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BIO-PROPERTY CONTRACTS IN A NEW ECOSYSTEM: GENETIC RESOURCES ACCESS AND BENEFIT SHARING

Mariko Kageyama*
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ABSTRACT

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity presents a relatively new international legal framework. Although the United States is not currently bound by this legal instrument, its impact may be felt in the life sciences innovation sector and beyond. Transnational implementation mechanisms for the Nagoya Protocol have a combination of property law and contract law as their theoretical underpinning. Stakeholders who are entering into an agreement with their foreign counterparts should honor the Access and Benefit-Sharing scheme as well as domestic laws and policies of Parties to the Protocol to access biological materials located in their jurisdictions. Users’ due diligence in obtaining prior informed consent and adhering to mutually agreed terms will contribute greatly to promoting the objectives of the Nagoya Protocol and the Convention on Biological Diversity.

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* Mariko Kageyama, University of Washington School of Law, J.D. Class of 2018. Special thanks go to Dr. Todd A. Wildermuth and Professor T. Andrew Culbert at the University of Washington School of Law for their helpful comments.
INTRODUCTION

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization ("Nagoya Protocol" or "Protocol")\(^1\) to the Convention on Biological Diversity ("CBD" or "Convention")\(^2\) presents a relatively new international legal framework with respect to cross-border transactions of biological resources. The Nagoya Protocol most likely affects biotechnological, pharmaceutical, cosmetic, agricultural, food, and other industries that obtain non-human genetic materials from other countries for developing useful...
biological products and processes. Although the United States is currently not a Party to the Convention, the treaty’s impact may be felt broadly in the life sciences innovation sector and beyond.

This emerging global standard, in combination with the domestic law of the member states, creates complexities with regard to what steps a stakeholder must take to be legally compliant and accountable for their conduct when working with genetic resources and knowledge attributable to a particular geographic region or indigenous community. The implementation mechanisms for this international law in each jurisdiction essentially come down to contracts over the exchange of property between providers and users, reflecting individually negotiated and mutually agreed-upon terms (“MAT”). Regardless of the United States’ status as a non-Party to the Nagoya Protocol, contractual obligations may be imposed on whoever wants to use biological resources of foreign origin under the Access and Benefit-Sharing (“ABS”) scheme. Such contractual terms will likely incorporate by reference relevant domestic laws of the resource provider. Users should defer to, rather than resist, the extraterritorial application of the provider country’s rules and policies.

I. NAGOYA PROTOCOL BACKGROUND

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity is an international agreement governing cross-border transactions of genetic resources. This legal instrument has been in effect since October 12, 2014. It is one of the supplementary agreements to the Convention on Biological Diversity, an umbrella treaty that has been universally adopted by almost the entire world except the United States. Largely

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3 As of 2018, the only other jurisdiction in the world that is not a Party to the Convention is Holy See, a church jurisdiction in Rome, Italy. See CBD List of Parties, https://www.cbd.int/information/parties.shtml.


5 The other supplementary agreement to the Convention is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, opened for signature May 15, 2000, 2226 U.N.T.S. 208 (entered into force Sept. 11, 2003), http://bch.cbd.int/protocol/text/.
unbeknownst to Americans, the Nagoya Protocol may have significant positive or negative impact on future global intellectual property strategies, particularly in the life sciences innovation field as discussed below.

A. Nagoya Protocol’s Objectives

The Convention on Biological Diversity (“CBD”) is an international legally binding treaty with three main goals: the (1) conservation of biodiversity, (2) sustainable use of the components of biodiversity, and (3) equitable sharing of the benefits derived from the use of genetic resources.\(^6\) The Nagoya Protocol, a supplementary agreement to the CBD, is the legal instrument developed specifically to implement the last of these three core goals: providing access to and sharing the benefits arising from the utilization of genetic resources in a fair and equitable manner.\(^7\) The Nagoya Protocol is intended to accomplish this objective by facilitating access to genetic resources, transferring relevant technologies and knowledge, and by allocating appropriate funding. By doing so, the Protocol strives to contribute to the other two primary goals of the CBD: conservation of biological diversity and the sustainable use of its components.\(^8\)

B. Treaty Ratification Status

The CBD is one of the multilateral agreements hosted by the United Nations Environment Programme (“UNEP”). The Convention was opened for signature at the United Nations Conference on Environment and Development—known as the Rio Earth Summit—in 1992 and entered into force in December 1993.\(^9\) As of 2018, 196 countries—indeed, almost the entire world—have ratified the CBD.

The Nagoya Protocol was adopted by the Conference of the

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\(^6\) CBD art. 1.

\(^7\) Nagoya Protocol preamble; CBD art. 15.

\(^8\) Nagoya Protocol arts. 1, 9.

Parties of the Convention at its tenth meeting in October 2010 in Nagoya, Japan. It was opened for signature in 2011-2012\(^{10}\) and was entered into force in October 2014 pursuant to Article 33.\(^{11}\) As of April 2018, 105 countries—just over half of the 196 Parties to the CBD—have domesticated the instrument to become Parties to the Nagoya Protocol.\(^{12}\) Once joined, member states may not make reservations; they are fully bound by the provisions of the Nagoya Protocol.\(^{13}\) The Secretariat to both the Convention and the Nagoya Protocol is located in Montreal, Canada,\(^{14}\) although ironically Canada, a Party to the CBD, has yet to sign the Nagoya Protocol as of this writing.

The United States remains a non-Party to both the Convention and the Nagoya Protocol. The CBD is a non-self-executing treaty under the United States’ laws, and thus by itself does not give rise to a domestically enforceable law. Instead, the U.S. government treats the CBD as an Article II treaty, for which the Constitution’s Treaty Clause requires that two-thirds of the Senate give its advice and consent, before the President may ratify the agreement.\(^{15}\) In June 1993, then-President Bill Clinton signed the Convention. However, the treaty has never received an affirmative vote of the Senate, partly due to its low priority status on the Congress’s political agenda.\(^{16}\) Because the United States has yet to become a

\(^{10}\) *Id.* art. 32.

\(^{11}\) *Id.* art. 33 (providing that the protocol would enter into force on the 90th day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession by States . . . that are party to the Convention).


\(^{13}\) Nagoya Protocol art. 34.


\(^{15}\) U.S. CONST. art. II, § 2, cl. 2.

Party to the Convention, it is automatically ineligible to become a Party to the Nagoya Protocol pursuant to the CBD provision.  

C. Nagoya Protocol’s Vocabulary

The Protocol’s use-of-terms and scope provisions are found in Articles 2 and 3, respectively. They incorporate and are consistent with the corresponding provisions of its parent treaty. In addition to genetic resources themselves, the Nagoya Protocol applies to traditional knowledge associated with genetic resources and to the benefits arising from the utilization of such traditional knowledge within the scope of the Convention.

However, neither the scope provision nor the use-of-terms provision is definitive enough to create a consensus among Parties over the meaning of key terms, such as “genetic resources” and “traditional knowledge,” which would facilitate communication about these important concepts with stakeholders. The term “genetic resources” seems intentionally excluded from the list of definitions in the Protocol. This obvious gap is filled by the Convention, which defines “genetic resources” merely as genetic material of actual or potential value; and “genetic material” as any material of plant, animal, microbial, or other origin containing functional units of heredity.

In fact, only five terms are defined under the Protocol Article 2. One such term is “utilization of genetic resources,” which Article 2 defines as the act of conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. “Biotechnology” is defined as any technological application that uses biological systems, living organisms, or derivatives thereof, to response to the Convention).

17 CBD art. 32(1).
18 Nagoya Protocol arts. 2–3; CBD arts. 2, 4.
19 Nagoya Protocol arts. 3, 12.
20 CBD art. 2, para. 11.
21 Id. art. 2, para. 9 (emphasis added).
22 The remaining two terms listed under Article 2 are “Conference of the Parties” and “Convention.” Nagoya Protocol art. 2(a) & 2(b).
23 Id. art. 2(c).
make or modify products or processes for specific use. \textsuperscript{24} “Derivative” is further defined as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."\textsuperscript{25} Accordingly, the subject matter of the Nagoya Protocol should be construed much more broadly than just DNA itself.

The only explicit threshold to the otherwise highly inclusive concept of “genetic resources” is that human genetic resources are excluded from the framework of the Protocol.\textsuperscript{26} Still, traditional knowledge associated with genetic resources of non-human origin is possessed by particular indigenous peoples or individuals, and therefore the Protocol still has legal and ethical implications specifically relating to human subjects research.\textsuperscript{27} In the treaty’s attempt to grasp the constantly evolving nature of life sciences and biotechnology fields, omitting a definition of “genetic resources” likely reflects the drafters’ intention to allow the scope of “genetic resources” to broaden in the future. This would allow the term to cover novel types of materials as they became available with advancements in technology and applications to a wider array of biological resources. For example, over the last several years, the Conferences of the Parties have considered whether to enlarge the scope of the Protocol to encompass such items as digital genetic

\textsuperscript{24} Id. art. 2(d).
\textsuperscript{25} Id. art. 2(e) (emphasis added).
\textsuperscript{26} CBD, Decision Adopted by the Conference of the Parties to the CBD [COP] at its 10th Meeting X/1, Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, at 3, U.N. Doc. UNEP/CBD/COP/DEC/X/1 (Oct. 29, 2010) (reserving the right to place human genetic resources within the scope of the Protocol by stating “without prejudice to the further consideration of this issue by the [COP]”).
sequence information or microorganisms manipulated by synthetic biological techniques. Although the underlying context is different, difficulty in delineating the scope and range of biotechnology subject matter is somewhat analogous to patent subject matter eligibility jurisprudence surrounding nucleic acids, proteins, and other biochemical compounds, which has independently developed under the patent laws of the U.S., European Union, and other jurisdictions.

Other legal terms of art that are not separately defined in the treaty provisions but are frequently used throughout the text of the Protocol include prior informed consent ("PIC") and mutually agreed terms ("MAT"), in addition to Access and Benefit-Sharing ("ABS") and its equivalent phrases. The following sections provide more context to these key terms as they are normally understood in the Nagoya Protocol’s ABS framework.

D. Nagoya Protocol’s Conceptual Framework

The Nagoya Protocol asserts that the first two of the three pillars of the CBD are promoted through fulfilling its third and final goal—fair and equitable sharing of the economic value of ecosystems and biodiversity, which encompasses benefits derived from the use of

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29 See, e.g., Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (ruling that isolated DNA is not within the scope of patent eligible subject matter under the U.S. Patent Act, 35 U.S.C. § 101); see also Convention on the Grant of European Patents [European Patent Convention (EPC)] art. 52 & EPC Implementing Regulations r. 27(a) (allowing biological material isolated from its natural environment or produced by means of a technical process as a patentable biotechnological invention).
genetic resources.  

Economics play a role here in understanding the Nagoya Protocol’s underlying principle. The Protocol introduces an economic perspective to transnational genetic resources management by first recognizing public awareness of the economic value of ecosystems and biodiversity. It further recognizes that the fair and equitable sharing of this economic value with the custodians of biodiversity is a key incentive for the conservation of biological diversity and the sustainable use of its components. Under the CBD, custodians of biodiversity include sovereign states as well as indigenous and local communities.

As far as the semantic relationship between the “ecosystem and biodiversity” and “genetic resources” is concerned, the former describes certain variable modes of the natural environment and its elements, while the latter—despite the term not having been explicitly defined in the Protocol itself—ordinarily refers to tangible materials existing as integral components of a certain biological system with intrinsic value recognized at the molecular level. Of course, if digital DNA sequence data falls within the scope of “genetic resources,” then the term would cover not only tangible property, but also intangible information.

On one hand, an ecosystem may exhibit inherent economic value

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30 CBD art. 1; Nagoya Protocol preamble (emphasis added).
31 Nagoya Protocol preamble.
32 Id. (emphasis added).
33 CBD art. 2, paras. 1 & 8 (defining ecosystem as “a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit,” whereas defining biological diversity as “the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems”).
34 See supra text accompanying notes 20–21; see also, e.g., Morten Walløe Tvedt & Peter Johan Schei, The Term ‘Genetic Resources’: Flexible and Dynamic While Providing Legal Certainty?, GLOBAL GOVERNANCE OF GENETIC RESOURCES: ACCESS AND BENEFIT SHARING AFTER THE NAGOYA PROTOCOL 18 (Sebastian Oberthür & G. Kristin Rosendal eds., 2014) (illustrating rather inconsistent meanings of the term “genetic resources” as adopted by international organizations).
35 See Bagley, supra note 28.
in the biosphere and provide measurable benefits to human beings. This concept is recognized today in the ecosystem services and natural capital contexts. On the other hand, scientific inquiries and sophisticated technology can enhance the economic value of genetic resources as property by deciphering genetic codes and their functions in the living system. It is unlikely that genetic resources as they exist in nature become automatically more valuable in economic terms by virtue of being harvested. In this regard, genetic resources are different from other kinds of natural resources, such as oil and gas. But there are similarities, too. For example, both are commonly viewed as non-ubiquitous, finite resources that should not be overexploited. Indeed, one could even argue that the traditional rule of capture or the labor theory of property would apply to genetic resources in determining property ownership, since those concepts apply to other migratory resources like oil and gas.

To attain the primary objective of the Nagoya Protocol and ultimately reach the overarching goals of the umbrella biodiversity treaty, baseline research and development activities utilizing genetic resources must increase. An increase would provide for the creation of new intellectual property and commodities, promote technology transfer and commercialization in industries, and establish cross-border revenue streams in a fair and equitable manner under the Protocol’s grand scheme.

But an increase would come with costs, as it requires both money and manpower to actively protect and conserve biodiversity in balance with other competing economic interests. Further, it is prohibitively more expensive to try to restore habitats once destroyed or lost. Therefore, to promote a sound and balanced economy, the Protocol urges prospectors of genetic resources to either pay the cost up front or to return a part of the profits, assets, and knowledge generated to source countries or communities in exchange for benefits arising from such genetic resources. The term Access and Benefit-Sharing (“ABS”) captures this concept.

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However, uncertainty remains as to whether new international rules governing the use of natural resources have sufficient legal force to mandate resource providers—who are mostly developing countries and indigenous communities—to return benefits to society by fully committing to sustainable development and local capacity building. For example, it is unclear whether resource providers are required to allocate a set amount of funding for regional habitat restoration efforts or for biotechnology specialists training.38

E. Challenges Posed by the Protocol

As reaffirmed in its preamble, the Nagoya Protocol is grounded in the fundamental idea that each country should exercise its sovereign rights over its natural resources.39 This is a fundamental departure from the traditional view that biological resources on Earth are in the public domain and in should be freely available as global common goods. Yet in the property paradigm, countries enforcing their sovereign rights too strictly over biotic resources—including forms of living organisms such as human pathogens and microorganisms found within its national territory—generate concerns that the Protocol’s scheme will eventually languish under the tragedy of the anticommons. The tragedy of the anticommons describes a legal environment where multiple owners are each endowed with the right to exclude others from a scarce resource, with no one person possessing an effective privilege of use.40 When there are too many owners holding rights of exclusion, the resource is prone to underuse.41 On the contrary, lack of international coordination on the use of finite natural resources on the planet may

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38 Nagoya Protocol art. 22 (focusing capacity-building efforts on the least developed countries, small island developing states, and indigenous and local communities); id. art. 22, para. 5(h) (listing enhanced contribution of ABS activities to the conservation and sustainable use of biodiversity as a capacity development measure); see also infra note 53. But see id. art. 9 (merely encouraging, but not requiring, directing benefits towards the biodiversity conservation).

39 Nagoya Protocol preamble.


41 Id. at 624.
lead to the tragedy of the commons, where the resources are prone to overuse.\textsuperscript{42} An example of this is found in marine biodiversity beyond national jurisdictions, where each country attempts to claim rights over resources on the high seas beyond any country’s exclusive economic zone.\textsuperscript{43}

In addition to concerns over resource underutilization, apparent regulatory complexities set by the Protocol can stifle innovations and sound competition in a manner contrary to the Protocol’s purposes of encouraging active use of genetic resources in the global bioeconomy. This means that unless it is properly administered, the treaty may have a chilling effect on bona fide international bioprospecting activities, and may even create a hostile environment for noncommercial biodiversity researchers.\textsuperscript{44}

Furthermore, depending on the degree of flexibility in enforcing the treaty provisions to realize fair and equitable transactions of genetic resources, the Protocol may have substantial implications on global health agenda, such as distribution of drugs, vaccines and antibiotics to developing countries. For example, in pre-Nagoya 2007, Indonesia refused to share its clinical specimens of H5N1 avian flu virus to the World Health Organization (“WHO”) in retaliation for the inequitable virus sharing practice in the global health sector that existed at the time.\textsuperscript{45} The Indonesian avian flu strain was supposed to be used for vaccine production by a private entity in Australia that planned to use this free virus sample to patent

\textsuperscript{42} Id.
\textsuperscript{44} See, e.g., Jörg Overmann & Amber Hartman Scholz, Microbiological Research Under the Nagoya Protocol: Facts and Fiction, 25 TRENDS IN MICROBIOLOGY 85 (2017) (arguing that non-commercial basic research will be negatively affected by restrictive policies under the Protocol).
a vaccine, and sell the product back to Indonesia at an unaffordable price. This illustrates the frequent tension between stakeholders with competing interests over valuable biological property. As here, these are interests in securing access to human pathogens for public health purposes, protecting intellectual property for profits, and preventing valuable resources from being exploited by foreigners. The avian flu vaccine served as a great lesson for WHO, as WHO and CBD now work together closely to strengthen linkages between biodiversity and human health—particularly in the context of sharing pathogens and relevant clinical information during public health emergencies.

A pragmatic solution to overcome these various challenges would be to keep implementation mechanisms for the Nagoya Protocol simple, transparent, and flexible. A balance must be struck under this paradigm so that legitimate rights holders are adequately protected from unfair dealings, while for-profit bio-prospectors are still deterred from unjust enrichment. As analyzed in the later section on the Access and Benefit-Sharing Clearing-House, the high-level monitoring of ABS activities would probably be the best way for the Protocol to strike this balance. At the same time, the Protocol should allow provider-user negotiation at the ground level to maximize the Parties’ freedom of contract. Using the instrument’s terminology, as long as prior informed consent (“PIC”) can be secured, mutually agreed terms (“MAT”) between parties in private contracts are best left to negotiation to the extent permitted by the provider’s domestic laws. This approach will maximize the

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46 Sedyaningsih et al., supra note 45, at 486.
47 World Health Organization [WHO], Review of the Pandemic Influenza Preparedness Framework: Collaboration with the Secretariat of the CBD and Other Relevant International Organizations, at 2, WHO Doc. A70/57 (May 4, 2017) (recommending that the WHO flu preparedness framework be recognized as a specialized international ABS instrument under the Protocol and that CBD share with WHO information regarding the ABS implementation on health emergency cases through a national reporting system under Nagoya Protocol arts. 4(4) & 8(b) & 29); see also Daniel Cressey, Treaty to Stop Biopiracy Threatens to Delay Flu Vaccines, 542 NATURE 148 (2017) (highlighting WHO’s direction to integrate a benefit-sharing mechanism into the global vaccine supply system to expedite seasonal flu vaccine production).
48 Nagoya Protocol art. 6.
49 Id. art. 5.
positive effects of freedom of contract while promoting access to untapped genetic resources found within the territory of each provider country.

F. Nagoya Protocol and Intellectual Property

Although the subject matter of the Nagoya Protocol is primarily biological, its reach is not limited to environmental and natural resources laws as implied by the parent treaty’s title, Convention on Biological Diversity, implies. As demonstrated by the example of the Indonesian avian flu virus, the Protocol frequently implicates law regarding technology and intellectual property. Technology transfer is an important part of the Protocol’s objective, as the Protocol purports to contribute to sustainable development by building research and innovation capacities in developing economies, and adding value to genetic resources. Each Party to the Protocol is required to take necessary legislative, administrative or policy measures as appropriate to establish clear rules and procedures for mandating and establishing MAT, including benefit-sharing clauses that address relevant intellectual property rights. This means that under the Nagoya framework, intellectual property rights are presumed to be among a “bundle of rights” to be considered up front in bilateral negotiations between providers and users of genetic resources, and memorialized in a written contract called a material transfer agreement.

Developing MAT over intellectual property rights, or other forms of benefits expected from the use of genetic resources, is similar to drafting a standard technology licensing agreement. This is especially true if benefit-sharing can be unambiguously written in financial terms, such as royalties. However, MAT established under Nagoya are still distinguishable from terms of a technology license in some critical respects. First, although individually negotiated and agreed-upon terms are flexible to a certain extent, they must conform with the domestic laws of the provider country implementing the treaty. The Protocol is designed so that specific measures to implement its ABS scheme are largely left to the

50 Id. preamble.
51 Id. art. 6.3(g)(ii).
52 Id. annex 1(d).
prerogative of each Party. Unless the provider country explicitly disclaims its rights to genetic resources leaving its jurisdiction as a matter of public policy, the provider country’s laws may have an extraterritorial reach over all contracting parties, and may even override a contradictory MAT. This could interfere severely with the Parties’ freedom of contract.

Another idiosyncratic aspect of an ABS material transfer agreement is that intellectual property may not have been fully developed, or vested, at the time the Parties entered into an executory agreement. Original source organisms or isolated biochemical compounds themselves are merely raw materials of limited commercial value. They are tangible and exhaustible personal property. But intellectual property assets, once successfully developed out of such exhaustible resources of intrinsic value, become significantly more economically valuable. Moreover, intellectual property is inexhaustible and can be shared with others without diminishing its value. Quid pro quo in this context dictates granting relevant intellectual property rights or other forms of economic benefits to the source country in return for gaining access to its original raw ingredients. Regarding benefits, the Protocol assumes a broad range of beneficial arrangements as acceptable forms of benefits that can be exchanged under the ABS scheme. For reference, a non-exhaustive list of different types of benefits, both monetary and non-monetary, is found in the Annex to the Protocol.53

Compared to standard technology licensing, parties may have to allow material transfer agreements to contain indefinite language where intellectual property has yet to be developed. This requires parties to initially assume higher risk under the ABS framework, even though they may be able to reassess, and modify original terms after they execute an original agreement. From the industries’ perspectives, it may take years for companies to develop patentable products such as pharmaceuticals. In such circumstances, the party requesting access would likely favor a risk-averse approach, such as

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53 Id. annex (listing plausible types of non-monetary benefits, inter alia, sharing of results and collaboration in research programs; participation in product development; admittance to ex situ facilities and databases; education and training; transfer of knowledge and technology; capacity-building; food and livelihood security benefits; social recognition; and joint ownership of intellectual property rights).
first conducting preliminary testing, and evaluating target materials before expanding the project to a full industrial scale to lower the risk of breaching any MATs.

In recent decades, traditional knowledge is a type of community-owned intellectual property right recognized not only by the CBD and Nagoya Protocol, but also by the international intellectual property sector. As discussed earlier, the term “traditional knowledge” is not defined within the Protocol or the Convention. However, the World Intellectual Property Organization (“WIPO”) defines traditional knowledge as a living body of knowledge passed on from generation to generation within a community that often forms part of a people’s cultural and spiritual identity. The CBD Working Group has intensively reviewed the term and concept of traditional knowledge since the 2000s. Referred to as Article 8(j), the current proposed definition of traditional knowledge is:

"the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."

It is generally understood that traditional knowledge has greatly contributed to the discovery, creation, and preservation of valuable community knowledge related to medicinal, therapeutic, and other beneficial use of certain biological resources. However, dealing with traditional knowledge in the context of a material transfer and technology licensing agreement poses novel challenges for most stakeholders.

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56 CBD Executive Secretary, Glossary of Relevant Key Terms and Concepts Within the Context of Article 8(j) and Related Provisions, U.N. Doc. CBD/WG8J/10/3 (Sept. 10, 2017).

57 CBD art. 8(j) (“[P]romote . . . wider application of traditional knowledge . . . with the approval and involvement of the holders of such knowledge . . . and encourage the equitable sharing of the benefits arising from the utilization of such knowledge.”).

58 CBD Executive Secretary, supra note 56, annex.
Because added value of genetic resources partly comes from its essential attribution to a particular species or variety that originated in a specific locality, geographical indication is presumed to be another type of an intellectual property right to be accounted for in benefit-sharing negotiation, despite absence of the term in the Protocol text. Basically, provider countries would like to protect and control geographical indications over new innovative products that are developed in exchange for genetic resources uniquely sourced from their respective territories. The geographical origin of products has likewise been contemplated in the international trade context. In particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”) has a whole section dedicated to geographical indications, with special reference to wines and spirits.\(^{59}\) “Geographical indications” are defined as indications that identify a good as originating in the territory of a member state, or a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin.\(^{60}\)

Finally, as far as patent law is concerned, a great deal of unknowns exist in current national policies among the member states as to whether, when a claimed invention is based upon genetic materials sourced from another jurisdiction bound by the Protocol, domestic patent law requires applicants to comply with the Nagoya Protocol as a prerequisite for granting a biotechnology patent. For instance, domestic legislation could create new obligations for a patent applicant to submit an official permit or certificate of compliance to the national patent office.\(^{61}\) Or the national patent

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\(^{60}\) TRIPS Agreement, supra, art. 22, ¶ 1.

\(^{61}\) See Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement and the Convention on Biological Diversity, Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group, at 2, WTO Doc. TN/C/W/59 (Apr. 19, 2011) (proposing an amendment to the TRIPS Agreement by inserting Article 29bis, which requires that patent applicants provide a copy of an Internationally Recognized Certificate of Compliance with the Nagoya Protocol, infra text
office could require applicants to disclose the country of origin of foreign genetic materials that led to a claimed invention in a patent publication. Such mandatory disclosure in published patent applications would put countries and communities on notice, and may allow them to challenge patentability in a timely manner. Of course, these public parties must show standing as holders of property rights or traditional knowledge in interest, as well as a valid claim under the applicable law of any given jurisdiction. Relatedly, a domestic law, either by statute or case law, may enable the court to invalidate a patent or render it unenforceable if the alleged infringer can show that the patent-in-suit was derived from genetic resources that were unlawfully acquired in noncompliance with a provider country’s laws implementing the Protocol.

accompanying notes 87–90 [hereinafter TRIPS Agreement Article 29bis].

62 See, e.g., Zhonghua Renmin Gongheguo Zhuan Li Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, last rev'd Dec. 27, 2008, effective Oct. 1, 2009), art. 5, para. 2 (“Patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations.”); id. art. 26, para. 5 (“With regard to an invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources. If the applicant cannot indicate the original source, he shall state the reasons.”), http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html; but see, e.g., Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, recital 27, 1998 O.J. (L 213) 13, 15 (EC) (“[I]f an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents”); see generally WIPO, DISCLOSURE REQUIREMENTS TABLE (Oct. 2017), http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_dislosure.pdf (providing a non-exhaustive list of disclosure requirements related to genetic resources or traditional knowledge in thirty-three jurisdictions).


64 See TRIPS Agreement Article 29bis, supra note 61, at 3 (providing under Article 29bis, paragraph 5, that if relevant national legislation of a provider
II. Access and Benefit-Sharing Clearing-House

The Access and Benefit-Sharing Clearing-House is a public website administered by the CBD Secretariat.\(^6^5\) It is designed to serve as a one-stop shop for obtaining comprehensive information about the ABS-related activities, such as a list of countries bound by the Nagoya Protocol, each country’s point of contact, the status of national legislation, and policy documents.\(^6^6\) It also provides web links to general administrative information released by the Secretariat, such as minutes and decisions of Conferences of the Parties.\(^6^7\) Not only government officials, but also innovation business owners, corporate counsel, scientists, technology transfer practitioners at universities, and non-governmental organizations, should be cognizant of what is available on the ABS Clearing-House by visiting the site as often as necessary to obtain the latest information. The site should be particularly useful for keeping those working on projects involving bioscience or biotechnology informed about how this evolving regime may directly affect their activities. The following sections provide important points for these individuals to contemplate before further exploring ABS opportunities, as well as general guidance on where to locate relevant information within the ABS Clearing-House.

A. Two Perspectives of a Party

When reviewing the Nagoya Protocol’s Access and Benefit-Sharing framework through the ABS Clearing-House, it is important to consider that being a Party to the Protocol as a sovereign state

country is violated, the country may impose sanctions, including revocation of the patent). In the United States, even if misappropriation of genetic resources constitutes a violation of a foreign national law, it is unlikely to give rise to unenforceability of a U.S. patent for inequitable conduct without a finding of but-for materiality of withheld information to patentability; see Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed. Cir. 2011) (en banc).

\(^6^5\) Nagoya Protocol art. 14.


means being bound by two sets of reciprocal rules in multilateral transactions of genetic resources: rights and obligations of a provider, and rights and obligations of a user. To illustrate this, Figure 1 exhibits a simplified interrelationship between Parties under the Nagoya Protocol framework. This article discusses the Access and Benefit-Sharing principle primarily with United States users in mind. However, it is important to keep providers’ interests in mind to achieve one’s intended business objectives without risking encroaching on others’ interests.

At the national level, each Party is responsible for implementing its commitment to the treaty through domestic legislation, regulations, and administrative and policy measures. Subject to these domestic laws, a Party exercises state sovereignty over genetic resources as both a provider country and user country with associated rights and obligations. The Party’s designated authority, called Competent National Authority, reviews individual access requests containing provisions in the MAT. The authority may encourage benefit-sharing terms so that upon alienation of genetic resources, the Party may retain a right to claim a share in benefits from foreign users. Within the exercise of sovereign rights, the Competent National Authority makes a final determination whether to deny or approve such an access request, and issues a permit or equivalent written evidence certifying that the access requirements have been met.

On the receiving end, as soon as genetic materials of foreign origin are brought into its jurisdiction by users’ request, the Party is obligated to coordinate with the Secretariat to monitor the domestic

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68 Nagoya Protocol art. 5 (benefit sharing); art. 6, para. 3 (access); arts. 15–16 (compliance).
69 Id. art. 13.
70 See id. art. 13, para. 2 (“Competent national authorities shall . . . be responsible for advising on applicable . . . requirements for obtaining [PIC] and entering into [MAT].”).
71 Id. (“Competent national authorities shall . . . be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met”).
activities of the people and entities participating in the system as individual resource users.\textsuperscript{72} The monitoring is done by designated in-country Checkpoints to enhance transparency regarding the use of genetic resources after permits are granted.\textsuperscript{73} The Party also has a duty to report these ABS-related events through the Clearing-House.\textsuperscript{74} Unsurprisingly, any given Party may be involved in the treaty predominantly as a resource user, a resource provider, or both. Presumably, countries and indigenous communities embracing biodiversity hotspots,\textsuperscript{75} areas particularly rich in endemic plant and animal species, tend to have greater economic interests at stake as a provider than a user.

In accordance with domestic legislation, negotiation over MAT may happen directly between the individual user, and the provider country represented by the Competent National Authority or National Focal Points in some cases.\textsuperscript{76} However, depending on the individual circumstances, the MAT and PIC negotiation process may also involve private rights owners. Rights owners in this context include private property owners that grant direct access to genetic resources as they are requested. In addition, indigenous or local community representatives holding traditional knowledge associated with genetic resources may also be involved. To complicate the whole picture further, another category of parties in interest may be actively involved in this legal ecosystem as well. Examples are \textit{ex situ} biorepositories, such as non-human gene banks and culture collections, where organisms of different geographic origins are stored in centralized facilities abroad. Stockpiled genetic resources like these are generally publicly available to legitimate

\textsuperscript{72} Nagoya Protocol arts. 17, 29; \textit{see also} id. art. 15, para. 2 \& art. 16, para. 2 (requiring that each user country take appropriate, effective, and proportionate measures to address situations of non-compliance with adopted measures).

\textsuperscript{73} \textit{Id.} art. 17, para. 1.

\textsuperscript{74} \textit{See id.} art. 14, para. 2 \& art. 17, para. 1(a)(iii) (providing that sharing information on ABSCH is without prejudice to the protection of confidential information).


\textsuperscript{76} \textit{Id.} art. 13; \textit{id.} preamble (“/[R]ecognizing the importance of promoting equity and fairness in negotiation of [MAT] between providers and users of genetic resources.”).
researchers upon access request, such as the National Museum of Natural History in the Smithsonian Institution.\textsuperscript{77} Indeed, noncommercial researchers worldwide have heavily relied on these authentic third-party biological collections, even though existing biorepositories would not completely substitute scientists’ need for acquiring specimens of particular groups of organisms from \textit{in situ} sources, such as their native habitats.\textsuperscript{78} These additional players are not represented in Figure 1, but the situation would likely create a legal relationship similar to a trusteeship, guardianship, custodianship, or stewardship.\textsuperscript{79}

\textbf{B. Information Available at the Clearing-House}

The Access and Benefit-Sharing Clearing-House’s web interface has gone through extensive overhaul and redesigning to improve user-friendliness.\textsuperscript{80} Publicly available data stored in the database has grown rapidly in recent years.\textsuperscript{81} Most of the records

\textsuperscript{77} See OFF. OF DIR., NAT’L MUSEUM OF NAT. HISTORY, SMITHSONIAN INST., ACCESS AND BENEFIT SHARING POLICY ON GENETIC RESOURCES (effective June 23, 2012) (expressing the full institutional commitment to the CBD and related international instruments, including requesting PIC and MAT before the collection or transport of genetic resources.).

\textsuperscript{78} See Myrna E. Watanabe, \textit{The Nagoya Protocol on Access and Benefit Sharing: International Treaty Poses Challenges for Biological Collections}, 65 BIOSCIENCE 543 (2015) (highlighting perspectives of noncommercial researchers concerning how the Nagoya Protocol may affect their collection-based work.); see also D. Neumann et al., \textit{Global Biodiversity Research Tied Up by Juridical Interpretations of Access and Benefit Sharing}, ORGANISMS DIVERSITY & EVOLUTION 1, 4 (Nov. 27, 2017), https://doi.org/10.1007/s13127-017-0347-1 (asserting that simplified measures should be created specifically for noncommercial research as provided under the Protocol’s article 8(a)).

\textsuperscript{79} Peter H. Sand, \textit{Sovereignty Bounded: Public Trusteeship for Common Pool Resources?}, 4 GLOBAL ENVT'L. POL’YS 47, 52 (2004). An alternative interpretation applicable to new acquisitions of genetic resources is that a jurisdiction in which a public biorepository resides becomes a provider country on a parity with the country of origin of such resources, as long as that repositary country has acquired the genetic resources in accordance with the Protocol and the CBD. See Nagoya Protocol art. 5, para. 1; art. 6, para 1.

\textsuperscript{80} ABSCH, supra note 12.

\textsuperscript{81} As of the ABSCH’s official launch date Oct. 12, 2014, the database under ABS Measures was populated with 26 national records from three jurisdictions;
posted are available with direct web links or for free download in .pdf format. The search engine allows site users to run a query based on specific key words, or to narrow data to a specific country. However, navigating through the Clearing-House is still far from intuitive for first-time users, and takes practice to efficiently locate and retrieve required information. Information at the ABS Clearing-House is organized into three main categories: (1) national records, (2) reference records, and (3) records managed by the Secretariat.\(^8^2\)

1. National Records

National records are published by participating governments and include national information relevant to the implementation of the Nagoya Protocol, as well as information Parties are obliged to provide in accordance with the Protocol. Types of records indexed under this section include: ABS National Focal Points; Competent National Authorities; ABS Measures; National Websites and Databases; Internationally Recognized Certificates of Compliance; Checkpoints; Checkpoint Communiqués; and Interim National Reports.\(^8^3\)

Because non-Parties are encouraged to contribute appropriate information to the ABS Clearing-House, even the United States has an entry in the database with its minimum country profile.\(^8^4\) Furthermore, though as many as ninety-four countries are currently listed as non-Parties to the Protocol, that does not necessarily mean that those countries lack relevant domestic legislation. For instance, Brazil is not yet a Party, but it has recently enacted a federal law providing for its own ABS framework that has a similar effect when combined with a user registration system.\(^8^5\) By filtering and sorting

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\(^8^2\) ABSCH, supra note 12.


\(^8^4\) Nagoya Protocol art. 24.

\(^8^5\) Lei No. 13.123, de 20 de Maio de 2015, Diário Oficial da União...
the database, the ABS Clearing-House provides an entry point for obscure information pertaining to Brazil and other non-Parties.\footnote{86} It is noteworthy that the Secretariat is the only authority to issue an Internationally Recognized Certificate of Compliance based on a national permit granted and other related information submitted by the Competent National Authority of a provider country concerning an individual access request.\footnote{87} Certificates of Compliance serve as evidence of the authority’s decision to grant PIC and of the establishment of MAT.\footnote{88} Certificates of Compliance are published on the ABS Clearing-House under the National Records section.\footnote{89} These Certificates may disclose additional detail about PIC and MAT as well as specific subject matter covered, whether commercial use is allowed by the permit, and conditions for third-party transfer of genetic resources and associated intellectual property rights.\footnote{90} Although analysis of individual ABS projects is beyond the scope of this article, information disclosed in Certificates of Compliance should be highly relevant to other stakeholders as existing model cases.

2. Reference Records

Reference records include resources and information

\footnote{86} See, \textit{e.g.}, ABSCH, Brazil– Country Profile, https://absch.cbd.int/countries/BR (last visited Mar. 1, 2018).
\footnote{87} \textit{Id.} art. 6, para. 3(e).
\footnote{88} \textit{Id.} art. 17, para. 3.
\footnote{89} \textit{Id.} art. 17, para 2; ABSCH, Internationally Recognized Certificates of Compliance, https://absch.cbd.int/search/nationalRecords?schema=absPermit (listing over 140 Certificates of Compliance that have been issued based on twelve provider countries so far, including Belarus, Bulgaria, Dominican Republic, Guatemala, India, Kenya, Malta, Mexico, Panama, Peru, South Africa, and Spain, among which India has processed the largest number of requests that have led to eighty-six Certificates) (last visited Mar. 1, 2018).
\footnote{90} Nagoya Protocol art. 17, para. 4.
immediately relevant to Access and Benefit-Sharing stakeholders. They can be submitted by any registered user of the ABS Clearing-House, including Parties, non-Parties, governments, international organizations, indigenous and local communities, and other key stakeholders. Types of records found under this section are: Virtual Library Records; Capacity-building Initiatives; Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards; and Community protocols and procedures and customary laws. Among these, model clauses, guidelines, best practices and standards seem immediately helpful.

3. Secretariat Managed Records

The CBD Secretariat (“SCBD”) regularly publishes official information under this section, including meetings, news stories, notifications, and formal statements. These are classified into: What’s New; Notifications; Meetings; and News within this section.

III. ACCESS AND BENEFIT-SHARING IN ACTION

A. Implementation and Enforcement

The new multilateral legal landscape that has loomed for the last several years under the ABS framework is still in flux. As of 2018, a majority of Parties have been actively working on establishing national programs and building domestic capacity to become fully compliant with the treaty provisions, but there is still considerable

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work to be done. For example, as of April 2018, Competent National Authorities have been designated and reported to the ABS Clearing-House from fewer than half of the 105 Parties. Likewise, legislative, administrative, and policy measures have been published by only about half of the Parties. Moreover, these country-level implementing measures have not been cross-checked, let alone harmonized.

Legal unpredictability also remains high with respect to the Protocol’s cross-jurisdictional enforcement mechanisms. As the Protocol’s Article 18 stipulates, each Party is deemed to make efforts to promote mutual recognition and enforcement of foreign judgments and arbitral awards through international dispute resolution mechanisms, which is in line with the comity of nations doctrine. The Protocol at least provides for access to justice by means of an opportunity to seek recourse in cases of disputes arising from MAT. The treaty encourages MAT to include a dispute

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95 ABSCH, https://absch.cbd.int/countries/status/party (displaying 45 out of 105 Parties in total as those having at least one Competent National Authority designated, among which Mexico designates as many as six Competent National Authorities) (last visited Mar. 1, 2018).

96 Id. (displaying 45 out of 105 Parties as those having at least one legislative, administrative, or policy measure published, among which India has as many as thirty implementing measures published) (last visited Mar. 1, 2018).

97 Nagoya Protocol art. 18, para. 3(b). See also id. art. 15, para. 3 & art. 16, para. 3 (requiring that parties cooperate in cases of alleged violation of domestic ABS legislation or regulatory requirements as far as possible and as appropriate).


99 Nagoya Protocol art. 18, para. 2.
settlement clause that prescribes the jurisdiction to which providers and users will subject any matters of dispute, the applicable law, and options for alternative dispute resolution. On top of that, the dispute settlement provision under the Convention also applies to the Protocol, which provides that if negotiation or third-party mediation does not resolve a dispute, parties must bring a case before an international arbitral tribunal or the International Court of Justice (“ICJ”) as a means of dispute settlement. However, an individual or a private entity cannot be a party to ICJ proceedings, nor are ICJ judgments automatically enforceable as domestic law in national courts.

Pursuant to Article 31 of the Protocol, the Conference of the Parties is going to undertake an evaluation of the effectiveness of the Protocol including both its implementation and enforcement mechanisms for the first time on October 12, 2018, four years after entering into force. This assessment must be a critical checkpoint for assuring continued development of the Protocol as an effective legal instrument to further its goal of equitable benefit sharing between users and providers of genetic resources.

Moreover, for a number of years international organizations such as WHO and WIPO, as well as the World Trade Organization (“WTO”) and other intergovernmental bodies with overlapping global agendas, have recognized some gaps or incongruence in the CBD and Nagoya Protocol with other legal instruments in several key aspects. Nevertheless, the process of reconciliation has thus far been slow.

\[100\quad \text{Id. arts. 6, para. 3(g)(i) & art. 18, para 1; see also WIPO, WIPO Alternative Dispute Resolution (ADR) for Biodiversity, http://www.wipo.int/amc/en/center/specific-sectors/biodiversity/ (last visited Mar. 1, 2018) (“Biodiversity disputes can concern a wide range of highly specific subject matters relating... to patents, genetic resources, traditional knowledge, plant varieties, environment, and food. They... can also involve sensitive non-legal components of a commercial, cultural, ethical, or moral nature.”).}\\]

\[101\quad \text{CBD art. 27, para. 3(b) & 5.}\\]

\[102\quad \text{Statute of the International Court of Justice [ICJ] art. 34, ¶ 1, June 26, 1945, 59 Stat. 1055, T.S. No. 993 (“Only states may be parties in cases before the [ICJ]”); Medellin v. Texas, 552 U.S. 491, 511 (2008).}\\]

\[103\quad \text{Nagoya Protocol arts. 18, para. 4 & 31.}\\]

\[104\quad \text{See supra notes 47, 55, 59, 61. See also, e.g., Matrix on Trade-Related}\\]
Aside from large-scale initiatives leveraged at the governmental and intergovernmental levels supporting this dynamic legal ecosystem, the question of whether the Nagoya Protocol can continue to operate effectively and sustainably in the future comes down to individual users’ due diligence as primary contracting parties of ABS agreements. In other words, the whole legal ecosystem would hardly function without positive participation and cooperation of individual users complying with established procedures and MAT under the rule of law. Contract disputes will inevitably arise from MAT. Because of the significantly contractual basis of how the treaty is going to be implemented, as explained above, appropriate conflict resolution rules must be established to govern conflict of laws in cross-border contract disputes involving genetic resources. International rules for construing bio-property contracts under the Nagoya Protocol are urgently needed to improve predictability of this instrument’s enforceability.

B. Implications for United States Stakeholders

The United States’ status as a non-Party to the Nagoya Protocol notwithstanding, it is in the best interest of Americans to keep the door open to opportunities for exploring untapped genetic resources located outside the U.S. boundaries, as firms and institutions benefit from continued engagement in joint enterprises with global partners from member states. These countries include economically important jurisdictions like the European Union, Mexico, China, India, and South Africa.\(^\text{105}\) In these scenarios, it would be unwise to steer clear of international research and development opportunities in fear of stepping into the unknown realm of the Nagoya Protocol. However, once bound by the ABS scheme, it is difficult to imagine that any government authority would grant special exceptions or privileges to American users merely on the ground that the U.S. is a

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\(^{105}\) See ABSCH, supra note 12.
non-Party to the Protocol. As the Protocol Article 24 sets forth, Parties must encourage non-Parties to adhere to the Protocol.\textsuperscript{106}

More broadly, any attempt to import biological materials into the United States without proper documentation, including a formal permit issued by a provider country’s government, might invoke U.S. domestic laws like the Lacey Act.\textsuperscript{107} The Lacey Act can hold a party liable for transporting species taken illegally in violation of a foreign law, although its enforceability in the ABS context is unknown.\textsuperscript{108} Therefore, even on a voluntary basis, one should defer to the international regulatory framework and abide by MAT as the best course of action. This recommendation is valid even with the U.S. government’s current status as a non-Party to the Convention—an outlier in the United Nations community for unrelated political or diplomatic reasons.

From a more practical standpoint, it would be prudent for U.S. stakeholders, or potential users in any other jurisdictions that are non-Parties, for that matter, to first identify and collaborate with their foreign counterparts and legal counsel licensed in their respective jurisdictions. Realistically, this would be the only way American stakeholders can make an informed decision beyond just obtaining baseline knowledge through the ABS Clearing-House, because unlike the treaty member states, the U.S. federal government currently lacks an office, website, and budget formally dedicated to providing services on ABS-related matters for American general public.\textsuperscript{109} In contrast, stakeholders in member states should have more direct access to relevant information resources as well as the country’s administrative departments that serve as National Focal Points or Checkpoints for their citizens.

\textsuperscript{106} Nagoya Protocol art. 24.
\textsuperscript{108} Id. § 3372 (making it unlawful for any person to import in foreign commerce any fish, wildlife, or plant, whether live or dead, including parts taken, possessed, transported, or sold in violation of foreign laws.).
\textsuperscript{109} But see CBD, United States of America – Country Profile, https://www.cbd.int/countries/nfp/default.shtml?country=us (listing U.S. Department of State and other federal government agencies’ representatives as National Focal Points) (last visited Mar. 1, 2018); see also Digital Sequence Information on Genetic Resources Public Meeting, 82 Fed. Reg. 28927 (June 26, 2017) (indicating the U.S. Department of State as the agency point of contact for a CBD-related public hearing in the U.S.).
They should be able to tell the current status of domestic implementing measures and guide you through necessary application procedures. Until the international standard and best practices are sufficiently established, each provider country will continue to be responsible for educating potential users of legal procedures and paperwork required to meet specific ABS requirements. The need for such foresight is obvious, given that provider countries are the ones in the best position to expound their own domestic statutes, rules, court decisions, and policies. Meanwhile, relevant industries that are likely subject to the Nagoya Protocol regulations in their primary activities should seriously address the compliance issue in their risk assessment in relation to international project management, technology transfer, and global intellectual property rights management.

CONCLUSION

Once the Nagoya Protocol becomes fully operational as a globally recognized system in the next few years, there should be increased transparency, consistency, and accountability for transactions of genetic resources among all players. Although the United States is neither a signatory to the Convention on Biological Diversity nor the Nagoya Protocol, American stakeholders are not free to disregard these international rules. Because the principal mechanism of implementing the Nagoya Protocol has a contractual basis characterized by the Prior Informed Consent and Mutually Agreed Terms, U.S. stakeholders who are going to enter into an agreement under the Access and Benefit-Sharing scheme should defer to this new international regulatory framework. Participants should acknowledge the Mutually Agreed Terms incorporating foreign domestic laws of a Party laid down to effectuate fair dealing in biological materials across jurisdictions.

The long-term success of the Nagoya Protocol depends on individual users’ due diligence and compliance with the new global standard of utilizing genetic resources in a fair and equitable manner. However, too much formality in procedures or extraterritorial restrictive control by governments may function as a strong disincentive to timely and efficient access to genetic materials and may have a chilling effect on bona fide biodiversity
research and bioprospecting activities that could lead to discoveries of next-generation cancer therapies or biotechnological breakthroughs. Nevertheless, it is in the interest of everyone involved in bio-property transactions to comply with local rules regardless of whether one’s home country is a signatory. While the regulatory landscape is still in flux, an initial comprehensive review of the Nagoya Protocol’s implementation status for the last four years—due in late 2018—will be an important stepping stone to envisioning the future development of this new ecosystem.

**Practice Pointers**

- Potential stakeholders planning to access genetic materials are strongly encouraged to familiarize themselves with the developing standards of the Nagoya Protocol through the online Access and Benefit-Sharing Clearing-House.

- As users of genetic resources, stakeholders are additionally expected to work closely with their foreign counterpart representing the country that is a Party to the Nagoya Protocol, and to exercise due diligence in obtaining information on domestic implementing measures of their jurisdiction for full legal compliance.
Figure 1. The Framework of the Nagoya Protocol.

Under the Nagoya Protocol’s Access and Benefit-Sharing (“ABS”) scheme, acquiring genetic resources is subject to Prior Informed Consent (“PIC”) of the provider country. Benefit-sharing will be executed according to Mutually Agreed Terms (“MAT”). Each country designates National Focal Points, which provide information on ABS to stakeholders and administer domestic regulations. An Internationally Recognized Certificate of Compliance is issued by the Secretariat based on national permits granted by the Competent National Authority of the provider country and is published on the ABS Clearing-House. Designated national Checkpoints collect relevant information, and monitor and report on the utilization of genetic resources to support compliance and increase transparency.
This article presents a patent litigation framework for other federal district courts to follow, using the example of the U.S. District Court for the Eastern District of Texas after TC Heartland. This article also provides an overview of the TC Heartland U.S. Supreme Court case and the In Re Cray Federal Circuit opinion, as well as how those two cases have impacted patent litigation in various district courts across the country, most notably in the District of Delaware. All district courts should learn various lessons from the District Court for the Eastern District of Texas and should model their practices after its approach to handling patent cases going forward.

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INTRODUCTION

Prior to the United States Supreme Court case of TC Heartland LLC v. Kraft Foods Group Brands LLC, the vast majority of the nation’s patent cases were filed in one court, and one court only: the United States District Court for the Eastern District of Texas. Because of the patent law expertise of the District’s judges, procedural advantages stemming from Local Patent Rules that tend to lead to faster trials, and the perception of the District being plaintiff-friendly in awarding multiple multi-million dollar jury verdicts for patentees, it became the preferred choice of venue for

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2 See Brian Howard, Lex Machina 2015 End-of-Year Trends: Patent Litigation, LEX MACHINA (Jan. 7, 2016), https://lexmachina.com/lex-machina-2015-end-of-year-trends/ (indicating 2,540 new patent cases filed in the U.S. District Court for the Eastern District of Texas [hereinafter EDTX] in 2015, accounting for 43.6% of all the patent cases filed in the U.S. District Courts in that year). See also Colleen V. Chien & Michael Risch, Recalibrating Patent Venue, 77 Md. L. Rev. (forthcoming 2018) (manuscript at 1), https://ssrn.com/abstract=2834130 (“[P]atentees have flocked to fewer districts, and in 2015, brought more than 40% of their cases in a single rural district with 1% of the US population, [EDTX].”).
3 See Brian J. Love & James Yoon, Predictably Expensive: A Critical Look at Patent Litigation in the Eastern District of Texas, 20 STAN. TECH. L. REV. 1, 1 (2017) (“[W]hat makes the [EDTX] so attractive to patent plaintiffs is the accumulated effect of several marginal advantages—particularly with respect to the relative timing of discovery deadlines, transfer decisions, and claim construction—that make it predictably expensive for accused infringers to defend patent suits filed in [EDTX].”).
many non-practicing entities ("NPEs") or patent assertion entities ("PAEs"), a subclass of them being referred to as "patent trolls."\(^4\)

In many ways, due to the sheer volume of patent cases overseen, the Eastern District of Texas became in essence a specialized federal district patent court.\(^5\) That is, an Article III district court that retains subject matter jurisdiction and expertise to hear patent cases, where appeals would go before the United States Court of Appeals for the Federal Circuit—the only appellate court that can hear patent appeals.\(^6\) *TC Heartland* significantly affected venue rules on where plaintiffs could file patent suits. In the wake of its ruling, a new court—most likely the United States District Court for the District of Delaware, or perhaps the District Court for the Northern District of California or the Central District of California\(^7\)—could become the new federal district patent court.\(^8\)


\(^5\) *See* Brief of Amici Curiae 56 Professors of Law and Economics in Support of Petition for Writ of Certiorari at 11, TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514 (2017) (No. 16-341), 2016 WL 6124403 (hereinafter Amicus Brief 56 Professors) ("[W]hen Congress decided to consolidate patent appeals in the newly-created United States Court of Appeals for the Federal Circuit, it deliberately chose to include both appeals from the United States Patent and Trademark Office and the district courts, so the new court would not hear only appeals from patent owners. And it considered and rejected proposals to create a specialized district court to hear patent cases. But the Federal Circuit’s interpretation of § 1400(b) has in practice created just such a court.")


\(^7\) *See* Howard, *supra* note 2 (demonstrating the Central District of California as the 3rd highest ranking venue where the most patent cases were filed, after EDTX (No. 1) and the District of Delaware (No. 2)).

\(^8\) *See* Chien & Risch, *supra* note 2, at 36 (predicting that after *TC Heartland*, a net shift of roughly 35% of cases being heard in EDTX would transition to roughly 37% of cases being heard in the Northern District of California or the District of Delaware, or 21% of all cases would be transferred from EDTX to those two other Districts, and also finding that for non-practicing entity [hereinafter NPE] cases, EDTX would drop from 64% to 19% of all NPE cases and the District of Delaware and the Northern District of California would rise
However, due to the lack of resources, patent law expertise, patent trial court experience, and lack of a deep bench of judges as in the case of Delaware, these courts might be ill-suited as transferee courts receiving the brunt of the nation’s patent cases. Furthermore, these courts, with the exception of the Northern and Central Districts of California, do not have Local Patent Rules. As a result, the District of Delaware and other courts that similarly do not have any special patent rules treat patent cases just like any other case involving federal civil litigation.

Most, if not all, potential transferee courts also lack many of the practices that the Eastern District of Texas (“EDTX”) has developed to make the adjudication of patent cases more efficient, fair, and in-depth. These practices include: working with technical advisor attorneys during complex Markman claim construction hearings, hiring judicial law clerks with significant patent litigation experience and science, engineering, or technical backgrounds, creating and applying Local Patent Rules, and adopting other procedures such as a consolidated scheduling conference for all patent cases. These practices make administration of patent cases collectively from about 10% to 43% of all NPE cases.


11 Michael C. Smith, July 25 Marshall Patent Case Scheduling Conferences, EASTERN DISTRICT OF TEXAS BLOG, https://edtexweblog.com/july-25-marshall-patent-case-scheduling-conferences/ (describing a procedure that District Judge J. Rodney Gilstrap would hold for upcoming patent cases in Marshall: “The most recent batch of bimonthly patent case scheduling conferences was last Tuesday in Marshall . . . 21 cases were set, with only four having other cases consolidated
Many academic commentators have recognized benefits from *TC Heartland*, such as halted forum shopping and a lower number of cases being filed in the EDTX. At the same time, attorneys can now learn from the EDTX’s success in handling patent cases to prepare whichever next federal district court(s) will receive the mantle of the new “federal patent district court.” That is also not to say that the EDTX will significantly lose its stature as one of the leading patent courts where the most patent cases are filed: recent predictions calculate that the court will remain within the top districts where patent cases will be heard, in part due to the court’s above-described expertise.\(^\text{12}\)

This paper describes the key points from the holding of the *TC Heartland* case, and its relevance to the EDTX and the next potential federal patent district court that may emerge in the wake of its ruling. Part I includes an abbreviated discussion of the EDTX history. Part II summarizes the *TC Heartland*, with the aftermath briefly described. In Part III, an argument will be posited that any future district courts that may hold the title of a “federal district patent court” can learn several things about the EDTX in going forward. Part IV suggests various implementation schemes, with Part V being the conclusion and a summary of the proposals made in this paper.

I. **AN ABBREVIATED HISTORY OF THE EDTX**

Amongst judges, lawyers and the legal community in Marshall, Texas a saying exists that the local federal courts “went from PI to IP.”\(^\text{13}\) According to a *New York Times* article, local lawyers “moved


\(^{13}\) Alan Cohen, *From PI to IP: Personal Injury Lawyers in Texas Want to Get Into Patent Litigation, and The Roth Law Firm is Leading the Stampede*, IP LAW & BUSINESS (November 2005),
out of personal injury and into intellectual property.” However, especially after the personal injury boom in litigation—a relatively minor hike compared to the subsequent explosion of patent cases that would occur later on, federal courts in the EDTX have been relatively uncrowded in terms of criminal cases. In the early 90s Texas Instruments (“TI”) had capitalized on the EDTX’s lighter caseload. TI, based in Dallas, was looking for a quieter, less crowded docket to file their patent cases in. The Northern District of Texas, another federal court in Dallas, was unduly occupied with criminal cases involving the “War on Drugs” and many other federal civil cases that took priority over patent cases. Therefore, TI started bringing their patent cases to the EDTX. T. John Ward was serving as local counsel to TI in these cases, when he heard his San Francisco co-counsel bemoan the lack of the Northern District of California Local Patent Rules in the EDTX.

District Judge Ronald M. Whyte of the Northern District of California (“NDCA”) created Local Patent Rules. Later sworn in

http://mesmith.blogs.com/eastern_district_of_texas/files/IP.pdf (“Still, Smith's firm gets noticed, for in Texas, particularly in East Texas towns like Marshall and Tyler and Longview, a lot of firms want to do what The Roth Law Firm has done: transition from personal injury work—in steady decline since the Texas legislature got serious about tort reform—to intellectual property work, where business is booming.”).


See Kaleigh Rogers, The Small Town Judge Who Sees a Quarter of the Nation’s Patent Cases, VICE: MOTHERBOARD (May 5, 2016), https://motherboard.vice.com/en_us/article/aek3pp/the-small-town-judge-who-sees-a-quarter-of-the-nations-patent-cases (“‘Marshall doesn’t have a criminal docket to speak of,’ said Michael Smith, an attorney in Marshall . . . . ‘Because it's a rural division, there's not a US attorney's office here. There's not a jail here. Less than 10 percent of the cases in Marshall are criminal cases, which is very unusual for a district court, and that is why the patent docket started here 23 years ago.’”).

Id.

See Senior Judge Ronald M. Whyte Takes Inactive Status November 1, 2016, U.S. DIST. CT. FOR N.D. CAL., https://www.cand.uscourts.gov/news/200 (“In his years as a federal district judge, Judge Whyte emerged as a leading expert on patent and technology litigation. He led the development of model jury instructions and innovative patent rules and model protective orders and lectured
as Marshall’s sitting federal district judge, T. John Ward brought the Local Patent Rules from the NDCA to the EDTX.\textsuperscript{18} The rules were designed to help the NDCA manage active patent cases, but they ended speeding up the administration of patent cases in Marshall significantly—and the EDTX became known as the “rocket docket” amongst patent litigation practitioners because of the lightning quick time-to-trial.\textsuperscript{19}

When Leonard Davis, another District Judge in nearby Tyler, Texas (roughly an hour’s drive from Marshall) joined the EDTX bench in 2002, the patent rocket docket was in full swing. The rapid-fire pace of patent trials and the efficiency with which Judge Ward, Judge Davis, Magistrate Judges Charles Everingham and John Love were able to handle technically complex pre-trial procedures was impressive to say the least. All handled technically complex pre-trial procedures such as \textit{Markman} claim construction hearings, a multitude of complex patent motions, and tried a new patent case every few weeks. The EDTX also became attractive to NPEs, PAEs\textsuperscript{20} and “patent trolls”—entities that do not make any products but simply file patents and sue parties with them. These entities preferred the low discovery costs and breakneck speed of patent trials afforded by the EDTX Local Patent Rules.

Soon, patentee plaintiffs—including various NPE/PAE/patent trolls—were winning large, multi-million-dollar verdicts, leading to the perception of Marshall and the EDTX forming a plaintiff-
friendly jurisdiction. This further increased the number of patent suit filings. In 2011, when Judge Ward retired, the Honorable J. Rodney Gilstrap became Marshall’s new District Judge.\(^{21}\) He was joined by the Honorable Roy S. Payne as Marshall’s Magistrate Judge, who had previously served as a Magistrate Judge in the U.S. District Court for the Western District of Louisiana for over eighteen years.\(^{22}\)

From 2011 to present, Judge Gilstrap established himself as the country’s “busiest patent judge” hearing the most patent cases of all time.\(^{23}\) Judge Payne also became the only federal judge, either District or Magistrate, who has construed the most patent claim terms during Markman claim construction hearings.\(^{24}\)

District Judge Robert W. Schroeder III took the bench in Texarkana, Texas during the year of 2014, while Judge Davis retired in 2015. Many sources, such as Lex Machina and Docket Navigator, consider Judge Schroeder the second most active patent District Judge in the country, hearing the highest number of patent cases behind Judge Gilstrap.\(^{25}\)

From 2011-2013, many academic law professors and other commentators started criticizing the rampant forum-shopping

\(^{25}\) See Matt Chiappardi & Daniel Siegal, Gilstrap Moves Over For America's Next Top Patent Judge, LAW360 (June 1, 2017, 7:39 PM), https://www.law360.com/articles/930023/gilstrap-moves-over-for-america-s-next-top-patent-judge (“Judge Gilstrap picked up 1,615 patent cases in 2015 alone, almost double the number taken by U.S. District Judge Robert W. Schroeder III, his Texas Eastern colleague who held the No. 2 spot.”).
inherent in the vast majority of patent cases being filed in the EDTX. NPR’s “This American Life” featured a broadcast on Marshall and the flood of patent cases in the EDTX. HBO’s Last Week Tonight with John Oliver did a segment on Marshall, commenting on the presence of the “Samsung Ice Skating Rink” erected by the company because it gets sued there so often. The Today Show even aired a profile of the town of Marshall on the eve of oral arguments for TC Heartland. Ironically, concerns raised by all of these commentators would be addressed by the case, which was decided on May 22, 2017.

II. A SUMMARY OF TC HEARTLAND

TC Heartland is a rather short, straightforward opinion as far as U.S. Supreme Court opinions are concerned. It was decided unanimously (8-0), with the majority opinion written by Justice Thomas. TC Heartland concerns two venue statutes: the patent specific venue statute, 28 U.S.C. § 1400(b), and the general venue statute, 28 U.S.C. § 1391(c). Before the TC Heartland ruling, the reason why so many plaintiffs could file patent suits in the EDTX was because § 1391(c) was interpreted as an amendment to § 1400(b). When both statutes are read together, they say that patent suits can only be filed “where the defendant resides or where the defendant has committed acts of infringement and has a regular and established place of business.” Based on this reading, § 1391(c)

26 See, e.g., Chien & Risch, supra note 2; Amicus Brief 56 Professors, supra note 5.
28 LastWeekTonight, Patents: Last Week Tonight with John Oliver (HBO), YOUTUBE (Apr. 19, 2015), https://www.youtube.com/watch?v=3bxcc3SM_KA.
31 28 U.S.C. § 1400(b) (emphasis added).
arguably amended the meaning of “resides” by stating that “[e]xcept as otherwise provided by law” and “[f]or all venue purposes,” a corporation “shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.”

Basically, a mass of patent plaintiffs could file patent suits in the EDTX by establishing personal jurisdiction in Marshall or Tyler or nearby. Plaintiffs often accomplished this by opening “fake offices” that manufactured personal jurisdiction for the purposes of venue. The Federal Circuit, in the interim appellate review of *TC Heartland*, actually affirmed this interpretation of the above two venue statutes and stated that it was valid law. In other words, plaintiffs could sue defendants anywhere they could establish personal jurisdiction, and hence the EDTX counted. However, the Supreme Court overruled the Federal Circuit and declared that for venue purposes in all patent cases, “resides” is interpreted as place of incorporation. As a consequence, many patent cases may shift venue to Delaware, because numerous companies have incorporated in that state.

In the case of *Fourco Glass Co. v. Transmirra Products Corp.*, the Supreme Court concluded that for purposes of § 1400(b) a domestic corporation “resides” only in its state of incorporation, essentially rejecting the argument that § 1400(b) incorporates the broader definition of corporate “residence” contained in the general venue statute, 28 U.S.C. § 1391(c). Congress has not amended § 1400(b) since *Fourco*, but it amended § 1391 twice. Section 1391 now states: “[e]xcept as otherwise provided by law” and “[f]or all venue purposes,” a corporation “shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.”

Respondent Kraft Foods filed a patent infringement suit in the District Court for the District of Delaware against Petitioner TC

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32 *TC Heartland LLC*, 137 S. Ct. at 1517–18.
33 See *THIS AMERICAN LIFE*, supra note 27 (describing the many empty offices with just names of companies on the doors that were NPEs/PAEs).
34 See generally *In re* TC Heartland LLC, 821 F.3d 1338 (Fed. Cir. 2016).
36 28 U.S.C. § 1391(a), (c) (2012); *TC Heartland*, 1317 S. Ct. at 1517.
Heartland, a competitor that is organized under Indiana law and headquartered in Indiana but ships the allegedly infringing products into Delaware. TC Heartland then moved to transfer venue to a District Court in Indiana, claiming that venue was improper in Delaware. Citing Fourco, petitioner argued that it did not “resid[e]” in Delaware and had no “regular and established place of business” in Delaware under § 1400(b). The District Court in Delaware rejected these arguments. The Federal Circuit, in In re TC Heartland, denied a petition for a writ of mandamus, concluding that § 1391(c) supplies the definition of “resides” in § 1400(b). The Federal Circuit reasoned that because petitioner resided in Delaware under § 1391(c), it also resided there under § 1400(b).37

The Supreme Court held that, as applied to domestic corporations, “resid[ence]” in § 1400(b) refers only to the state of incorporation.38 The amendments to § 1391 did not modify the meaning of § 1400(b) as interpreted by Fourco. The Supreme Court also held that:

(a) The venue provision of the Judiciary Act of 1789 covered patent cases as well as other civil suits.39 In 1897, Congress enacted a patent-specific venue statute.40 This new statute permitted suit in the district of which the defendant was an “inhabitant” or in which the defendant both maintained a “regular and established place of business” and committed an act of infringement. A corporation at that time was understood to “inhabit” only the State of incorporation. This Court addressed the scope of § 1400(b)’s predecessor in Stonite, concluding that it constituted “the exclusive provision controlling venue in patent infringement proceedings” and thus was not supplemented or modified by the general venue provisions.41 In 1948, Congress recodified the patent venue statute as § 1400(b). That provision, which remains unaltered today, uses “resides” instead of “inhabit[s].” At the same time, Congress also enacted the general venue statute, § 1391, which defined “residence” for corporate defendants. In Fourco, the U.S. Supreme

37 TC Heartland, 1317 S. Ct. at 1517–18.
38 Id.
40 Id.
41 Id.
Court reaffirmed Stonite’s holding, observing that Congress enacted § 1400(b) as a standalone venue statute and that nothing in the 1948 recodification evidenced an intent to alter that status, even the fact that § 1391(c) by “its terms” embraced “all actions.” The Court also concluded that “resides” in the recodified version bore the same meaning as “inhabit[s]” in the pre-1948 version.43

This interpretation remained effectively unchanged until 1988, when Congress amended the general venue statute, § 1391(c). The revised provision stated that it applied “[f]or purposes of venue under this chapter.” In VE Holding Corp. v. Johnson Gas Appliance Co., the Federal Circuit held that, in light of this amendment, § 1391(c) established the definition for all other venue statutes under the same “chapter,” including § 1400(b).44 In 2011, Congress adopted the current version of § 1391, which provides that its general definition applies “[f]or all venue purposes.” The Federal Circuit reaffirmed VE Holding in the In re TC Heartland opinion.

(b) In Fourco, the Supreme Court held that the word “reside[nce]” in § 1400(b), as applied to domestic corporations, refers only to the state of incorporation.45 Because Congress has not amended § 1400(b) since Fourco, and neither party asked the Court to reconsider that decision, the only question in the TC Heartland case was whether Congress changed § 1400(b)’s meaning when it amended § 1391. “When Congress intends to effect change of that degree, it ordinarily provides a relatively clear indication of its intent in the amended provision’s text. No such indication appears in the current version of § 1391.” Respondent argued current § 1391(c) provides a default rule that, on its face, applies without exception “[f]or all venue purposes.” But the version at issue in Fourco similarly provided a default rule that applied “for venue purposes,” and those phrasings are not materially different in this context. The

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43 Id. at 226.
45 Fourco Glass, 353 U.S. at 226.
47 Id. at 1520.
addition of the word “all” to the already comprehensive provision does not suggest that Congress intended the Court to reconsider its decision in *Fourco*. Arguments based on this language read weaker now than when the Court rejected them in *Fourco*. The *Fourco* Court held that § 1400(b) retained a meaning distinct from the default definition contained in § 1391(c), even though the latter, by its terms, included no exceptions. The current version of § 1391 includes a saving clause, which expressly states that the provision does not apply when “otherwise provided by law,” thus making explicit the qualification that the *Fourco* Court found implicit in the statute. Finally, no indication exists that Congress ratified the Federal Circuit’s decision in *VE Holding*.49

III. *IN RE CRAY*

A. The EDTX Case of Raytheon v. Cray

Following *TC Heartland*, the focus of venue in patent litigation was on the meaning of the phrase “regular and established place of business,” as defined by the 1985 Federal Circuit case of *In re Cordis*.50 In the *In re Cordis* case, the Federal Circuit stated that when analyzing the “regular and established place of business” requirement, “the appropriate inquiry is whether the corporate defendant does its business in that district through a permanent and continuous presence” and not “whether it has a fixed physical presence in the sense of a formal office or store.”51 In an EDTX case that shortly followed the *TC Heartland* ruling, *Raytheon Co. v. Cray, Inc.*, Judge Gilstrap held that venue was proper under the holding of *In re Cordis*.52 Judge Gilstrap created and utilized a four-part test “gleaned from prior courts and adapted to apply in the modern era” as a tailored “totality of the circumstances” approach to venue, “guided by the important goal of administrative

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49 *TC Heartland*, 1317 S. Ct. at 1519.
50 *In re Cordis Corp.*, 769 F.2d 733 (Fed. Cir. 1985).
51 *Id.* at 737.
simplicity” to gauge whether a defendant had a “regular and established place of business.” The four factors are:

1) Physical Presence–The extent to which a defendant has a physical presence in the district, including but not limited to property, inventory, infrastructure or people.

2) Defendant’s Representations–The extent to which a defendant represents, internally or externally, that it has a presence in the district.

3) Benefits Received–The extent to which a defendant derives benefits from its presence in the district, including but not limited to sales revenue.

4) Targeted Interactions with the District–The extent to which a defendant interacts in a targeted way with existing or potential customers, consumers, users, or entities within a district, including but not limited to through localized customer support, ongoing contractual relationships, or targeted marketing efforts.

B. Related District of Delaware Cases

Chief Judge Leonard Stark of the District of Delaware also reached a similar conclusion in applying the In re Cordis holding to venue in two cases. Notably, in the Boston Scientific opinion, Judge Stark cited In re Cordis to hold that analyzing whether a defendant has a “regular and established place of business” requires

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53 Id. at 796.
54 Id. at 796–797.
55 Id. at 797–798.
56 Id. at 798.
57 Id. at 798–799.
“a fact intensive inquiry focused on whether the defendant does business in this District through a permanent and continuous presence here.”\textsuperscript{59} In the \textit{Mylan} opinion, Judge Stark ordered further discovery after he was unable to determine whether Mylan had a regular and established place of business in Delaware. Intensive discovery was necessary in this case even though “Mylan’s business model is in large part predicated upon participating in a large amount of litigation” involving drug patents that frequently take place in the District of Delaware.\textsuperscript{60}

\textbf{C. The Background of Raytheon \textit{v.} Cray}

\textit{Raytheon v. Cray} was pending for pre-trial matters before Judge Payne and was scheduled for trial in March of 2017 before Judge Gilstrap. Defendant Cray filed several motions, including a motion to dismiss for improper venue, or, in the alternative, to transfer to the Western District of Washington under the first-to-file rule.\textsuperscript{61} In February 2017, plaintiff Raytheon was allowed to continue the trial from March to August 2017. After the \textit{TC Heartland} decision came out on May 22, 2017, Defendant Cray requested and received an expedited briefing schedule for its motion to transfer to the Western District of Wisconsin under 28 U.S.C. § 1406(a).\textsuperscript{62} Briefing closed for the motion to transfer on June 22 and on June 26, and the case was reassigned to Judge Gilstrap. On June 29, 2017, Judge Gilstrap denied Cray’s motion to transfer, which resulted in the above-discussed opinion.\textsuperscript{63} On July 14, Cray filed a petition for a writ of mandamus with the Federal Circuit and on July 18, Judge Gilstrap stayed the case \textit{sua sponte}.

\textbf{D. The In Re Cray Federal Circuit Writ of Mandamus Order}

\textsuperscript{59} \textit{Boston Sci.}, 269 F. Supp. 3d at 249.
\textsuperscript{60} \textit{Bristol-Myers Squibb}, 2017 WL 3980155, at *22.
\textsuperscript{63} Raytheon Co. \textit{v.} Cray, Inc., 258 F. Supp. 3d 781, 783–84.
On September 21, 2017, the Federal Circuit granted Cray’s petition for writ of mandamus, reversed Judge Gilstrap’s ruling on Cray’s motion to transfer, and directed transfer of the Raytheon v. Cray case to the Western District of Wisconsin.  

When determining venue and interpreting the language “where the defendant. . . has a regular and established place of business” under 28 U.S.C. § 1400(b) the Federal Circuit held that: (1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant. Each of the three prongs are addressed in turn.

1) First Requirement–Physical Place in The District

The first requirement requires there “must be a physical place in the district”: specifically, “[t]he statute [1400(b)] thus cannot be read to refer merely to a virtual space or to electronic communications from one person to another” and while the “place” need not be a “fixed physical presence in the sense of a formal office or store” there “must still be a physical, geographical location in the district from which the business of the defendant is carried out.”

2) Second Requirement–The Place Must Be A Regular and Established Place of Business

The second requirement requires the place “must be a regular and established place of business” and that while a business can certainly move its location, it must for a meaningful time period be stable, established . . . [I]f an employee can move his or her home out of the district at his or her own instigation, without the approval of the defendant, that would cut against the employee’s home being considered a place of business of the defendant.

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64 In re Cray, Inc., 871 F.3d 1355, 1357 (Fed. Cir. 2017).
65 Id. at 1360.
66 Id. at 1362.
67 Id. at 1363.
3) Third Requirement–The Regular and Established Place of Business Must be the Place of the Defendant

The third requirement requires that the “regular and established place of business” must be “the place of the defendant.” It “must be a place of the defendant, not solely a place of the defendant’s employee,” and

[r]elevant considerations include whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place. . . . Another consideration might be whether the defendant conditioned employment on an employee’s continued residence in the district or the storing of materials at a place in the district so that they can be distributed or sold from that place.68

E. The Federal Circuit’s Reasoning in In Re Cray

After concluding that the EDTX’s refusal to transfer was an abuse of discretion, the Federal Circuit relied on the facts regarding Cray’s locations and applied the three requirements outlined above.69

Cray is a Washington corporation with its principal place of business located in Washington. Cray does not rent or own an office or any property in the EDTX, but allowed two employees, Mr. Harless and Mr. Testa, to work remotely from their respective homes in the district.70 Facts establishing the presence of Mr. Harless in the EDTX included: (1) his EDTX personal home location on an internal Cray “America Sales Territories” map, (2) how he received reimbursement for his cell phone usage for business purposes, internet fees, and mileage or “other costs” for business travel, and (3) how Cray provided Harless with “administrative

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68 Id. (citations omitted).
69 Id. at 1364–1365.
70 Id. at 1357.
support” from its Minnesota office.\textsuperscript{71} In denying Cray’s motion to transfer, Judge Gilstrap found that the activities of Harless were factually similar to the activities performed by the representatives in \textit{In re Cordis}.\textsuperscript{72} However, the Federal Circuit noted that Judge Gilstrap did not analyze Mr. Tesla’s activities in determining whether venue was proper in denying the motion.

After discussing the standard for writs of mandamus and the onslaught of motions to transfer following \textit{TC Heartland}, the Federal Circuit distinguished \textit{In re Cordis}, arguing that venue was not evaluated in light of § 1400(b): “the world has changed since 1985 when the \textit{Cordis} decision issued. In this new era, not all corporations operate under a brick-and-mortar model. Businesses can be conducted virtually. Employees increasingly telecommute.”\textsuperscript{73}

The third requirement that the “regular and established place of business” must be “the place of the defendant” was also vital to the Federal Circuit’s holding because the facts did not support a finding that the home of Harless was a “regular and established place of business” of Cray. “The fact that Cray allowed its employees to work from the [EDTX] is insufficient.”\textsuperscript{74} There is also no indication that Cray owns, leases, or rents any portion of the home of Mr. Harless in the EDTX. The Federal Circuit also distinguished the present facts from the facts of \textit{In re Cordis}, where Cordis was dependent on employees being physically present in the district, yet all administrative support and reimbursements for Cray’s employees were provided from outside the EDTX.\textsuperscript{75} The Federal Circuit then concluded that its decision was consistent with other venue decisions from the Seventh and Fourth Circuits.\textsuperscript{76}

After \textit{In re Cray}, the Federal Circuit development on an indirectly related patent venue jurisprudence was \textit{In re Micron Technology}, which held \textit{TC Heartland} constituted an intervening change in the law by changing “controlling law in the relevant

\begin{footnotes}
\noindent \textsuperscript{71} Id.
\noindent \textsuperscript{72} Id. at 1358.
\noindent \textsuperscript{73} Id. at 1359.
\noindent \textsuperscript{74} Id. at 1363.
\noindent \textsuperscript{75} Id. at 1365.
\noindent \textsuperscript{76} Id. at 1366.
\end{footnotes}
sense.” Therefore, parties can now successfully argue that they have not waived their venue defense because the Federal Circuit ruled that such a defense was not even available prior to the TC Heartland ruling. The In re Micron Technology holding is part of a trend by courts to make it harder for parties, predominantly plaintiffs, to stay in the forum where the patent case was filed, namely the EDTX.

IV. THE AFTERMATH OF TC HEARTLAND AND IN RE CRAY

The immediate aftermath of TC Heartland and In re Cray resulted in decreasing filings in the EDTX, and increasing filings in Delaware. For example, the 2017 Q3 litigation report from Lex Machina concludes that because of the “sea change” of TC Heartland:

[T]he Eastern District of Texas, typically the district seeing the most patent litigation, has finally been supplanted as the top district for patent suit filings. During 2017’s third quarter, that title belonged to the District of Delaware, which saw 212 case filings during the recent quarter as opposed to the 139 cases filed in Eastern Texas. Collectively, these two districts saw 35 percent of all patent cases filed in U.S. district courts during 2017’s third quarter. A figure showing patent suit filings in the 90-day periods both leading up to the TC Heartland decision and after is a pretty stark indicator of the effects of that case. 377 patent cases, a full 33 percent of all patent cases filed in the 90-day window before TC Heartland, were filed in Eastern Texas; 153 cases, or 13 percent, were filed in Delaware. In the 90 days after TC Heartland, 13 percent of patent cases (129 suits) were filed in Eastern Texas and 26 percent of cases (263 suits) were filed in Delaware. 78

77 In re Micron Tech., Inc., 875 F.3d 1091, 1094 (Fed. Cir. 2017).
78 Steve Brachmann, Lex Machina Q3 Litigation Update Shows Effects of TC
The majority of patent litigation activity that has transferred from the EDTX to the District of Delaware are cases filed by high-volume plaintiffs. 79 Furthermore, statistics from the 2017 Q4 litigation report reveal that defendants are able to successfully move to transfer for improper venue out of the EDTX at even greater rates when compared to other districts.80

In Lex Machina’s Q1 litigation report, the research firm concluded that although filings for the beginning of 2017 were higher in the EDTX, they plateaued after May, when the *TC Heartland* case was decided, with Delaware picking up the slack.81

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79 See id. (“According to [Lex Machina Data Scientist and Associate General Counsel Brian] Howard, the primary driver of increased litigation levels in Delaware were high-volume plaintiffs, entities filing 10 or more patent cases within a year’s time. This same constituency had been a major contributor to Eastern Texas’ dominance in the patent litigation landscape leading up to *TC Heartland*. . . . [H]igh-volume plaintiff filings had dipped below filings from low-volume plaintiffs for the first time since the third quarter of 2011. Conversely, high-volume plaintiffs in Delaware began closing the gap between low-volume plaintiffs through 2017’s third quarter. . . . ‘If [Delaware] cases get tied up in claim construction, plaintiffs may decide to go elsewhere.’”).

80 See id. (“Although a good deal of media attention surrounding the post- *TC Heartland* patent world was piqued by *[In re Cray]*, a case in [EDTX] in which Judge Rodney Gilstrap denied a motion to transfer venue, [EDTX] has proven to be a venue out of which defendants are increasingly able to transfer at an even greater rate than other districts. The success rate of motions to transfer venue out of [EDTX] in the 90-day period before *TC Heartland* was decided was 40 percent, but that increased to an 84 percent success rate in the 90 days after *TC Heartland*. In all other districts, the success rate of motions to transfer venue pre- *TC Heartland* was 48 percent and that percentage only rose to 70 percent post- *TC Heartland*. To Howard, this higher rate of successful motions out of [EDTX] is not necessarily an indication that plaintiffs without proper venue were choosing [EDTX] as a preferred venue anyways. [Howard said,] ‘[B]etter lawyers on average [are] defending cases in [EDTX] than . . . across all other districts[,] [T]here’s more money at issue in [EDTX] cases . . . . [B]etter lawyers are writing more successful motions.’”).

According to the Orrick IP Law Blog, EDTX fell to half of its current filings with Delaware nearly doubling in filings and other courts such as NDCA increasing by a third.\textsuperscript{82} However, as some commentators suggest, \textit{TC Heartland} will not end EDTX’s influence over patent law or as a top patent venue. There are still benefits to litigating in EDTX by virtue of the now lighter docket, greater resources for efficiently handling legitimate cases, and fewer meritless cases filed by plaintiffs in bulk to extract settlements. The EDTX has more time to concentrate on a broader array of different types of lawsuits.\textsuperscript{83} As a result it is likely to remain the second most selected venue for patent case filings after the District of Delaware. The EDTX will still lead patent jurisprudence without showing the overwhelming dominance it has had in the past decade. However, considering how over-burdened with patent cases the EDTX was, that may be a good thing for patent litigation across the country.

\textbf{V. SUGGESTED FRAMEWORK}

Whirlpool’s amicus brief for \textit{TC Heartland}, summarizes many of the benefits that the EDTX possesses for both patent plaintiffs and defendants:

\begin{quote}
Whirlpool’s experience as both a plaintiff and a defendant is that patent practice in the Eastern District of Texas is neither abusive nor unreasonable.
\end{quote}

\begin{flushright}
\textsuperscript{82} Ant\-\y{O}n\-y Pfeffer, \textit{TC Heartland – One Month Later Delaware, Texas, California and Illinois Courts Most Popular Venues}, ORRICK: IP LANDSCAPE (June 22, 2017), http://blogs.orrick.com/iplandscape/2017/06/22/tc-heartland-one-month-later-delaware-texas-california-and-illinois-courts-most-popular-venues/ (“The ranking of the top 10 jurisdictions based on percentage of patent cases filed has changed somewhat in the days post-\textit{TC Heartland} versus the year and a half preceding the decision. The top two jurisdictions have switched places, with Delaware taking a solid lead, close to tripling its percentage of filings from 2016. Meanwhile, Texas has fallen to around half its percentage of filings. Other courts that have seen large increases in their percentage of cases include the Northern District of California and the Northern District of Illinois”).
\end{flushright}
While ‘patent trolls’ seeking nuisance value settlements no doubt file cases there, it is also an attractive venue for serious litigants looking to resolve meritorious claims. The reasons are not abusive: the judges are experienced with patent law, the local patent rules are predictable, and cases proceed to trial without undue delay. Whirlpool’s water filter patent litigation does not display any of the hallmarks of abuse emphasized in the briefing before this Court, yet Whirlpool has benefited from the experience, predictability, and speed offered by the Eastern District of Texas.\textsuperscript{84}

EDTX is still a preferred District for patent defendants who are sued because of the knowledge and expertise of the EDTX, where the cases get resolved as meritoriously as possible. Experience, predictability, and speed are three hallmarks that the next federal patent district court should strive for in handling the majority of the nation’s patent cases transferred its way.

\textit{A. Experience}

Experience is established not only through the number of patent cases a judge hears, but also through the types of judicial law clerks the judge hires. By hiring law clerks with technical, scientific, or engineering degrees and significant patent litigation experience, judges in future federal patent district courts can gain knowledge to better handle complex patent cases. They also can consult with experienced clerks in drafting, researching, and writing optimal orders. By seeking out clerks with significant patent law experience as well as technical backgrounds, future federal patent district court judges will be able to speed up their understanding of patent law, and therefore make the adjudication of patent cases more efficient. In addition, promoting a cultural tradition of judicial law clerks with

the aforementioned experiences bolsters the institutional knowledge of the future patent district court. This not only benefits current litigants, but fosters sound developments in patent law jurisprudence, for example, the ability to adapt and be more flexible. Judges can further educate themselves and build their experience in adjudicating patent cases optimally, by taking classes in patent law or intellectual property, or reading materials such as the Patent Case Judicial Management Guide.85

B. Predictability

Predictability can be established through consistency in prior rulings, especially in Markman claim construction rulings. To that end, the use of technical advisors assisting judges during Markman claim construction hearings is crucial: not only will the technical advisor provide top-notch legal and technical analysis for the judge, but they may remind the judge of previous decisions and rulings so that the court is consistent with prior holdings or claim constructions.

One complaint from patent litigators in Delaware is the variability and unpredictability in each judge’s claim construction. This could be a result of not using technical advisors, and simply relying on less consistent factors in rendering a Markman claim construction opinion. If technical advisors could be utilized, coupled with the patent law expertise and experience of judicial law clerks versed in patent law, predictability of a federal district court patent judge would be unparalleled, making the district court an attractive forum to file a patent law suit in.

C. Speed

To optimize speed for patent trials, future federal patent district courts should follow the example of the EDTX and NDCA by

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adopting Local Patent Rules. Adoption of these rules not only makes adjudication and administration of patent cases more efficient, but also pressures the parties to settle or only bring meritorious cases. Local Patent Rules also contribute to both the predictability and experience prong because they help judges make consistent rulings at a faster rate. Future federal district patent courts should also use procedures designed to increase the speed of patent cases such as holding monthly group scheduling conferences or standing orders on specific procedures within patent law, say motions having to do with a specific statute such as 35 U.S.C. § 101.

**Conclusion**

Attorneys can derive a variety of lessons from the EDTX to make future federal district patent courts more efficient, predictable and faster. TC Heartland may change the nature of filing suits, but should not change how a district court can continually improve in becoming a desired federal district patent court where parties wish to file patent cases, or a court that actively promotes and leads development of both procedural and substantive patent law across the nation.
REPORT AND RECOMMENDATIONS OF THE ARIZONA TASK FORCE ON COURT MANAGEMENT OF DIGITAL EVIDENCE

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ABSTRACT

The court record has three components, each historically paper-based and tangible: (1) filings; (2) transcripts; and (3) exhibits. Given technology changes, filings and transcripts now are often kept as digital files. Exhibits, however, continue to be received and held by the court in tangible form. Technology changes mean that will
soon change, and will change drastically.

The 2016 Joint Technology Committee Resource Bulletin: Managing Digital Evidence in Courts, warned that “[c]ourt management systems are not currently designed to manage large quantities of digital evidence, which means that courts and industry must find creative ways to deal immediately with the dramatically increasing volume of digital evidence, while planning for and developing new capabilities.” This article is the first published response to that urgent warning.

The article summarizes recommendations for court management of digital evidence. The article next discusses the evolving court record format and the truly digital evidence concept. Detailed workgroup reports follow, addressing: (1) digital formats; (2) storage and management; and (3) rules, including suggested rule changes. The article is designed to make sure this critical analysis is available now as well as to serve as a resource for courts, academics, technology experts, and others for years to come.

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INTRODUCTION

Arizona Supreme Court Chief Justice Scott Bales issued Administrative Order 2016-129, establishing the Arizona Task Force on Court Management of Digital Evidence (the “Task Force”), on December 6, 2016. The Task Force is the result, in no small part, of the recent exponential growth of digital evidence used in court, from devices such as smart-device cameras, body-worn cameras, and other public and private surveillance equipment.¹ The Task Force was created to address the unique challenges faced by courts in receiving, retrieving, accessing, formatting, converting, and retaining digital evidence.

The administrative order cites to the Joint Technology Committee Resource Bulletin: Managing Digital Evidence in the Courts as providing “a good framework for discussion and relevant

policy development.”2 The bulletin is a February 2016 publication of the Joint Technology Committee established by the Conference of State Court Administrators, the National Association for Court Management, and the National Center for State Courts.3 The Task Force was charged with making recommendations on five policy questions posed in the bulletin:

- Should standardized acceptable formats, viewing, storage, preservation, and conversion formats or technical protocols for digital evidence be adopted for all courts?
- Should court digital evidence be stored locally, offsite, or using cloud services, and how long and in what manner should such evidence be retained?
- Should management of court digital evidence be centralized or decentralized, considering technology costs, expertise, and infrastructure necessary to manage it?
- Should court rules governing public records be revised to address access and privacy concerns, including for victims, non-victim witnesses, and other identifying information often included in video evidence?
- Should new or amended rules on chain of custody evidence be developed for handling court digital evidence?4

The Task Force Process

Members of the Task Force were selected to represent a wide variety of perspectives in the Arizona judicial system. The Task Force undertook various outreach efforts and solicited and encouraged input from interested stakeholders and the general public.

The Task Force met approximately monthly, learning about and discussing various issues and technology related to digital evidence formats, storage, and management, and considered how best to approach the policy questions and what recommendations to make.

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3 See JTC RESOURCE BULL.
The Task Force formed three workgroups: (1) digital formats, (2) storage and management, and (3) court rules. Each Task Force member was affiliated with one workgroup. Between Task Force meetings, the workgroups met to investigate, develop, and refine recommendations addressing these key components of the Task Force’s work. Task Force meetings included workgroup presentations, during which the members took questions and feedback from all Task Force members about the efforts of the individual workgroups. This facilitated input from different perspectives, avoided communication gaps, accounted for overlap among workgroups, and ensured the workgroups were not working in isolation.

**Summary of Task Force Recommendations and Ongoing Efforts**

In response to the policy questions listed above, the Task Force developed a strong consensus supporting the following recommendations for court management of digital evidence:

1. A standardized set of formats and technical protocols should be identified, adopted, and set forth in the Arizona Code of Judicial Administration (“ACJA”) for all courts for the submission, viewing, storage, and archival preservation of digital evidence. Standardization requirements should account for five interdependent principles: (1) efficient handling of digital evidence at all phases—from submission of the evidence to the court through viewing, storage, and archival preservation; (2) rapidly changing technologies; (3) flexibility to account for technology in a specific case to ensure the just resolution of the case; (4) maintaining the integrity of the evidence; and (5) reasonable access to the parties and the public.

2. The ACJA should be amended to require digital evidence to be submitted in a standard format, unless a court makes a specific finding that the admission of evidence in a non-standardized format is necessary in the interests of justice. The recommended exception should include a requirement that the party submitting digital evidence in a non-standardized format provide technology to allow the evidence to be played or otherwise used in court. Training for
judicial officers is also recommended to assist the court in determining whether non-standardized formats are necessary.

3. Deciding whether digital evidence should be stored locally, off-site, using cloud services, or some combination or alternative, as well as whether storage and management should be centralized or decentralized, should be guided by a set of minimum technical requirements. Local courts should include specific considerations in their decision-making, including the capacity to afford and maintain the necessary technology, availability of adequate bandwidth, storage capacity expansion, and integration capabilities with other existing or future software applications.

4. Courts should take measures to enhance the use and presentation of digital evidence in the courtroom, including the use of technology to accept digital evidence in the courtroom, how parties can submit and present digital evidence from personal devices (including necessary conversion and redaction), and staff training for the acquisition, storage, and management of digital evidence. These measures should include guidance for self-represented litigants.

5. The Arizona Administrative Office of the Courts (“AOC”) should develop best practices, as well as policies and procedures, to increase the success of digital evidence management solutions adopted. The AOC should also work with local courts on developing a means to offset the costs associated with technology needs created by the increased receipt and storage of digital evidence.

6. Arizona Supreme Court Rules 122 and 123 govern public access to court records. The rights and privacy of victims and non-victim witnesses can be at opposition with the right of the public to access evidence admitted into the court record. Rule 123 should be amended to ensure that it addresses digital evidence, including exhibits, and that the portions of the rule that govern public access, particularly remote electronic access, be amended to ensure sufficient protection of victims’ rights and privacy concerns. The Arizona Supreme Court should work with local courts, prosecuting and defending agencies, law enforcement groups, media
organizations, and other stakeholders to develop consistent policies around the issue of non-victim witnesses. In addition, consideration should be given to the management of digital evidence introduced by self-represented litigants that may not be redacted to protect victim and non-victim witness privacy rights upon submission to the court.

7. The Arizona Rules of Evidence should be amended to expressly address digital evidence, including adding a definition of “video” to Rule 1001 and adding references to “video” in Rules 1002, 1004, 1006, 1007, and 1008.

8. Amendments should be made to various Arizona rule sets to modernize them to include references to digital evidence and electronically stored information, as has already occurred in other rule sets such as the Arizona Rules of Civil Procedure.

9. A standard definition of digital evidence should be added to various Arizona rule sets where not otherwise included. The original recommendation was “Digital evidence, also known as electronic evidence, is any information created, stored, or transmitted in digital format.” The recommendation was later changed to use the phrase “electronically stored evidence” in various Arizona rule sets where appropriate, as reflected in a rule change petition filed January 10, 2018.

10. Education and training, on both legal and technical competence, should be developed and implemented to facilitate and advance court management of digital evidence, for attorneys, parties (including self-represented persons), court staff, and judicial officers. The AOC should develop resource guides for self-represented litigants, as well as templates for local court use, that include information on requirements surrounding redaction, standardized formats, converting, submitting, and using digital evidence in the court.5

5 An unabridged version of this report with appendices, originally issued October 1, 2017, along with other Task Force information, can be found at http://www.azcourts.gov/cscommittees/Digital-Evidence-Task-Force.
I. MANAGEMENT OF DIGITAL EVIDENCE

A. Background

For centuries, the court has been the keeper of the record for court cases. This court record could be categorized as having three components that, until recently, consisted of paper documents or paper documents and other physical items: (1) written filings by the parties; (2) a written word-by-word transcript of hearings; and (3) exhibits used at hearings, consisting of documents, pictures, and items, such as guns, drugs, etc. Keeping this court record involved making sure paper filings were in the physical file, transcripts were in or accounted for in that physical file, and exhibits received by the court were accounted for in the physical file, an exhibit locker, or a storage location.

These documents and other items were expected to follow the case wherever it went. If a case resolved with no appeal, these documents and items in the court record would be physically transferred to storage to be held for the appropriate retention period. On the other hand, if there was an appeal, these documents and items (or at least many of them) would be physically transferred to the Arizona Court of Appeals, then perhaps to the Arizona Supreme Court, and then perhaps to the United States Supreme Court. In a criminal case, there could be a second round of litigation through post-conviction relief proceedings following a similar path, and a third round of litigation in habeas corpus proceedings in federal court. For each, these paper documents and items in the court record would physically follow the case wherever it went.

A common characteristic of these three components of the court record was that they could be touched, physically delivered, received, returned, seen, found, stored, and, on occasion, lost. They were physical items that could be observed by a person with their senses without the aid of technology.

B. The Evolving Court Record Format

Technological advancements have resulted in profound changes to the nature of the court record. As noted in summarizing court
systems in a somewhat different context, “these paper-based institutions appear increasingly outmoded in a society in which so much daily activity is enabled by the internet and advanced technology.” The computer age has substantially changed filings and transcripts, two of the three key components of the court record, with a profound impact on how the court record is kept.

Filings by the parties are, quite often, electronic, not in paper form, and may include materials that never existed in paper form. Frequently, electronic filing (e-filing) of pleadings and motions is required, absent leave of court to make paper filings. For e-filing, there is literally no physical thing provided to the court where the filing is made. Rather than a physical thing moving from a party to the court, a digital file crosses that threshold. That filing is then kept by the court as a digital file in the court record that follows the case wherever it goes.

Similarly, the transcript of court proceedings frequently is provided in a digital file or recording. The digital transcript then becomes part of the court record kept by the court, or submitted to the court on appeal, with the digital file following the case wherever it goes. As with e-filings, such a digital transcript is kept by the court in a digital file, rather than a physical, paper-based file.

By contrast, the handling of exhibits in the court record has changed very little. Exhibits continue to be offered, received, handled, held, and transported by the court in physical form in much the same way they have been for decades. A party wishing to offer an exhibit has the clerk of court mark a physical exhibit—be it a document, a picture, a disc, a tape containing a video, a gun, etc.—for identification. For evidence stored digitally, this typically requires transferring that digital file to a physical thing like a disc, which is then marked by the clerk of court as an exhibit for identification. Even when a digital file can be submitted to the court on a Universal Serial Bus (“USB”) drive, it is the USB as a thing that is received and used by the court.

If admitted into evidence, the physical exhibit is received by the court, used by witnesses, counsel, parties, the court, and jurors and then safely held by the clerk of court. That physical exhibit then

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becomes a tangible part of what, until recently, was a paper court record, including the paper filings and paper transcripts. Except for exhibits, there is increasingly not a paper component of the court record. Thus, exhibits have become the outliers; often they are the only tangible, non-digital part of the court record. Given the technology-driven changes to the first two key components of the court record (the result of e-filing and electronic transcripts) but not the third (exhibits), and the increasing instances of exhibits originating in digital form, the Task Force looked to see how the process might change if exhibits were treated more like e-filings and electronic transcripts.

The need to consider allowing digital evidence to cross the threshold from party to court in digital form was further enhanced by the increase in technology used in capturing and storing digital evidence for use at trial. Body-worn camera use has expanded at an almost algebraic rate, and its use promises to continue to expand. Current technology allows body-worn camera images to be captured and stored in digital files. Those files are digital when created and remain digital until the eve of trial (from creation, to capture, to disclosure by law enforcement to a prosecutor, to disclosure by a prosecutor to a defense attorney). The issue, then, is whether there is a way for digital images to cross the threshold from a party to the court as an exhibit to be used in court without having to transfer the digital images onto a physical disc or similar thing to be marked as a physical exhibit. If so, what additional issues would such a transfer

7 See, e.g., Kami N. Chavis, Body-Worn Cameras: Exploring the Unintentional Consequences of Technological Advances and Ensuring a Role for Community Consultation, 51 Wake Forest L. Rev. 985, 987 (2016) (“Currently, one-third of the nation’s 18,000 local and state police departments use body-worn cameras, but these numbers are growing rapidly, with the federal government’s support encouraging this effort.”) (footnotes omitted); Kyle J. Maury, Note, Police Body-Worn Camera Policy: Balancing the Tension Between Privacy and Public Access in State Laws, 92 Notre Dame L. Rev. 479, 486 (2016) (“Body camera implementation is a tidal wave that cannot be stopped.”); Kelly Freund, When Cameras are Rolling: Privacy Implications of Body-Mounted Cameras on Police, 49 Colum. J.L. & Soc. Probs. 91, 94 (2015) (citing October 2012 survey for the proposition that “[a]pproximately a quarter of the country’s police departments use body-mounted cameras, and 80% are evaluating their possible use”); see also Haire & Emery, supra note 1.
in digital form create?

C. The Truly Digital Evidence Concept

One charge of the Task Force was to analyze the implications of allowing exhibits to cross the threshold from parties to court in digital form and then, going forward, using them in digital form. This truly digital concept would apply to exhibits that exist only in digital format and to those that can easily be converted into or scanned into digital format by the parties.

Building on this issue, the Task Force discussed technology that would facilitate a trial with truly digital evidence—not a trial using technology to present evidence in the courtroom, but a truly digital trial. Building on this issue, the Task Force discussed technology that would facilitate a trial with truly digital evidence—not a trial using technology to present evidence in the courtroom, but a truly digital trial. Focusing on court management of digital evidence, the Task Force looked at functionality and related issues of an electronic portal to an electronic data repository that could be populated and used by all in final trial preparation, at trial, and beyond (with the same concept also applying to non-trial evidentiary hearings).

The concept would be court-driven, confirming the critical aspect of the clerk of court in receiving, managing, and securing evidence for use before, during, and after trial. The concept could consist of an electronic portal where digital evidence could be submitted to the clerk of court in digital form, in advance of or at a hearing or trial. The portal concept would (1) allow exhibits to cross the threshold from parties to court in digital form and (2) allow electronic submission and marking of potential exhibits by a party to the case outside of normal court business hours.

Looking to e-filings as a guide, the Task Force discussed a possible user fee (perhaps per exhibit or per case) to help offset the cost of technology. In doing so, the Task Force recognized statutory restrictions on fees, fee waiver requirements, and other issues governing the collection of fees in various case types and allowing for court access regardless of financial resources. Any user fee concept would need to account for those issues and restrictions.

By submitting exhibits to the clerk in digital form, the exhibits would be ready to use in court at the appropriate time. Digital

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8 Perhaps the closest example of a truly digital trial in the United States in the sense the Task Force considered is described in Leonard Polyakov, Paperless Trials Are The New Litigation Reality, 57 Orange County Law 36 (2015).
exhibits would reside in digital form in an electronic repository managed by the clerk. At the appropriate time, digital exhibits marked for identification could be accessed in court by the parties, counsel, the court, witnesses, and the clerk, using courtroom monitors or on a network allowing access on monitors provided by the parties.

If a digital exhibit was admitted into evidence, this electronic portal concept would allow the clerk to mark the exhibit in the electronic repository as having been admitted in evidence. As with physical exhibits currently, this would allow the participants to use the exhibit for proper purposes, including viewing it on courtroom monitors. Similarly, a digital exhibit marked but not received in evidence would be treated in the same manner as such an exhibit is treated currently. Applying the concept to deliberations, the jurors could access admitted exhibits in digital form using technology in the deliberation room.

At trial’s end, the admitted exhibits would be preserved for future reference; exhibits not admitted would be deleted (or retained, if necessary for subsequent proceedings). Again, however, given that the exhibits would be in digital format, and not physical objects, there would be no need to store them in a physical location. Adequate server space, however, would be required.

Admitted exhibits would be included in the record on appeal and transmitted electronically. The courts on appeal (and for subsequent or collateral proceedings) could then access the admitted exhibits as needed for years to come. It is this electronic portal and electronic repository concept, and various related issues, that the Task Force contemplated in addressing court management of digital evidence.

For decades, there has been a good deal of helpful information about how to conduct a trial using exhibits in electronic form in the courtroom after exhibits are submitted to the clerk in paper form or on disc. But the focus of the Task Force was different: a truly digital

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9 See, e.g., David L. Masters, How to Conduct a Paperless Trial, 39, No. 3 LITIGATION 52 (2013); Thomas E. Littler, Litigation Trends in 2013, 49 ARIZ. ATT’Y 30 (2013); Thomas I. Vanaskie, The United States Courts’ Case Management/Electronic Case Filing System: Perspectives of a District Judge, 8, No. 3 E-FILING REPORT 1 (2007) (predicting, in discussing “The Paperless Trial Court Record,” that “[a]s use of evidence presentation technology expands, it may...
trial where exhibits cross the threshold from parties to court in digital form and remain in digital form thereafter.

The Task Force contacted many groups to see if such a concept is being used anywhere in the United States, including the Federal Judicial Center, the United States Administrative Office of the Courts, the National Center for State Courts, The Sedona Conference, private sector entities, other state court systems, and many other entities and individuals. The Task Force found no court in the United States that currently uses this concept. As such, the hope that the Task Force could follow in the wake of work done by others or adapt in Arizona what was being done elsewhere in the United States did not prove to be fruitful. Therefore, the Task Force contemplated the electronic portal and electronic repository concept in addressing court management of digital evidence without the benefit of best practices and lessons learned by other courts in the United States.  

D. Task Force Meetings

The Task Force met in person seven times. Meetings included an overview of the background and substance of the Joint Technology Committee Resource Bulletin by Paul S. Embley, Chief Information Officer, Technology, National Center for State Courts; presentations and discussions on digital evidence from various perspectives; the exhibit workflow process; case management systems; OnBase technology; and court use of cloud technology, as well as presentations by the Arizona State Library, Archives and Public Records, and the Arizona Commission on Technology.

During these meetings, and at separate workgroup meetings, the Task Force discussed draft workgroup reports as well as drafts of

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be that the actual exhibits introduced at trial will be the digital version that counsel utilize in their presentation.”); Carl B. Rubin, A Paperless Trial, 19, No. 3 Litigation 5 (1993).

10 A London-based entity has launched a system in British courts that appears to have some similarities to the truly digital evidence concept the Task Force considered. See Caselinettes The Digital Court Platform, www.caselinettes.com (last visited Feb. 6, 2018). At present, it does not appear that any court in the United States has adopted that technology.
the final Task Force report. The product of that discussion and supporting rationale are set forth here, as supplemented in a rule change petition filed January 10, 2018.\textsuperscript{11}

II. WORKGROUP REPORTS

A. Digital Formats Workgroup Report

1. Summary

The Digital Formats Workgroup (“DFW”) addressed the following policy question: “Should standardized acceptable formats, viewing, storage, preservation, and conversion formats or technical protocols for digital evidence be adopted for all courts?”\textsuperscript{12} Ultimately, the DFW concluded that standardized formats and technical protocols for the viewing, storage, and preservation of digital evidence should be adopted for all courts. Further, it concluded that standardization requirements should reflect and account for five interdependent principles: (1) the requirements must promote the efficient handling of digital evidence at all phases—from submission of the evidence to the court through viewing, storage, and archival preservation; (2) the requirements must account for rapidly changing technologies; (3) the requirements must be flexible enough to account for technology in a specific case to ensure the just resolution of the case; (4) the requirements must maintain the integrity of the evidence; and (5) the requirements must permit reasonable access by the parties and the public. Consistent with these general principles, the Arizona Supreme Court has already promulgated rules that provide a useful framework for standardization of digital evidence. These rules can

\textsuperscript{11} Along with preparing this report, Administrative Order 2016-129 directed the Task Force to “file a rule change petition not later than January 10, 2018, with respect to any proposed rule changes.” That petition, designated R-18-0008 and pending as of the date of this article, and related comments, can be found on the Arizona Supreme Court’s Court Rules Forum. See http://www.azcourts.gov/Rules-Forum.

\textsuperscript{12} See supra note 4.
be found in the ACJA, particularly Chapters 5 (Automation)\textsuperscript{13} and 6 (Records).\textsuperscript{14}

The ACJA, however, expressly applies to the court and to court records, and thus, it applies only to digital evidence that qualifies as a court record and ultimately places the burden for compliance on the court.\textsuperscript{15} The ACJA includes administrative, case, electronic, and online records within the definition of court records.\textsuperscript{16} It broadly defines each type of record to encompass a wide range of content.\textsuperscript{17} The definitions do not require the material to be admitted in evidence as a court record and do not require the material to be created by the court.\textsuperscript{18} The definitions contemplate and include material created outside the court and offered to the court in an official manner, such as a filing or a marked exhibit.\textsuperscript{19} Although these references are helpful, because of the rapidly changing pace of technology, the ACJA’s technical regulations should be reviewed and updated at least every other year to ensure consistency with current technology.

2. Conversion

By adopting a policy that requires court records to comply with standard formats, the ACJA implies that a record that does not comply with the standard formats must be converted to one that is compliant. “Courts shall not create or store electronic records using systems that employ proprietary designs, formats, software, or media or that require use of non-standard devices to access records, in accordance with ACJA § 1-504(C)(1).”\textsuperscript{20} Thus, this provision sets forth the requirement that court records must comply with standard formats and be accessible with standard devices.

Similarly, the ACJA specifically addresses conversion and

\begin{itemize}
  \item\textsuperscript{13} Ariz. Code Jud. Admin. §§ 1-501–507.
  \item\textsuperscript{14} Ariz. Code Jud. Admin. §§ 1-601–606.
  \item\textsuperscript{15} See, e.g., Ariz. Code Jud. Admin. §§ 1-504, 1-602(C), (D).
  \item\textsuperscript{16} Ariz. Code Jud. Admin. § 1-507.
  \item\textsuperscript{17} Id.
  \item\textsuperscript{18} See id.
  \item\textsuperscript{19} See, e.g., Ariz. Code Jud. Admin. §§ 1-504(A), 1-506(A), 1-507(A), 1-602(A).
  \item\textsuperscript{20} Ariz. Code Jud. Admin. § 1-507(D)(1)(a).
\end{itemize}
preservation by requiring courts to “preserve all electronic documents so that the content of the original document is not altered in any way and the appearance of the document when displayed or printed closely resembles the original paper without any material alteration, in accordance with ACJA § 1-506(D)(1).”\textsuperscript{21} This requirement applies only to electronic documents and is easily met via conversion to a portable document format (“PDF”) or other comparable standardized file format for electronic documents.\textsuperscript{22}

At the same time, “[c]ourts shall preserve evidence and fingerprints in their submitted format—hardcopy items shall not be converted to electronic records for the purpose of storage and electronically submitted items shall not be converted to hardcopy for the purpose of storage.”\textsuperscript{23} This provision contemplates that a court may receive evidence electronically or physically and prohibits the court from altering the evidence from its submitted format. In other words, it prohibits conversion of hardcopy or electronically submitted items for storage. This provision also may conflict with the ACJA § 1-507(D)(1) prohibition on using proprietary designs, formats, devices, etc., when creating or storing electronic records.

Lastly, the ACJA contemplates the handling of digital files beyond just documents. “Graphics, multimedia and other non-text documents may be permitted as follows: Other multimedia files (for example, video or audio files) shall adhere to established industry standards and shall be in a non-proprietary format (for example, MPEG, AVI, and WAV).”\textsuperscript{24}

The desirability of standard, non-proprietary file formats for court records applies equally to digital evidence received by the court and may necessitate conversion (by a party before offering the evidence) from an original, proprietary or non-standard format to a standardized, non-proprietary format. Additionally, changes to software and digital devices may necessitate conversion by the courts during viewing, storage, or preservation.

Standardization requirements favoring conversion of digital evidence from non-standard or proprietary formats must, however,

\begin{footnotes}
\item[22] Id.
\end{footnotes}
allow for exceptions when the interests of justice cannot be met through strict compliance with the requirement. First, standardization requirements must provide for exceptions when conversion will compromise the integrity of the evidence. For example, a video introduced at trial to prove the exact moment a gun was fired may lose its evidentiary value if converted to a standardized format that alters the frame rate such that the exact moment of firing is no longer discernable. But if that same video was introduced to prove that a person was at a specific location when the gun was fired, not the exact moment of firing, minor alterations that result from conversion would not appear to impact its evidentiary value.

Standardization requirements must also provide for an exception to accommodate the resource limitations of the parties when necessary to effectuate the just resolution of a case. Litigants, particularly self-represented litigants, may lack the technological tools necessary to convert digital evidence and may be unable to acquire such tools without undue hardship. For example, if critical evidence of an event was captured on a surveillance camera that used a proprietary video format, and this video could not be converted to a standardized format without significant costs to the party, a court may determine that admission of the non-standard format is necessary to ensure justice.

For these reasons, there was a consensus among the DFW that the ACJA and any rules of procedure dictating standardized digital evidence formats must allow for reasonable exceptions when required to serve the interests of justice. The DFW recommends an amendment to the ACJA defining the criteria a court must use in deciding when an exception to the standardized format requirement is warranted and the conditions the party must meet in order to submit evidence in non-standard or proprietary format.

Additionally, judges should make specific findings and create a record to document why a non-standard or proprietary format is necessary. Judges should also ensure the clerk of court is notified that additional measures may be needed for proper use, retention, and preservation of evidence admitted in a non-standard or proprietary format. Finally, training is necessary for judges to recognize, evaluate, and analyze whether an exception to standardization is necessary. When non-standard or proprietary
formats must be used, the party offering the non-conforming digital evidence should generally have the responsibility to ensure the court is provided with the necessary technology (“native player”) to allow viewing of the evidence both during the proceedings and after the matter has concluded.

3. Viewing and Presentation

Viewing and presentation of court records typically contemplates two scenarios. One scenario is litigation of a case or controversy in a court. In this scenario, digital evidence is likely offered by a party to or a participant in the litigation. The digital evidence becomes a court record when it is filed, marked as an exhibit, or otherwise offered to or received by the court. The primary concern in this scenario is the ability of the court and the parties to view and present the digital evidence at court proceedings.

The second scenario is public access to court records, which can include media requests. In this scenario, a person who is interested in the litigation, but not involved in it, seeks to access the digital evidence in a case or controversy. The primary concern in this scenario is the ability of persons unrelated to cases to view the digital evidence.

Adopting standard formats for digital evidence will likely maximize the ability of litigants and the public to access court records before, during, and after litigation is resolved. The ACJA accomplishes this by addressing these scenarios in separate sections as discussed above. In addition, the court rules for the various types of cases are consistent with the ACJA in that they govern the nature of the material that might become a court record at the request of a party to the case. When a litigant complies with both the rules and the ACJA, it maximizes the probability that the record will be accessible now and in the future.

4. Storage

The ACJA also contains requirements for storage of court records, addressing primary and secondary electronic storage and specifying hardware, power support and redundancy requirements
for court records.25 “Storage” is specifically defined as “a permanent repository for holding digital data that retains its content until purposely erased, even when electrical power is removed” and applies “to electronic case records, administrative records and regulatory case records in the custody of judicial entities in Arizona, as defined by Supreme Court Rule 123.”26 Another provision addresses the electronic archives of closed cases in limited jurisdiction courts in recognition of the challenges unique to those courts, given the types of records and the more limited resources of those courts.27

The DFW concluded the current language of the ACJA sufficiently addresses the policy questions on storage requirements. The ACJA sections reviewed here are flexible enough to account for new and existing technologies and the ever-increasing volume of digital evidence that will need to be stored. There is nothing in the storage-related provision of the ACJA, or any other provision of the sections cited here, that would prevent a court from accepting evidence electronically submitted, regardless of whether on a compact disc, by email, or through information sharing on the cloud. Once received by the court, however, digital evidence should be stored in the format in which it was received.28

5. Preservation

The ACJA does not clearly distinguish between storage and preservation, and while it defines the former, it does not define the latter.29 The provision setting forth storage requirements does not discuss preservation.30 The provision addressing preservation does so primarily by referencing retention schedules:

Records generated by or received by courts shall be preserved in accordance with the applicable records retention schedule. Case records required to be

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29 See id. at § 1-507(A).
30 See id. at § 1-507(D)(3).
Collectively, these provisions require courts to employ various procedures, including refreshing electronic records, replacing or upgrading systems to ensure records do not become “obsolete,” and using backward-compatible software to address access to electronic records over a long period of time. Thus, the distinction between storage and preservation in the ACJA suggests that “storage” refers to a shorter and more immediate time frame, while the term “preservation” suggests a longer and more enduring time frame.

Regardless of the time frame involved, the storage and preservation processes are compatible. The main challenge of preservation is maintaining the accessibility of records, including digital evidence, with minimal alteration, over a long period of time. These challenges are more closely aligned with the policy questions addressed by the Storage and Management Workgroup. The DFW supports the recommendations of the Storage and Management Workgroup as to the setting of minimum requirements for any digital evidence storage and management solution adopted by the AOC or a local court.

B. Storage and Management Workgroup Report

1. Summary

The Storage and Management Workgroup (“SMW”) addressed the following policy questions:

• “Should digital evidence be stored locally, offsite, or using cloud services and how long and in what manner should such evidence be retained?”

31 Id. at § 1-507(D)(5)(c); see also id. § 1-507(D)(5)(f) (also addressing preservation).
32 See supra note 4.
• “Should management of digital evidence possessed by courts be centralized or decentralized considering technology costs, expertise, and infrastructure necessary to manage it?”  

The digital world is not new to courts. For nearly a generation, courts have used and managed digital documents, digital recordings, e-filing, and, to a much lesser degree, digital evidence. Currently in Arizona, digital evidence is offered into evidence in a physical form, such as a photo, a smart phone screen shot transferred to paper, or a document or video captured on another electronic media storage device. Judges, clerks of court, and court administrators apply existing rules to constantly evolving technology. For the most part, it works. However, the rapid increase in offering digital evidence in court is very real, particularly given the growth in law enforcement body-worn cameras, digital video captured by cell phones, security cameras, and other digital media generated from Amazon Echo, Google Home, traffic control systems, and other devices that make up the Internet of Things.  

Most courts are just beginning to experience the increase in the volume and types of digital evidence they are required to manage. Fortunately, for planning purposes, courts are at the bottom of the evidence screening funnel. For example, in criminal cases, law enforcement, prosecutors, and defense attorneys must review and manage many times the volume of digital evidence than ultimately is deemed to be relevant and admissible in a case, or that is marked as an exhibit. However, the rapid increase in digital evidence requires courts to implement policies and technical standards that are flexible enough to accommodate tomorrow’s storage needs.

Policy decisions require consideration of whether management of digital evidence should be centralized or decentralized and whether storage should be local, off-site, or in the cloud. These decisions should be guided by a set of technical requirements and policy considerations discussed below.

Arizona establishes technical requirements and policy through

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33 See supra note 4.
34 See, e.g., supra note 1.
the ACJA. The ACJA establishes minimum technical requirements for Electronic Reproduction and Imaging of Court Records;\textsuperscript{35} Enterprise Architectural Standards;\textsuperscript{36} Filing and Management of Electronic Court Documents;\textsuperscript{37} and Protection of Electronic Case Records in Paperless Court Operations.\textsuperscript{38} While not establishing technical requirements per se, for storage and management of digital evidence, what follows is a list of suggested minimum requirements to consider in addressing those issues.

2. Suggested Requirements

The following minimum technology requirements should apply to any digital evidence storage and management solution used by Arizona courts—centralized or decentralized.

1. **Single Solution.** Whenever possible, a single-source solution should be acquired for the storage and management of all digital material acquired by, generated by, and stored with the judiciary.

2. **Solution Integration.** Whenever a single solution is not available or feasible, the solutions adopted must have the ability to integrate with other software solutions to reduce the need for numerous applications to store and manage not just digital evidence, but all digital material.

3. **Media Type.** Any storage and management solution adopted must be able to accept all types of digital media and files. The DFW Report thoroughly discusses the current ACJA requirements related to standardized formats for digital evidence submitted to a court. The SMW supports those recommendations, including both for standardized formats as well as discretion to allow submissions of digital evidence in a non-standard or propriety form.

The adoption of digital evidence storage and management solutions will likely require changes to the rules surrounding what types of content a court is required to store, as well as how that

\textsuperscript{35} See Ariz. Code Jud. Admin. § 1-504.
\textsuperscript{36} See id. at § 1-505.
\textsuperscript{37} See id. at § 1-506.
\textsuperscript{38} See id. at § 1-507.
content will be received by a court (e.g., admitted versus tendered evidence or redacted versus un-redacted versions of digital evidence). Such issues must be considered and resolved parallel to the decision-making process for adopting a new solution.

4. Sealing, Restricting, and Redacting. Any software solution for the storage and management of digital evidence must be able to mark digital evidence as sealed or restricted from general access to account for redaction or other protection of confidential or sensitive information. Further, any solution must have capabilities for redaction in the rare circumstances a court orders the clerk of court to redact a copy of digital evidence. This is imperative to protecting evidence not available for general viewing in accordance with law.

5. Security. Any solution adopted to store and manage digital evidence must meet the most current cyber security requirements as set forth in the ACJA for all types of digital evidence, as well as be capable of meeting ever-evolving cyber security standards.

6. Data Backup and Recovery. All hardware and software solutions must meet the data backup and recovery requirements set forth in the ACJA.

7. Authentication and Audit Trails. Software solutions must be able to provide an audit trial for purposes of authenticating and establishing the reliability of the evidence. This consideration must take into account the requirements of evidentiary and procedural rules to ensure the software does not alter digital evidence in uploading, retrieving, viewing, or retaining the material.

8. Retention. All hardware and software solutions must be capable of storing and preserving digital evidence in the format submitted for the applicable retention periods and any other retention schedules applicable to court records.39

9. “Physical Digital” Security. Currently, digital evidence submitted to a court via a physical format, such as a disc, cannot be

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connected to network computers (e.g., Arizona Justice Information Network (“AJIN”) or Criminal Justice Information Systems (“CJIS”) computers). This prevents such evidence from being uploaded to case management systems for storage and use in court hearings and trials. Any digital evidence storage and management solutions should include a safe pathway to eliminate the need to store digital evidence in physical formats instead of electronically.

10. Public Access. All software solutions must meet the requirements for user access as set forth by rule and the ACJA if the application will be accessible via remote electronic access. This includes protections afforded to media designated as confidential, sealed, or otherwise restricted from public access.

11. Viewing. Any software solution adopted for the storage and management of digital evidence must allow a user to preview the content of the evidence in the application while searching or indexing. As an alternative, the software solution must allow for some type of description of the evidence beyond what a file name provides. Such functionality is for the purposes of ease of searching for and indexing digital evidence.

3. Additional Considerations

The SMW is aware that economies of scale and the limited capacity of many courts to store and manage digital evidence locally may necessitate that digital evidence storage and management solutions be centralized. However, who should store and manage digital evidence—local courts or more globally as part of a centralized solution—is not the whole of the question. There is not a one-size-fits-all solution for digital evidence storage and management. Any court that can meet the minimum technical requirements in the ACJA should be able to store and manage digital evidence locally if it wishes to do so.

The following additional considerations should be a part of a local court’s analysis of whether to be a part of a centralized solution

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or to adopt a decentralized solution:

- **Capacity to Manage Locally (Cost and Technology).** The fiscal challenges and technical abilities of local courts must be considered. Even with a centralized system, local courts will be required to have the operating power and equipment to connect with the centralized system. Such needs ultimately will require budget increases that often are difficult to acquire from local funding sources. Moreover, local court staff will need to quickly acquire and constantly update the skills to enter and retrieve digital material from the centralized system throughout the time a legal matter is pending and retained with the court.

- **Bandwidth.** Changes and improvements to digital evidence storage and management solutions likely will come with a greater need for bandwidth, particularly when the storage and management system is centralized at an off-site location or in the cloud. Bandwidth issues continue to be a hurdle for local courts, even in the most urban areas. In making decisions about storage and management solutions, it is imperative that the solutions adopted will be functional in each court. Limited or insufficient bandwidth that impedes the ability to upload and retrieve digital evidence so that it can be used quickly and effectively will be a detriment to day-to-day court proceedings as well as public access.

- **Resource Capabilities.** Assessment of the magnitude of the impact of electronically storing digital evidence is imperative. Moreover, adoption of a storage and management solution that is capable of expansion and can remain integrated with new software (both updated versions and later acquired) is necessary for local courts to effectively serve the parties and the public.

- **Self-Represented Litigants.** Self-represented litigants may lack the knowledge of the legal requirements or lack the tools and abilities to comply with redaction requirements. It may be that future technological advances will help resolve these important issues. For now, however, the AOC should look to determine what efforts for self-represented litigants may be appropriate to
ensure that they do not submit digital evidence containing confidential or otherwise restricted information, recognizing such efforts should not place court personnel in a position of providing legal advice or improperly assisting a specific party. At a minimum, the AOC should develop resource guides for self-represented litigants or templates for local courts use that include information on requirements surrounding redaction, standardized formats, converting, submitting, and using digital evidence in the court.

4. Other Issues

The SMW was charged with policy questions that focus on what to do once digital evidence is received by the court—the “back end” of the process of digital evidence after it crosses the threshold from parties to the court. Many courts are experiencing self-represented litigants, in cases like small claims or protective order matters, who wish to offer in evidence smart phone photos, recordings, or other digital evidence from portable or home devices that are not reformatted and submitted via a disc. Guidance should be developed for litigants presenting and courts managing this type of evidence.

The SMW recommends that the AOC work with local courts in developing policies and procedures and implementing technological solutions (where feasible) for cases in limited jurisdiction courts to account for the specific needs in such cases. The following areas were identified for consideration:

- **Courtroom recordings.** Many courtrooms are equipped with digital recording devices used to record audio, video, or both. Ideally, digital evidence played in limited jurisdiction courts would be captured and preserved by the court’s digital recording device. Rule changes allowing this in certain cases may be needed.

- **Courtroom presentation.** There needs to be a manner of connecting litigant technology to courtroom technology or otherwise using courtroom technology to capture presentation of digital evidence presented in court by litigants, particularly self-represented litigants, for admission into the record and meeting
evidence retention requirements.

- **Transition to a new digital solution.** The implementation of storage and management solutions for digital evidence will require time for acquisition, implementation, and training on its use. The difficulty will be compounded by the need to timely tackle a fast-approaching problem using new, emerging, and constantly-evolving technology and training court staff and judges on how to use that technology. Information on submitting and presenting digital evidence for litigants, particularly self-represented litigants, is also necessary.

- **Cost recovery.** The cost of new technology is always relevant in this discussion. The SMW recommends establishing a fee, where appropriate and permissible, for submission of digital exhibits. Such a fee could help offset the costs associated with digital evidence storage and management solutions.

### C. Rules Workgroup Report

1. **Discussion**

   The Rules Workgroup (“RW”) addressed the following policy questions:

   - “Should court rules governing public records be revised to address access and privacy concerns, including for victims, non-victim witnesses, and other identifying information often included in video evidence?”[^41]

   - “Should new or amended rules on chain of custody evidence be developed for handling court digital evidence?”[^42]

   In substance, digital evidence is not new or different evidence. Digital evidence involves the same types of evidence courts, attorneys, and parties have always handled. It is the form of the

[^41]: *Supra* note 4.
[^42]: *Supra* note 4.
evidence and media the evidence is produced on that have changed. For instance, reports are no longer printed on paper, photos are no longer chronicled on film, videos are no longer recorded on a Video Home System (“VHS”) tape or digital video disc (“DVD”), and audio recordings are no longer captured on an audio tape or disc. Instead, this evidence is saved and stored in some type of digital format, often one that is stored on a portable device or on a server, either locally or in the cloud.

The most significant issue regarding digital evidence that may necessitate rule changes is volume. The volume of digital evidence will create the need for a significant increase in digital storage capacity and require additional time for redactions, such as that created by body-worn cameras and other footage captured on digital recording devices to protect victims’ rights and citizens’ privacy interests.43

The RW reviewed various Arizona rule sets, including evidence, civil criminal, family and juvenile, probate, protective orders, eviction actions, Arizona Supreme Court Rule 123, as well as rules, statutes, and constitutional provisions involving victims’ rights. The RW also reviewed relevant portions of the ACJA.

This review revealed that current rules overall appear to be working when it comes to disclosure and submission of digital evidence for use at a hearing or trial. As such, the procedural rules do not need wholesale substantive revision to address the increasing use of digital evidence, although a few areas for revision were identified and are discussed below. And although current rules are working, the RW believes the rules need modernization to use language that includes digital media types of today and the future.

The following is a summary of the rule changes recommended by the RW:

1. Defining “Digital Evidence.” The phrase digital evidence should be defined. The following definition was proposed: “Digital evidence, also known as electronic evidence, is any information created, stored, or transmitted in digital format.” This recommendation was later changed to use the phrase “electronically stored evidence,” as used in the Arizona Rules of Civil Procedure

43 See Maury, supra note 7.
for nearly a decade, in various other Arizona rules sets where appropriate, as reflected in a rule change petition filed January 10, 2018.

2. Arizona Rules of Evidence. In addressing the Arizona Rules of Evidence, the focus was on the rules on authentication and identification (Article IX) and the contents of writings, recordings, and photographs (Article X). The Arizona Rules of Evidence do not require any amendments, changes or additions to authenticate or identify digital evidence for use in court proceedings.

Conversely, the language and concepts in Rules 1001 through 1008 do need modernization. In particular, the definition of “recording” is limited to “letters, words, numbers, or their equivalent recorded in any manner.” Although recognizing that the phrase “their equivalent” currently is applied to digital images and video that involve non-verbal action not involving any “letters, words, [or] numbers,” the rules should be updated to include video as a defined term. After considering various definitions of the term and the variety of digital evidence that is not a still image as contemplated by the current definition of the term “photograph,” the following definition was suggested: “Video is an electronic visual medium for the recording, copying, playback, broadcasting, or displaying of audio or moving images,” later refined to “Video is an electronic visual medium for the recording, copying, playback, broadcasting, or displaying of moving images, which may or may not contain an audio recording.” Rules 1002, 1004, 1006, 1007, and 1008 should be amended to insert the newly defined term video.


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44 Given amendments effective January 1, 2012, as applicable here, the Arizona Rules of Evidence “correspond to the Federal Rules of Evidence as restyled.” ARIZ. R. EVID. Prefatory Comment to 2012 Amendments.
45 ARIZ. R. EVID. 901–903.
46 Id. 1001–1008.
47 Id. 1001(b).
48 See id.
49 ARIZ. R. EVID. 1001(c).
During the workgroup’s consideration, a rule petition was pending before the Arizona Supreme Court that would significantly change many of the civil rules surrounding discovery and disclosure. After review of the rules in place and the pending rule petition, and given the change in recommendation from defining “digital evidence” to using the phrase “electronically stored information,” the RW determined that the Arizona Rules of Civil Procedure thoroughly address digital evidence, particularly the disclosure and discovery rules (Article V).

4. Arizona Rules of Criminal Procedure. The Arizona Rules of Criminal Procedure, including Rules 15.1, 15.2, 15.4, 15.5 (disclosure rules), and Rule 22.2 (materials used during jury deliberation), were considered to determine if any changes were needed to address the handling of digital evidence. Currently, the disclosure rules do not appear to be causing any challenges in relation to the disclosure of digital evidence, despite there not being language that specifically includes disclosure of materials or information that exists in a purely digital format. As the use of digital evidence increases, its disclosure via electronic means will increase and, correspondingly, its disclosure on a tangible item (like a disc or in a physical format like paper) will decrease. The RW notes that Rules 15.1 and 15.2 do not contain language that includes video, digital evidence, or other electronically stored information. Accordingly, the RW recommends that Rules 15.1 and 15.2 be amended to include language specifically identifying disclosure of digital evidence, later refined to electronically stored information. A similar amendment was later recommended for Rule 15.3.

The RW reviewed language that, in 2017, required disclosure of “a list of all papers, documents, photographs and other tangible objects.” The increase in digital evidence, such as body-worn...
camera video and digital video, images, or other content from smart phones or other personal recording devices, is not accounted for in the specific language of the rules. The RW notes that, particularly as disclosure of the evidence moves toward a cloud-based model, the rules need modernization.

Rule 22.2 addresses materials that may be used during jury deliberations. The rule refers to “tangible evidence as the court directs,” with no mention of evidence that is in a purely digital form, such as admitted evidence that has not been transferred to a tangible physical thing like a disc. Currently, in Arizona, digital evidence is submitted and admitted for trial after being transferred to a tangible item. However, digital evidence is increasingly cloud-based, and disclosure of that evidence is increasingly becoming possible via cloud-based file sharing.

For example, prosecutors and law enforcement officers in some locations use a digital drop-box to transfer or disclose digital evidence to the defense. Another example is body-worn camera manufacturer Axon’s (formerly Taser International) deployment of a cloud-based portal (evidence.com) to allow cloud sharing between law enforcement agencies and prosecutors, and its ongoing development of cloud-based disclosure between prosecutors and defense counsel. This expansion of cloud-based sharing of digital evidence is quickly coming to courts. If Arizona were to adopt rules and procedures for allowing cloud-based submission and admission of digital evidence, then Rule 22.2(d) would require amendment to account for both tangible and cloud-based evidence.

5. **Arizona Rules of Family Law Procedure.** The RW recommends that Rule 49 be changed to include a subsection on

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54 See id.
55 Ariz. R. Crm. P. 22.2(d).
56 Id.
electronically stored information. Several subsections of Rule 49 refer to disclosure and discovery of such information.\textsuperscript{58} As currently written, Rule 49 does not, however, provide guidance for parties regarding their duty to confer about the form in which the information will be produced or resolution of disputes related to disclosure or discovery of electronically stored information.\textsuperscript{59} As property records and financial records are increasingly available via the Internet and as more and more people manage finances electronically, having guidelines and procedures in place for managing this type of discovery will be increasingly beneficial to parties and the courts.

The RW also recommends that a task force currently addressing the Arizona Rules of Family Law Procedure consider the amendments to the updated Arizona Rules of Civil Procedure to ensure digital evidence is expressly addressed in that rule set.

6. Arizona Rules of Protective Order Procedure. Increasingly, persons seeking orders of protection and injunctions against harassment come to court with some form of digital evidence to demonstrate to the court the need for the protective order. Rule 36, addressing admissible evidence in contested protective order hearings, should be modernized to include digital and electronic evidence specifically, when the truly digital evidence concept is adopted in Arizona.

7. Arizona Rules of Probate Procedure. The Arizona Rules of Probate Procedure incorporate by reference Rules 26-37 of the Arizona Rules of Civil Procedure.\textsuperscript{60} As such, the Arizona Rules of Probate Procedure address electronically stored information; therefore, no amendments are recommended. The Arizona Rules of Probate Procedure are heavily driven by statutory requirements. If statutory changes occur in the future, then rule changes would need to follow. Future rule changes should keep in mind the changing landscape of digital evidence and its role in legal proceedings.

8. Arizona Rules of Juvenile Court. The current disclosure and

\textsuperscript{58} ARIZ. R. FAM. L.P. 49(E)(2), (E)(5), (E)(6), (F)(1).
\textsuperscript{59} See id.
\textsuperscript{60} ARIZ. R. PROB. P. 28(B).
discovery rules do not include any reference to digital or electronic evidence. Despite the lack of such specificity, the rules currently appear to work. However, considering the increasing volume of digital evidence, including in delinquency matters, as with adult criminal matters, an amendment that would modernize the language of the rule is recommended.

For these reasons, changes should be made to Rules 16(B)(1)(d), 16(C)(3)(c), 44 and 73 of the Rules of Juvenile Court to include reference to digital and electronic evidence, later refined to electronically stored information.

9. Arizona Justice Court Rules of Civil Procedure. Arizona Justice Court Rules of Civil Procedure, particularly Rules 121-127, appear to adequately address electronically stored information and digital evidence. This rule set both directly addresses electronically stored information and incorporates some of the Arizona Rules of Civil Procedure that similarly address disclosure and discovery of such information.\(^{61}\) Moreover, although not using the phrase “digital evidence,” Rule 125(a) references “electronically stored information.”\(^{62}\) No changes are recommended to this rule set.

10. Arizona Rules on Eviction Actions. The Arizona Rules on Eviction Actions do not need substantive changes to address digital evidence. However, an amendment should be made to include digital evidence or electronically stored information in Rule 10, which addresses the types of content that must be disclosed.

2. The ACJA.

The ACJA is an excellent framework for requirements pertaining to digital evidence. The Digital Formats and Storage and Management Workgroups were tasked with policy questions more directly aligned with the ACJA provisions that address digital evidence. Throughout its review, the RW provided input and feedback to those workgroups as they reviewed ACJA sections. The RW has no recommendations beyond those made by the Digital


\(^{62}\) \textit{E.g.}, \textit{Ariz. Justice Ct. R Civ. P.} 125(a).
Formats and Storage and Management Workgroups. The following describes the thought processes regarding relevant ACJA sections and any overlap with procedural rules discussed above.

The ACJA provides standards that apply to all records imaged by courts, including methods used to create or reproduce records electronically. The ACJA designates the methods and formats that must be used to maintain and preserve electronically stored and archived records and the reproduction of such records. The ACJA also covers general requirements for security to ensure evidence is not destroyed or altered and addresses accessibility. Courts must ensure that the public is afforded reasonable access to records via the public access portal managed by the AOC, at a minimum. Further, courts are required to ensure records sealed or designated confidential by rule, law, or court order contain appropriate metadata to enable any electronic document management system in which they reside to protect them from inappropriate access.

The ACJA provides standards for filing and management of electronic court documents, expressly stating it “provides administrative requirements, standards and guidelines to enable Arizona courts to implement a uniform, statewide, electronic filing system and to achieve the reliable, electronic exchange of documents within the court system as well as between the court and court users.” The ACJA also provides standards for the protection of electronic case records. These provisions address most types of digital evidence, including formatting and authentication of such evidence. Two ACJA sections provide standards addressing accessibility to digital court records, which would include digital evidence, both of which address the ability to access court records remotely.

In summary, the RW does not have recommendations, independent from those of the other workgroups, regarding changes

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64 Id.
65 Id.
67 Id.
69 Id. at § 1-506(B).
70 See id. at § 1-507.
3. Privacy and Digital Evidence.

Victims have concerns regarding privacy in the digital age that differ significantly from the issues faced by courts and attorneys. Crime victims are pulled into the inner workings of the criminal justice system by the unlawful acts, often physically and emotionally harmful, of others. In addition, victims’ knowledge of the criminal justice system and the courts, understandably, may be limited. It is not uncommon for victims to become increasingly concerned with privacy, especially as it relates to images and information captured via digital devices like body-worn cameras, cell phone video, digital photographs of injuries, crime scenes, and autopsies. Particular sensitivity surrounds the public’s ability to obtain this digital evidence through court filings, evidence received in court, and the record of court proceedings more generally.

Arizona’s Victims’ Bill of Rights guarantees crime victims a right to justice, due process, and to be treated with fairness, respect, dignity, as well as to be free from intimidation, harassment, and abuse. The open records policies applicable in Arizona’s courts may cause victims concern.

The Arizona Supreme Court has enacted rules related to victims’ rights. For example, the Arizona Rules of Criminal Procedure provide an avenue for victims to seek protection of their identity and location. This provision is cross-referenced in several rules related to discovery and disclosure, including consideration of victims’ rights in broadcasting trials and limiting public access to court records when confidential or sensitive information is involved and where access is otherwise restricted by statute.

An increased use of digital evidence may result in an increase in public requests, including media requests, for access to such digital evidence which, in turn, may implicate victims’ rights and privacy concerns. In addition, although the various rules mentioned above currently work to protect victims’ rights, victims continue to

73 See Ariz. R. Crim. P. 39.
74 See Ariz. Sup. Ct. R. 122, 123.
advocate for additional protections.

For rules governing public records, which implicate access and privacy concerns, Arizona appears to treat digital evidence like traditional evidence, and current policies and procedures applicable to all types of evidence, including digital evidence, are working. However, the rule does not consistently address digital evidence, including exhibits, received by a court.\textsuperscript{75} The RW recommends that this rule be amended to ensure that it addresses digital evidence, including exhibits, and that the portions of the rule that govern public access, particularly remote electronic access, be amended to ensure sufficient protection of victims’ rights and privacy concerns.

A related issue is that digital evidence regularly, but incidentally, captures images of individuals and their property, including personal identifying information. Often this information and these images are captured in public places where individuals do not have privacy rights as parties or victims. The ease of using facial recognition software or access to databases that may lead to identification of these individuals may create concerns regarding expectations of reasonable anonymity. Moreover, such information is not relevant to why the digital evidence is being offered in a specific matter and may be concerning to bystanders, given issues of safety, identity, contact information, etc. Therefore, it is recommended that the AOC (a) work with local courts, prosecuting and defending agencies, law enforcement groups, media organizations, and other interested individuals and organizations to develop consistent policies and approaches addressing these issues, and (b) consider how to handle un-redacted digital evidence being introduced in evidence by self-represented litigants.

\textsuperscript{75} See ARIZ. SUP. CT. R. 123.
THE STATE DEPARTMENT CAN GUN DOWN 3-D PRINTED FIREARMS

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http://digital.law.washington.edu/dspace-law/handle/1773.1/1789

ABSTRACT

In 1976, Congress enacted the Arms Export Control Act (“AECA”), giving the President broad power to control imports and exports of defense articles. At the time, defense articles included any “technical data” relating to weapons, such as the manufacturing blueprints of a firearm. Generally, this technical data was only in the hands of weapon manufacturers. After forty years of technological advances, however, this “technical data” can now be accessed by anyone in the world in a matter of seconds. Thanks to 3-D printing, a person can use this data to personally manufacture a fully functional plastic weapon within a few hours, for just a few hundred dollars. This same plastic weapon could slip past an airport security metal detector without triggering an alarm. Within a few minutes, a user could melt the weapon down to destroy any evidence of its use.

This article explores the limits that the First and Second Amendments place on regulating 3-D printed weapons. Additionally, this article explores how the current regulations would pass a Constitutional challenge based on the First or Second Amendment.

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INTRODUCTION

Technological advances have given rise to a new industrial age: 3-D printing. With 3-D printing, people can make parts for all sorts of products with the touch of a button.\(^1\) 3-D printing has removed the skill and expertise typically required for manufacturing, allowing anyone with a computer and 3-D printer to produce a part in the comfort of their home.\(^2\) The flexibility and low cost of 3-D printing has led to many improvements in society, such as in the medical field where custom made 3-D printed casts can be perfectly

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2. *Id.*
fitted to a patient’s body.³

While many consider the changes brought on by 3-D printing to be beneficial, some advances are more controversial, such as 3-D printed firearms.⁴ In 2013, Cody Wilson of Defense Distributed fired the first gun made from nearly all 3-D printed parts.⁵ Within a few weeks, Defense Distributed posted the design model online, which was downloaded over 100,000 times in two days.⁶ The model allowed anyone in the world with the right 3-D printer to create a fully functional firearm within a few hours.⁷

Concerned over regulatory issues, the State Department quickly stepped in and required the model be immediately taken offline.⁸ The State Department asserted that Defense Distributed needed a license under the International Traffic in Arms Regulations (“ITAR”) to be able to post their gun models online for download.⁹

Defense Distributed contested the State Department’s position and argued that the State Department infringed on two discrete Constitutional rights.¹⁰ First, Defense Distributed believed the model available online was speech, and thus, the State Department

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⁴ Adam Gabbatt, Shots fired from world’s first 3D-printed handgun, GUARDIAN (May 6, 2013), https://www.theguardian.com/world/2013/may/06/3-handgun-fired-cody-wilson.
⁵ Id.
⁷ See id.
⁹ See id.
restrictions had to overcome a First Amendment challenge. Second, Defense Distributed believed the State Department’s restrictions improperly regulated guns for American citizens, and thus, implicated the Second Amendment.

This article explores the arguments of both Defense Distributed and the State Department. First, this article examines the background behind 3-D printed firearms. Second, the article explores the case law on First and Second Amendment challenges as they relate to 3-D printed firearms. Third, the article explores the State Department’s arguments that its regulations were constitutionally sound, and how the State Department’s regulations overcame the First and Second Amendment challenges. Finally, the article discusses whether the current regulations are adequate, or if they need to be expanded.

I. BACKGROUND

A. The Basics of 3-D Printing

3-D printing is an additive manufacturing process that creates three-dimensional solid objects from a digital file. The printer creates an object by repeatedly laying down successive layers of material. Each successive layer is a cross-section of a three-dimensional digital object. The object is finished when the printer lays down every cross-section.

To print an object, users must first create or download a three-dimensional model of the desired object she would like to print. These three-dimensional models are known as computer-aided design models, or CAD models. Next, the CAD model needs to be prepared for printing by determining each layer needed for

11 Id.
12 Id.
13 What is 3D printing?, supra note 1.
14 Id.
15 Id.
16 Id.
17 Id.; see generally https://grabcad.com/library/software/solidworks for a website that offers CAD files.
18 Id.
printing. Once the model is prepared and uploaded, the printer begins laying down material.

B. What it Takes to Print the Liberator

The Liberator is the first fully functional pistol assembled from nearly all 3-D printed parts. Only two out of eighteen parts are not plastic, which is for functionality and legal reasons. The creator of the Liberator, Cody Wilson, uploaded a printable CAD model of the pistol online, along with instructions for how to assemble the pistol. With the CAD model online, all that is required to make the gun is a 3-D printer, 3-D printing ink, a firing pin, and the downloaded model. To make the gun legal, the design also requires placing a six-ounce steel block into the trigger guard so the gun comports with The Undetectable Firearms Act of 1988.

C. Benefits of 3-D Printed Firearms

Creating firearms with a 3-D printer lowers the access barrier to obtaining a gun. Prior to 3-D printing, a person looking to build their own firearm from scratch would need to know how to use the

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19 Id.
20 Id.
22 Id.
23 Sebastian Anthony, The Liberator: The first downloadable 3D-printed gun gets test fired, EXTREME TECH, https://www.extremetech.com/extreme/155084-the-liberator-the-first-downloadable-3d-printed-gun-gets-test-fired (last visited Jan 2, 2017) (pending litigation, the design has been removed from online).
machinery required for gunsmithing, like a mill or lathe. But with 3-D printing eliminating the difficulty to “machine” parts for a firearm, a person now needs only to know how to download and print a file on a 3-D printer to own a gun.

3-D printing firearms are also opening the door to technological innovation. To some, 3-D printed weapons seemed like science fiction a few years ago. Now that the first 3-D printed weapons have arrived, people are beginning to ask where else this technology can take us. Allowing 3-D printed weapons to continue to grow unrestricted may cause others to push the boundaries of this technology through further development and innovation.

D. The State Department’s Concerns with 3-D Printed Firearms

The State Department’s concerns surrounding 3-D printed firearms stemmed from what Cody Wilson believes is one of the greatest benefits of the technology: lowering the access barrier to owning a gun. Placing the designs online allows anyone with an internet connection and 3-D printer to download the files and begin manufacturing weapons. While this technology improves access to firearms, critics focus on the fact that these weapons can be manufactured in a way that allows for the weapon to be undetectable by conventional security measures. This scenario could allow a person to sneak past an airport security checkpoint with a gun intact.

The State Department is concerned not only with the

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27 Id.
28 Id.
29 Clay Dillow, supra note 26.
30 Andy Greenberg, This is the world’s first entirely 3D-Printed gun, FORBES, http://www.forbes.com/sites/andygreenberg/2013/05/03/this-is-the-worlds-first-entirely-3d-printed-gun-photos/#39038c816c18 (last visited Jan 2, 2017).
31 Clay Dillow, supra note 26.
32 See id.
34 Id.
35 Id.
36 See id.
implications 3-D printed weapons will have in the United States, but also in countries abroad. The State Department has stated that 3-D printed CAD models of firearms are “defense articles” and placing a downloadable model online is an act of exporting the model abroad. With Congress granting the President authority to regulate firearm exportation, the State Department believes anyone who wants to place CAD models of a firearm online will first need an export license.

II. INFRINGEMENT OF RIGHTS

The regulation of 3-D printed firearms implicates First Amendment rights. Congress granted the President authority to regulate the export of defense articles and services with the Arms Export and Control Act. These defense articles could include 3-D printable CAD models of firearms, which is where the free speech issues arise. Restricting CAD models from being spread arguably restricts speech, as CAD models are a form of technical information. Section A will explore the First Amendment’s protective reach into 3-D printed firearms.

Second Amendment rights are also implicated when attempting to regulate 3-D printed firearms. Individual rights for gun ownership were established in District of Columbia v. Heller and McDonald v. Chicago. However, with 3-D printed firearms emerging shortly after these decisions, the law has yet to clarify the extent of the individual rights as applied to 3-D printed weapons. Section B will explore the Second Amendment’s protective reach into 3-D printed firearms.

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37 See id. at 17.
38 Id. at 13.
39 Id.
42 562 U.S. 742 (2010).
A. First Amendment

The First Amendment protects different types of expressions from regulation by the government.\(^{44}\) Regulations may violate the First Amendment in primarily two ways: by involving content-based restrictions or prior restraints.\(^{45}\) Regulations that impose these restrictions or restraints must pass strict scrutiny in order to be upheld.\(^{46}\)

Content-based restrictions prevent the government from restricting expression based on message, ideas, or content.\(^{47}\) These restrictions prevent the government from prohibiting the exchange of specific ideas or viewpoints in the marketplace.\(^{48}\) To avoid viewpoint discrimination, government regulations must be content-neutral.\(^{49}\)

Regulations are content-neutral when both the viewpoint and subject matter restrictions are neutral.\(^{50}\) Viewpoint neutrality requires that the restriction cannot be aimed at a particular view expressed.\(^{51}\) Subject matter neutrality prohibits regulations based on a topic of the speech.\(^{52}\) A law is content-neutral if it applies to all speech regardless of the message being conveyed.\(^{53}\) Content-neutral laws are generally subject to an intermediate scrutiny test.\(^{54}\)

What actions constitute a prior restraint is not completely clear.\(^{55}\) Generally, prior restraints on speech are a government order.

\(^{44}\) U.S. CONST. amend I.
\(^{47}\) See Police Dep't of Chicago v. Mosley, 408 U.S. 92, 95–96 (1972).
\(^{50}\) See id.
\(^{54}\) See id.
\(^{55}\) See, e.g., CHEMERINSKY ERWIN, CONSTITUTIONAL LAW: PRINCIPLES AND
that forbids a specific communication before the communication is made.\textsuperscript{56} However, even if a government order restricts a message before a person can bring that message, courts seem to shy away from calling the restriction a prior restraint, if the person can bring that message in another forum.\textsuperscript{57} Regardless, prior restraints on speech are the most serious and least tolerable infringements on First Amendment rights.\textsuperscript{58} Any system deemed a prior restraint of expression has a heavy presumption against its constitutional validity.\textsuperscript{59}

A classic example of prior restraint is a government licensing scheme that prevents speech from taking place prior to obtaining a license.\textsuperscript{60} In order for licensing schemes to pass a constitutional challenge, the government must have an important reason for licensing, clear standards that virtually eliminate government discretion, and certain procedural safeguards to mitigate the danger of censorship.\textsuperscript{61}

Regulating 3-D printed firearms implicates First Amendment protections due to the Arms Export and Control Act of 1976.\textsuperscript{62} This act gives the President authority to regulate exports of defense articles.\textsuperscript{63} Through the International Traffic in Arms Regulations (“ITAR”), the President delegated his authority to the Deputy Assistant Secretary of State for Defense Trade Controls.\textsuperscript{64} Under ITAR, any item deemed a defense article cannot be exported without a license.\textsuperscript{65} Exporting a defense article includes transmitting the article outside of the United States in any form.\textsuperscript{66} If the Deputy Assistant Secretary of State for Defense Trade Controls determines 3-D CAD models for firearms are defense articles under ITAR,

\begin{thebibliography}{9}
\bibitem{57} See \textit{e.g.}, \textit{Madsen v. Women’s Health Center}, 512 U.S. 735 (1994).
\bibitem{60} \textit{City of Lakewood v. Plain Dealer Publ’g Co.}, 486 U.S. 750 (1988).
\bibitem{61} \textit{Masero}, \textit{supra} note 45, at 1302.
\bibitem{63} Id.
\bibitem{64} 22 C.F.R. § 120.1.
\bibitem{65} 22 C.F.R. § 120.6.
\bibitem{66} 22 C.F.R. § 120.17(a)(1).
\end{thebibliography}
anyone wishing to publish the files online would need to first obtain
an export license. Thus, the First Amendment is implicated at two
points: designating the CAD models as defense articles and
requiring a license to publish the models online.

Though arguments can be made that ITAR’s effects on speech
are content-based restrictions, ITAR’s effects on 3-D printed
firearms will likely be scrutinized as a content-neutral restriction.
ITAR’s regulations center on controlling weapon exports; these
regulations are not centered on controlling aspects of speech.

Regulations that target conduct but incidentally impinge on speech
are required to pass the O’Brien Test set forth in United States v.
O’Brien. Each of ITAR’s regulations will be justified if, under the
O’Brien Test: (1) it is within the constitutional power of the
Government; (2) it furthers an important or substantial
governmental interest; (3) the governmental interest is unrelated to
the suppression of free expression; and (4) the incidental restriction
on First Amendment freedoms is no greater than is essential to the
furterance of that interest.

In addition to the content-based challenge, ITAR regulations
may also have to pass a prior restraint challenge due to the licensing
scheme. If deemed a prior restraint, the licensing scheme must serve
an important governmental interest, virtually eliminate official
discretion, and provide procedural safeguards against censorship
to survive a constitutional challenge.

B. Second Amendment

In District of Columbia v. Heller, the Court held that a ban on
possessing a handgun at home was a violation of the Second
Amendment. Shortly after Heller was decided, the Court applied

67 See id.
68 See Bernstein v. U.S. Dep't of State, 945 F. Supp. 1279, 1288 (N.D. Cal.
1996).
69 See United States v. Chi Mak, 683 F.3d 1126, 1135 (9th Cir. 2012).
70 See generally 22 C.F.R. § 120.
72 Id.
73 554 U.S. at 635.
the same standards set forth in *Heller* to the states.\(^74\) These cases stand for the proposition that the Second Amendment protects an individual’s right to own a firearm.\(^75\)

Nevertheless, while there is a right to possess a handgun, this is not an unrestricted right.\(^76\) The Constitution allows for regulating guns, so long as the regulations do not become an absolute ban on weapons used for self-defense in the home.\(^77\) Thus, it is possible for a law regulating 3-D printed firearms to pass a Second Amendment challenge.\(^78\)

Although the Supreme Court did not set forth a constitutional test for laws challenged under the Second Amendment, the federal courts of appeals have generally been uniform in their approach to a challenge.\(^79\) Regulations that are deemed longstanding are presumed not to infringe on Second Amendment rights.\(^80\) Regulations that do not severely restrict the core right of self-defense are subject to intermediate scrutiny.\(^81\) Regulations that severely restrict the core right of self-defense are subject to strict scrutiny.\(^82\)

In the case of 3-D printed firearms, regulations limiting access to the CAD models for printing will likely be subject to intermediate scrutiny. As people can still acquire other guns to protect themselves inside a home, regulating 3-D printed firearms will not severely restrict the core right of self-defense. Yet, these regulations will not be deemed longstanding. Because any regulation would not restrict the core right of self-defense and would not be longstanding, a challenge would be subject to intermediate scrutiny. Thus, these regulations will pass a challenge under the Second Amendment if the regulations further an important governmental interest and the means are substantially related to that interest.\(^83\)

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\(^74\) See *McDonald*, 561 U.S. at 750.
\(^75\) See *Heller*, 554 U.S. at 577.
\(^76\) See *id.* at 636.
\(^77\) *Id.*
\(^78\) See *id.* at 636.
\(^80\) *Id.*
\(^81\) *Id.*
\(^82\) *Id.*
III. The State Department’s Defenses

The State Department advanced a number of different arguments denying their licensing scheme infringes on First and Second Amendment rights. This section discusses those arguments advanced on appeal in the Fifth Circuit.

A. The First Amendment Defenses

The State Department first asserted its regulations avoid content-based restrictions and prior restraint issues altogether. The State Department claimed these regulations do not target the ability to express ideas, but rather apply only because the computer files at issue direct a computer to produce firearm components. In other words, there was no expression taking place because the computers were exchanging information that the user never saw. Because this content is never examined by a user, the State Department believed a First Amendment assertion was misplaced.

If the court disagreed and were to find a prior restraint due to the licensing scheme, the State Department asserted its scheme properly met the required standards. First, the State Department asserted that preventing firearm exports from falling into the wrong hands by using a licensing scheme is an important governmental interest. Next, the State Department asserted there is no ambiguity in the licensing scheme that would lead to undue discretion on behalf of the State Department. The statute at issue describes the scheme in plain and objective terms, which would offer no room for discretion. Finally, the State Department argued the licensing

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84 See Brief for Appellees at 13, Defense Distrib v. United States Dep’t of State, 838 F.3d 451 (5th Cir. 2016) (No. 15–50759), 2016 WL 614088 at *13.
85 Id. at 14.
86 Id.
87 See id.
88 See id. at 14–15.
89 See id. at 14.
90 Id. at 15.
91 Id.
scheme does not censor the dissemination of scientific ideas.\textsuperscript{92} The State Department asserted the regulations contain exceptions that allow for scientific discourse.\textsuperscript{93} The State Department further asserted that these exceptions were unnecessary because there is no dissemination of ideas between two people, but rather, two computers.\textsuperscript{94}

\section*{B. The Second Amendment Defenses}

The State Department argued its regulations do not implicate the Second Amendment.\textsuperscript{95} The State Department claimed “nothing in the statute or regulations prevents American citizens from obtaining [CAD] files. . .”\textsuperscript{96} This claim is centered on the current licensing procedures, which are in place to prevent foreigners from gaining access to firearm blueprints. By denying foreigners access to 3-D printed firearms, this procedure does not stand in the way of American citizens getting access to the firearms, nor does the procedure severely impair any core right of self-defense.\textsuperscript{97} Thus the State Department believed any Second Amendment challenge was misplaced.\textsuperscript{98}

Arguing in the alternative, if the Second Amendment is implicated, the State Department asserted the government has an important interest in the export licensing scheme, and that restrictions upon this scheme were justified intrusions on the Second Amendment.\textsuperscript{99} The State Department argued the license restrictions did not impose a burden on anyone from using a handgun in defense of their home.\textsuperscript{100} With their interest in regulating arms exports, the State Department contended this interest combined with a very
modest reach into the Second Amendment would pass a challenge under the Second Amendment.\textsuperscript{101}

IV. THE STATE DEPARTMENT’S RESTRICTIONS DO NOT VIOLATE THE FIRST AND SECOND AMENDMENT

The Fifth Circuit did not rule on the merits of the State Departments arguments.\textsuperscript{102} However, the Fifth Circuit specifically noted the legal questions presented by the parties were novel, and that the trial court will have to address these questions on remand.\textsuperscript{103} This section covers how the State Department’s arguments will hold up against First and Second Amendment challenges.

\textit{A. The State Department’s Restrictions Likely Pass a First Amendment Challenge}

Though the State Department’s licensing scheme would struggle to pass a prior restraint test under strict scrutiny,\textsuperscript{104} the current licensing scheme will likely avoid being deemed a prior restraint. ITAR’s regulations do not forbid CAD models from being shared or discussed – the regulations only forbid the models from being exported. In this sense, the licensing scheme doesn’t require state approval before any speech takes place; the licensing scheme restricts only one avenue through which the discussion can take place. Courts have been hesitant in the past to call schemes a prior restraint when there are other avenues where the speech can take place. As such, the State Department will likely overcome a prior restraint challenge.

The next challenge the regulation will have to pass is the O’Brien Test. Here, the government has the constitutional power to regulate the exports of firearms. There are a number of important governmental interests being advanced with this regulation, such as national security and complying with treaties. These interests are

\textsuperscript{101} See \textit{id}. at 40.
\textsuperscript{102} Defense Distrib v. United States Dep’t of State 838 F.3d 451, 461 (5th Cir. 2016).
\textsuperscript{103} Id. 461.
\textsuperscript{104} See New York Times Co., 403 U.S. at 714 (invalidating a prior restraint on speech despite the national security concerns advanced by the government).
unrelated to suppressing speech and any incidental restriction on speech is no greater than what is essential to the furtherance of the interest. Thus, the regulation will pass the O’Brien Test and a First Amendment challenge.

B. The State Department’s Restrictions Pass a Second Amendment Challenge

The State Department’s restrictions will pass a Second Amendment challenge. Despite the State Department’s contentions, the licensing scheme implicates the Second Amendment. However, because the licensing scheme does not target the core right of self-defense in the home, the scheme will only have to survive an intermediate scrutiny test. The governmental interest in national security will be more than enough to pass an intermediate scrutiny test. Thus, a Second Amendment challenge will not bar the licensing scheme.

V. ARE THESE REGULATIONS ENOUGH?

If the ITAR regulations withstand a Constitutional challenge, questions about whether these regulations are doing enough will remain. Currently, Defense Distributed is barred from posting the CAD models online. While online download is likely the preferred way to access the model, it is not the only way. Theoretically, people can still gain hard copies of the model through offline sources. Furthermore, it likely won’t be long before Defense Distributed obtains a license, allowing them to post the model online. Thus, many of the original concerns people had about this weapon are still present and unaddressed.

For now, it seems many of these concerns are being exaggerated. At this stage, the 3-D printed pistol itself is still somewhat primitive – in many cases the weapon can only fire one round before becoming unusable. In addition, 3-D printed technology is still not far enough along to massively lower the access barrier to a firearm. 3-D printers are still fairly expensive and require some advanced knowledge on how to operate them. Because of where 3-D printing technology is at today, leaving the current regulations as they are will not cause the widespread issues that many fear.
However, 3-D printing technology is rapidly growing. Costs of printers are decreasing. It is possible to 3-D print metal, instead of plastic. Engineers are constantly improving upon previous designs. Though the technology does not yet exist, it may not be long before 3-D printed weapons are just as common as weapons manufactured in a factory. Regulations will have to change to match the changing landscape.

CONCLUSION

While there are First and Second Amendment concerns about ITAR’s regulations, the State Department regulations will likely pass a constitutional challenge. Though this seems like a victory for those who want more gun regulations, it won’t be long before these weapons are back online and available for anyone to download. The concerns that many have about 3-D printed weapons still have yet to be fully addressed. If these concerns are to be put to rest, more regulations will be needed.

PRACTICE POINTERS

- If a court does not deem ITAR’s regulations as a prior restraint, the government can likely avoid First Amendment issues when regulating 3-D printed weapons
- 3-D printed weapons are still an obscure way for people to own a weapon. Until this process becomes more mainstream, regulating 3-D printed weapons will not violate the Second Amendment.