care,” lawyers and judges will look to relevant voluntary standards for guidance.

This is why courts in some states have specifically ruled that violating a voluntary standard for product safety is presumptively a sign of negligence (*M & R Investment Co. v. Anzalotti*). State legislatures have also passed statutes establishing a connection between standards and products liability. The state of Washington’s Products Liability Act, for example, allows juries in product liability cases to consider conformity to standards in determining whether a manufacturer has been negligent (Washington Revised Code 1981).

The connection between liability and standards also works to protect manufacturers. Legislatures in some states have approved laws providing that conformity with a relevant standard protects manufacturers from liability. Conformity, in other words, can create a rebuttable presumption that a product poses no unreasonable risk of harm.

Even in cases when product liability is determined under a liability test where negligence of the seller need not be proven, such as strict liability, standards are also sometimes accepted by courts as pivotal evidence. The strict liability standard adopted in many U.S. states basically holds sellers liable for harms caused by any products that are deemed to be “unreasonably dangerous” (ALI 1965). In these states, standards may be used by some courts in assessing whether a product meets the test of reasonable safety.

In California, for example, a strict liability test asks if a “product’s design creates preventable danger that is excessive in relation to the advantages of the design.” The state Supreme Court has held that conformity (or non-conformity) with standards can be relevant in assessing the risks and benefits of a product design (*Kim v. Toyota Motor Corp.*). Of course, some other states have differed—the Pennsylvania Supreme Court, for example, has held that conformity with an American Society of Mechanical Engineers standard was not relevant in a strict liability case (*Lewis v. Coffing Hoist Div., Duff-Norton Co.*).

PATENT LAW

Patents grant property rights and protections to the inventors of new products, machines, and processes, preventing others from using patented innovations without getting a license to do so from the patent owner. Many professionals in the standards world may already be familiar with issues surrounding standard-essential patents. When a standard necessitates the use of a technology protected by a patent, that patent is seen as a “standard-essential” one.

Based on contractual obligations, and consistent with the American National Standards Institute’s patent policy, the owner of a standard-essential patent must license its intellectual property to others on terms that are fair, reasonable, and non-discriminatory, or FRAND (Dahl 2020). (Sometimes professionals just use the term RAND, as “fair” and “reasonable” can be considered synonyms.)

The legal obligation to license standard-essential patents on FRAND terms helps prevent holdouts by patent owners seeking to extract rents from licensees. But as the words that comprise the FRAND acronym suggest, what is fair, reasonable, and non-discriminatory may not always be self-evident and uncontroversial. Although standard-setting organizations establish the expectations that standard-essential patents will be licensed on FRAND terms, they do not determine what counts as FRAND in any specific case. Patent owners and licensees must negotiate over license terms.

Sometimes these negotiations have broken down. In these instances, courts have provided some specificity to what FRAND entails. The federal court in *Georgia-Pacific Corp. v. United States Plywood Corp.* (1970) articulated a widely applied 15-factor test for assessing damages in patent infringement cases. In 2013, another federal court elaborated on the *Georgia-Pacific* test and modified it to apply to a standard-essential patent dispute more generally (*Microsoft v. Motorola*). Among other things, the court determined that when damages call for calculating the value of the patent, a court should not include the enhanced value that accrues due to the existence of a standard that necessitates the use of the patent. Instead, a court should just look to the value of the patent by itself.

These are not easy judgments to make. Over the last decade, a variety of other disputes over FRAND terms have resulted in litigation (Renaud, Wodarski, and Weinger 2020). The impact of standards on patent law practice—and on the outcomes of courts’ decisions in

patent disputes—will likely persist for many years to come.

CONTRACTS

As noted, the basis for a patent owner's FRAND obligation ultimately derives from contract law, as courts have found the membership agreements between patent owners and standard-setting organizations imply such an obligation. But standards can figure into legal contracts in many other ways.

Standards are often at the center of business transactions. Just as standards can be used to define the standard of care in product liability cases, they can be used as reference points for parties in defining contractual obligations. Contract language for goods or services often specifies that these goods and services must conform to specific industry standards, making contractually binding what otherwise might be "voluntary."

When disputes arise over compliance with the standards referenced in contracts, they can end up in court, where judges are asked to award remedies if the goods or services do not meet the standards specified in the contract. For example, when a crude oil contract called for independent third-party testing of the oil based on standards issues by ASTM International and the American Petroleum Institute, a court held that "the failure of such independent third party to follow the standards or procedures prescribed in the contract will invalidate any certification or determination so made" (*Cities Service Company v. Derby & Company*). In this way, standards often become the benchmarks for performance in contract disputes handled by lawyers.

ADMINISTRATIVE LAW

Administrative law refers to the body of procedures and doctrines that govern how commissions, boards, and agencies go about their work, such as making binding law through the rulemaking process. Each year, federal administrative agencies in the United

States issue thousands of rules, which are subsequently published in the *Federal Register*.

Some of these rules or regulations simply borrow from voluntary standards, thereby making them mandatory. In fact, the National Technology Transfer and Advancement Act (NTTAA) specifically encourages federal agencies that develop regulations to "use technical standards that are developed or adopted by voluntary consensus standards bodies" whenever practical (NTTAA 1996).

Often the incorporation of standards into regulations occurs "by reference." This means that the agency's rule does not actually spell out what the incorporated standard says, but simply refers to that standard using the name of the standard-setting organization and the name or number of the standard. According to a database maintained by the National Institute of Standards and Technology (NIST), federal regulations currently contain more than 26,000 provisions that incorporate standards by reference (NIST 2023).

Ordinarily, laws and regulations must be published in free, publicly accessible sources, such as the *Federal Register*. But because standards are created by private standard-setting organizations, many incorporated standards are copyrighted and cannot be reprinted in the *Federal Register* (Bremer 2015). This has led critics of the practice of incorporation by reference to charge that the process lacks transparency.

The Administrative Procedure Act only allows agencies to incorporate standards by reference into their regulations when the standards can still be made "reasonably available" to the public (APA 1967). Usually this requirement is met by a regulatory agency making the standard available for physical inspection at the agency's headquarters. As a practical matter, however, a regulated entity or member of the public seeking to read the content of an incorporated standard and understand what the law requires may need to purchase the standard from the standard-setting organization.

INTERNATIONAL TRADE

Standards can be important vehicles for facilitating international trade, such as by ensuring the interoperability of technologies and providing a common floor of safety and other product performance characteristics. But standards can serve as barriers to trade as well, especially if different standards apply in different countries. As a result, standards can pose large economic stakes for private businesses around the world.

The World Trade Organization's Agreement on Technical Barriers to Trade (WTO TBT) has sought to limit attempts by national governments to use domestic regulations and standards as "unnecessary obstacles to international trade" (WTO 1995). The TBT specifically contains provisions encouraging countries to harmonize their standards and rely whenever possible on international standards as a basis for domestic policies.

Because international trade law encourages countries to rely on international standards, this gives international businesses as well as national governments a strong reason to participate in international standard setting. In the United States, the NTTAA calls for NIST to take steps to ensure that the interests of U.S. businesses are sufficiently represented in international standard-setting processes. Other governmental entities, such as the Office of the U.S. Trade Representative (USTR) and the U.S. Agency for International Development, actively monitor and coordinate efforts to promote U.S. interests in standards development processes (USTR 2022). In addition, representatives from major federal agencies participate in a government-wide Interagency Committee on Standards Policy (ICSP) in an effort "to promote effective and consistent standards policies" across the federal government, as well as to "foster cooperation between government, industry, and other private organizations involved in standards activities" (ICSP 2021). Given the significant trade implications that standards can have, other countries' legal and

administrative bodies are similarly active in international standards development.

CRIMINAL LAW

In discussing the interaction of standards and law in each of the preceding domains, it has been presupposed that standards apply to private businesses and their products and services, which they mainly do. But standards can also apply to governmental bodies. Specifically, standards play a key role in the criminal courts of the United States by helping ensure the accuracy of forensic evidence presented to juries.

ASTM International has developed a comprehensive set of more than 60 forensic science standards on the storage, testing, and analysis of evidence (ASTM 2023). Courts now use conformity with ASTM standards to determine whether expert testimony on forensic evidence is admissible in criminal trials (*United States v. Weiss*).

In a pivotal case on DNA analysis, the Minnesota Supreme Court held that the admissibility of laboratory results in criminal cases ultimately "hinges on the laboratory's compliance with appropriate standards and controls" (*State v. Schwartz*). Today, standards' conformance with respect to laboratory techniques and operations is pivotal for forensic laboratories to receive accreditation.

Ensuring that forensic science standards are kept up to date is critical when courts mete out criminal punishments. Unfortunately, wrongful convictions remain a serious problem in the United States. The continued development of, and conformity with, state-of-the-art forensic science standards offer one avenue for minimizing error in the legal system.

CONCLUSION

Given the numerous ways that standards intersect with the legal system, it is important for lawyers, engineers, and other professionals working with both worlds (standards and

law) to understand each other and communicate effectively.

Unfortunately, lawyers historically have received far too little exposure to standards in their professional training (Kanevskaja 2020; Coglianesi and Raschbaum 2019). The Penn Program on Regulation (PPR) has sought to rectify this gap in legal education by developing, with support from NIST, a suite of curricular materials for use in law and policy courses. These materials, which are freely available at www.Codes-and-Standards.org, include a wide range of case studies, teaching guides, videos, slides, and references (PPR 2022).

Projects such as www.Codes-and-Standards.org provide resources to make it easier to educate legal professionals about the important work of standards professionals. After all, standards, like law, help govern business practices and product designs. They both can perform critical governance roles in today's economy. Indeed, standards arguably may be more important today than law in governing the fast-changing digital technologies that increasingly affect all our lives, such as artificial intelligence (Wallach and Marchant 2019). Rather than seeing law and standards as two separate worlds, we can and should see them for what they are: two intersecting and often complementary worlds.

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