



## Winter 2020

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## **PRESIDENT'S PODIUM**

### **Focus on Law Students**

This year, the FBA-NDOH is making a concerted effort to reach out to the law students in the Northern District of Ohio and build our membership base. Our District is fed by four law schools: Case Western Reserve School of Law ("CWRU"), Cleveland Marshall College of Law ("CML"), University of Akron School of Law and University of Toledo College of Law.

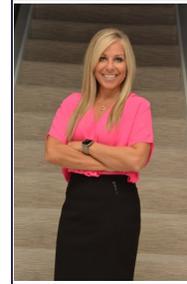
We are so fortunate that student membership in the Federal Bar Association ("FBA") is currently sponsored by our partner, Stout Risius. Thus, membership in the FBA is free to our student members and extends into their first year of practice.

A new development in recent years at the FBA has been the creation of student chapters across the country. In the past, law students participated in the FBA on their own, as an activity outside the law school. We are proud to announce that we are joining that movement. For the first time ever, two of our four law schools, CWRU and CML, have implemented student chapters of the FBA (special thank you to Jonathan Entin and Michael Borden). The student chapters, although autonomous, will operate under the arm of the Northern District Chapter. Each student chapter will have its own officers and activities but will also be included in the activities of the Northern District Chapter.

One of the main objectives in creating the student chapters is to further a more invested student membership. Our goal for the student chapters is to help foster a smooth transition from law students to practitioners.

To that end, this year, our Mentoring Program will work with the Young Lawyer's Section to put together programming and events to include the student members. The aim is for the student chapter members to have established relationships with practitioners in our Northern District Chapter upon graduation and for those relationships to endure.

Help us to continue to grow our Chapter and keep the FBA strong. For the experienced practitioners, please consider signing up to be a mentor to one of our student members. If you're young or newer lawyer, get involved in our effort. Help us bridge the generational gap with the student members and show them the value of FBA membership.



Deneen LaMonica  
FBA-NDOH President  
Zicarelli & Martello  
[www.zicarelliandmartello.com](http://www.zicarelliandmartello.com)

## Members in the News

By: Matt Barkett, Dix & Eaton

### Federal Bar Association Chapter Installs New Officers

CLEVELAND, OH—The Federal Bar Association—Northern District of Ohio Chapter, recently installed new officers and directors during a ceremony at the Carl B. Stokes US Court House in Cleveland. The new officers are:

- President: Deneen LaMonica, Zicarelli & Martello
- President Elect: Erin Brown, Robert Brown LLC
- Vice President: Derek Diaz, Federal Trade Commission
- Secretary: Hon. Amanda Knapp, Social Security Administration
- Treasurer: Brian Ramm, Benesch, Friedlander, Coplan & Aronoff, LLP

Deneen LaMonica is an experienced trial attorney in the Cleveland Office of Zicarelli & Martello. Her practice focuses on personal injury, business litigation, privacy claims and white-collar crimes. She has been practicing law since 2001 and has been featured as a top Ohio attorney on the ratings system Super Lawyers since 2017. She serves as a member of the Federal Bar Association, the Cleveland Metro Bar Association, the Justinian Forum and most recently, the Cleveland Academy of Trial Attorneys. LaMonica is the former president-elect of the Federal Bar Association-Northern District of Ohio Chapter.

Erin Brown is a partner at Robert Brown LLC, an immigration law firm in downtown Cleveland. Brown provides legal assistance for immigration matters including employment, family, adoption, removal and citizenship. She is a member of the American Immigration Lawyers Association and the William K. Thomas Inn of Court and trustee for the Cleveland Marshall Law Alumni Association. Brown has been featured in several publications, authoring several articles on topics ranging from citizenship to international adoption. Brown earned her juris doctorate from Cleveland Marshall School of Law where she graduated magna cum laude.

Derek Diaz, former secretary of the Federal Bar Association-Northern District of Ohio Chapter, is an attorney in the Cleveland office of the Federal Trade Commission [FTC]. His practice involves the pursuit of judicial and administrative actions against people and entities that violate the consumer-protection laws that the FTC is charged with enforcing. Diaz also serves as a judge advocate in the United States Navy Reserve. Diaz previously worked as a litigation partner at Hahn, Loeser & Parks, LLP; a law clerk to the Honorable Arthur I. Harris, United States Bankruptcy Court for the Northern District of Ohio; and as a judge advocate in the United States Marine Corps. He graduated from the Moritz College of Law at The Ohio State University.

Hon. Amanda Knapp serves as an Administrative Law Judge for the Social Security Administration. Prior to her current position, she practiced as a business litigator with the law firm Roetzel & Andress. She also served as a law clerk to U.S. District Court Judges Margaret Morrow and Garland Burrell. She is the former vice president of the Federal Bar Association-Northern District of Ohio Chapter. Judge Knapp earned her juris doctorate degree from Harvard Law School.

Brian Ramm provides legal assistance for the national defense of pharmaceutical companies in federal and state courts. His other areas of practice also include product liability, medical malpractice, toxic tort defense and personal injury claims. Ramm has been featured on the ratings system Super Lawyer since 2012. He was also rated AV Preeminent® by Martindale-Hubbell®. Ramm was elected to the Best Lawyers in America and awarded their Lawyer of the Year designation in 2018 for product liability defense in Cleveland.

## Members in the News



Effective January 1, 2020, Steve Jett opened a new law office, Jett Law LLC, having decided to now pursue his long-standing dream of owning his own practice. Steve will continue to practice in civil litigation, among other areas. Steve's new email is [sjett@jett.law](mailto:sjett@jett.law), and his phone number is 440-821-8515. His website is [www.jett.law](http://www.jett.law). Steve has been rated in Best Lawyers in America since 2014, and a Super Lawyer since 2013. Steve is also rated in Martindale-Hubbell with an AV (Preeminent) Peer review rating. Steve has 30 years of experience, practicing partner-level work at two large law firms. Previously, Steve was a litigation partner at Taft Stettinius & Hollister LLP and a litigation partner at Ulmer & Berne LLP. In his new role, Steve can handle varied and diverse matters of all sizes, large or small, in a cost-effective manner. We wish Steve all the best in his new practice!

### From Murder to Museums:

#### A special presentation sponsored by the FBA and Cleveland Marshall School of Law

By: Matt Barkett

FBA-NDOC Publicity & Public Relation Committee

In a 90-minute presentation that felt more like an intrigue novel than a legal discussion, internationally respected art and copyright attorney Raymond Dowd offered his perspectives on the arduous process of recovering art and property stolen from Jews by the Nazis in the 1930s and 1940s.

Mr. Dowd spoke to a crowd of approximately 50 rapt attendees at the Moot Court at Cleveland Marshall Law School on November 18. Mr. Dowd's presentation covered the process of deception, theft and monetization of Jewish property in Europe throughout the Holocaust. Starting in the early 1930s even before the Nazi regime took shape, systematic seizure of Jewish assets was eventually used to fund the massive Nazi war machine in the late 1930s and into the 1940s.

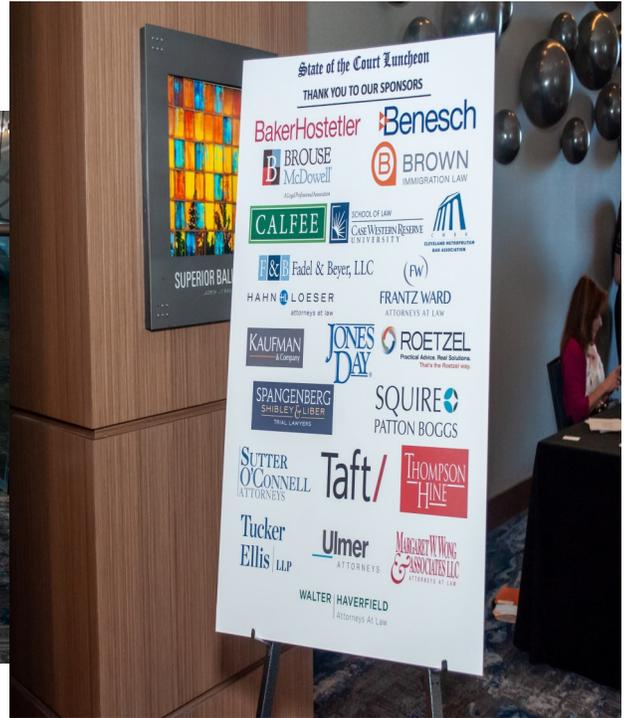
Mr. Dowd focused much of his presentation on artwork that was seized and then trafficked via Switzerland to countries with interested buyers, including some in the United States. Today, much of this artwork is found in museums around the world despite many decades of work by attorneys, including Mr. Dowd to return them to their rightful owners or their heirs.

Mr. Dowd discussed various legal components that have complicated recovery and restoration, including confiscatory US tax laws, fair market value deduction for artworks donated to museums, and an unwillingness of museums to look gift horses in the mouth. He revealed that there remain US museums with large inventories of unprovenanced works that left Europe after 1933 but were created prior to 1946, or as he characterizes it: History's greatest robbery long concealed by history's greatest murder.

Mr. Dowd closed his presentation with hopeful developments surrounding Congress passing the HEAR Act of 2016, which extended the statute of limitations for Nazi looted art claims and reaffirmed America's commitment to righting an historic wrong.

# Awards and Events in the News

## State of the Court Luncheon - September 20, 2019



## Awards and Events in the News Continued

2019-2020 Installment of Board Officers – October 1, 2019



**Clerk's Corner**  
**By Sandy Opacich**  
**Clerk of Court**

Thanks for the invitation to share Clerk's Office news with all of you from time to time through this newsletter. It is hard to believe that we are now in 2020, so before it disappears, allow me to share some news and highlights from the Clerk's Office from 2019:

**Court Business:** Business continues to be brisk in both our civil and criminal dockets. Overall case filings are up 23.2% from 2018. This increase is the 7<sup>th</sup> largest in the United States and 2<sup>nd</sup> largest in the Sixth Circuit. Most of the increase in civil case filings can be attributed to MDL 2804 National Prescription Opiate Litigation. The Court is currently assigned three MDL actions, comprising over 3,400 cases overall. Also of note, since 2017, criminal case filings have risen 75.3% and criminal defendants are up 81% per judgeship. Social security cases comprise 10% of civil filings in the district compared to 8.1% in the Sixth Circuit and 6.2% in the United States.

To ensure accuracy and consistency in our dockets as our caseload grows and we experience staff changes, Clerk's Office efforts have concentrated on data quality. In 2017, we implemented a customized web-based data quality system (QuEST) and training process. Most court documents are filed electronically, but data quality review is needed to ensure accurate docket sheets and Judiciary statistical reports. Our system enables our data quality analysts to review random samples of docket entries district-wide and then provides detailed reports on errors or inconsistencies for use in internal and external communication and training. The benefits of QuEST have been numerous, immediate, and visible to staff and management.

**Theme of the Year – Staff Changes:** As you may know, the federal judiciary grew rapidly between 1990-1995. Many of the employees who started their careers in the Clerk's Office during that period are now eligible to retire. As a result, today nearly 40% of our staff has been in their current position for less than one year! We are focused on onboarding and training as we recruit new employees, celebrate numerous promotions, and recognize the dedicated service of our veteran staff members who are retiring.

**What Has Not Changed:** The Clerk's Office is committed to excellence in service to all our customers and to earning the trust of all who rely upon us. Keep our Help Desk telephone number handy and call for assistance with electronic filing or other court business (800-355-8498).

**We Can Save You a Trip to the Court House:** Attorneys who wish to be admitted to practice in the Northern District of Ohio can now apply electronically through CM/ECF. Required documents can be completed and submitted electronically. Payment of fees is accepted through pay.gov. Check our website [www.ohnd.uscourts.gov](http://www.ohnd.uscourts.gov) for more information.

**Wait, We Want You to Come to the Court House for This!** We are already scheduling Electronic Courtroom Training in 2020. Join us for a one-hour class (CLE eligible!) that will provide an overview of our courtroom technology along with many tips to make your courtroom experience run smoothly. Dates and locations are as follows:

- \*Wednesday, April 1, 2020, Noon – 1:00 PM: Toledo, Courtroom 209
- \*Thursday, April 2, 2020, Noon – 1:00 PM: Cleveland, Courtroom 19A
- \*Friday, April 3, 2020, Noon – 1:00 PM: Akron, Courtroom 575
- \*Wednesday, November 4, 2020, Noon – 1:00 PM: Toledo, Courtroom 209
- \*Thursday, November 5, 2020, Noon – 1:00 PM: Cleveland, 19A
- \*Friday, November 6, 2020, Noon – 1:00 PM: Akron, Courtroom 575

To register, please send an email confirming your attendance to Dave Zendlo, A/V and Courtroom Technology Supervisor at [David\\_Zendlo@ohnd.uscourts.gov](mailto:David_Zendlo@ohnd.uscourts.gov).

**Speaking of Technology....**

- The Northern District of Ohio is now on Outlook email!
- The Northern District of Ohio provides training in the use of its Case Management/Electronic Case Filing System (CM/ECF) to all interested attorneys and their staff. For additional information please visit our website at <https://www.ohnd.uscourts.gov/training-seminars>.

## Clerk's Corner Continued...

- The Northern District of Ohio is currently implementing the central sign-on functionality of CM/ECF NextGen. Once we go live on February 10, 2020, users will be able to enter the same login ID and password to access the electronic filing systems of any appellate, district or bankruptcy court that is live on NextGen. To avoid any inconvenience in electronic filing, please note the following:

**\*Each filer must have their own PACER account.** Shared PACER accounts cannot be used by filing attorneys once the Court has upgraded to CM/ECF NextGen.

\*If your PACER account was created prior to August 11, 2014, it must be upgraded. See <https://www.ohnd.uscourts.gov/cmecf-nextgen-information> for details.

Sixty-two courts are currently live on NextGen (all of the Appellate Courts, 24 District Courts, and 25 Bankruptcy Courts). All courts are scheduled to be on NextGen by July 2021.

**In closing, a request:** The Court is in need of pro bono attorneys in all areas, but especially in prisoner civil rights cases. Please think about joining our roster. Pro bono service is a great way to gain experience in our Court while providing a valuable service to the communities where we live and work. In addition, did you know that you can receive CLE credits for your pro bono service? Attorneys can receive one CLE credit for every six hours of free service provided, up to six CLE credits per biennial reporting period. The Court will also reimburse certain expenses incurred in providing representation up to \$1,500. Please contact Ashley Belzer, Court Programs Supervisor, if you are interested. Ashley can be reached at [Ashley\\_Belzer@ohnd.uscourts.gov](mailto:Ashley_Belzer@ohnd.uscourts.gov) or (216) 357-7083.

## THE PATENT-ELIGIBILITY HYDRA GROWS ANOTHER HEAD

By: Dominic A. Frisina JD, MA

Buckley King, LPA

The U.S. patent system is indisputably in a decade long state of crisis because confusion in patent eligibility caselaw is depriving innovators of necessary economic protection ordinarily provided by patents. The crisis is further depriving the public of innovations that never advance to a product and depriving the United States of investment money that flows from patents. In recent testimony before Congress on the state of patent eligibility law, the Hon. Paul R. Michel echoed the frustration of many patent practitioners saying that he himself, a former Chief Judge of the Federal Circuit, could not reconcile recent patent eligibility cases, calling Federal Circuit and Supreme Court caselaw alike “unclear, inconsistent with one another and confusing.”<sup>1</sup> Judge Michel has notably referred to the body of patent eligibility caselaw as “a menagerie of inconsistency.”<sup>2</sup> Among a litany of confused decisions, Judge Michel zeroed in *American Axle v. Neapco* as illustrating just “how far astray” the courts have wandered from the plain language of statutory patent law, undermining “the very purpose of the Patent Act.”<sup>3</sup> The majority’s opinion, penned by Judge Dyk, in *American Axle v. Neapco* is remarkable for the chilling effect it will undoubtedly have on innovation and investment in the United States.

The claims invalidated in *American Axle* are drawn to a method of manufacturing automotive drivelines whereby acoustically tuned liners are selectively placed in a driveline shaft to damp particular vibrational modes.<sup>4</sup> Claims 1 and 22 were found representative; claim 1 is reproduced here for reference:

1. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:

providing a hollow shaft member;

tuning at least one liner to attenuate at least two types of vibration transmitted through the shaft member; and

positioning at least one liner within the shaft member such that the at least one liner is configured to damp shell mode vibrations in the shaft member by an amount that is greater than or equal to about 2%, and at least one liner is also configured to damp bending mode vibrations in the shaft member, at least one liner being tuned to within about  $\pm 20\%$  of a bending mode natural frequency of the shaft assembly as installed in the driveline system.<sup>5</sup>

<sup>1</sup>*The State of Patent Eligibility in America: Part I*, <https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i> (last visited Nov. 14, 2019).

<sup>2</sup>Brief for Hon. Paul R. Michel as Amicus Curiae Supporting Petitioners at 14, *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 915 F.3d 743 (2019)(2017-2508).

<sup>3</sup>*Id.* at 8 citing *American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC*, 939 F.3d 1355 (Fed. Cir. 2019).

<sup>4</sup>*American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC*, 939 F.3d 1355 (Fed. Cir. 2019).

<sup>5</sup>*American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC*, 939 F.3d 1355 at 1359 (Fed. Cir. 2019); U.S. Patent No. 7,774,911 col 10 l. 10-27 (filed Feb. 27, 2006).

In finding the claims invalid, the court indicated its concern that neither the claims nor the specification described how to tune liners to damp multiple vibrational modes simultaneously.<sup>6</sup> Particularly, Judge Dyk writes “the claims’ general instruction to tune a liner amounts to no more than a directive to use one’s knowledge of Hooke’s law, and possibly other natural laws, to engage in an *ad hoc* trial-and-error process”, adding that “[t]his case might well be significantly different, if, for example, specific [mathematical] models were included in the claims”.<sup>7</sup>

To appreciate the depth of confusion embodied by these statements, consider the rule that the court was applying. The test for patent eligibility was set forth by the Supreme Court in *Alice* and consists of two steps, of which the court was applying step one.<sup>8</sup> In *Alice* Step 1 the question is “whether the claims at issue are directed to” a judicial exception (*e.g.*, a natural law like Hooke’s Law in the present case).<sup>9</sup> Instead of articulating why the claimed steps amount to nothing more than Hooke’s Law, the court’s analysis focused on whether the tuning step teaches how to “produce the multiple frequencies required to achieve a dual-damping result”.<sup>10</sup> Of course, we have a statute that addresses the enabling quality of a patent’s teaching and the definiteness of its claims, but the relevant section is Section 112 rather than Section 101.<sup>11</sup> However, the court nonetheless seems caught up in an amalgamated Section 112 enablement/definiteness analysis rather than the Section 101 analysis embodied by *Alice* Step 1. Incorporating a 112 analysis into *Alice* Step 1, led the *American Axle* Court to the puzzling finding that a method of manufacturing a driveline is a law of nature. Like most inventions, the *American Axle* claims involve a law of nature, but they also include elements that are simply not laws of nature *e.g.*, providing a hollow shaft, attenuating two vibrational modes, and positioning a liner in the hollow shaft. Even more striking is the court’s suggestion that the outcome might have been different if the patentee had included a computerized mathematical model in its claim. In her dissent, Judge Moore commented that “[s]urely, this is the first time adding software to a claim would make it [patent] eligible.”<sup>12</sup>

Moving on to *Alice* Step 2, the court was to determine “whether the claims embody some ‘inventive concept’—*i.e.*, whether the claims contain ‘an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.’”<sup>13</sup> Finding that the claims include no “inventive concept”, the court first acknowledged the patentee’s argument that the claims were drawn to previously unknown subject matter and did not deny its truth, but the court then ignored the previously unknown subject matter, focusing instead on the lack of enabling details in the claims.<sup>14</sup> In other words, the court searched for an inventive concept and found one, but then ignored it, preferring instead to consider matters unrelated to patent eligibility. Judge Moore’s dissent poignantly identifies that “[t]he majority’s true concern with these claims is not that they are directed to Hooke’s Law..., but rather the patentee has not claimed precisely how to tune a liner to dampen both bending and shell mode vibrations.”<sup>15</sup>

The Section 101 caselaw has evolved into such a self-contradictory state that some judges now use it as a magic hat to find whatever they need to invalidate a claim whenever whim so strikes them. In the words of Judge Moore, “[t]he hydra has grown another head”.<sup>16</sup>

<sup>6</sup>*American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC*, 939 F.3d 1355 at 1360 (Fed. Cir. 2019).  
*Id.* at 1364.

<sup>7</sup>*Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 217-218 (2014) citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 75-79 (2012).

<sup>8</sup>*Alice*, 573 U.S. at 217.

<sup>10</sup>*American Axle*, 939 F.3d at 1362-1364 (“Most significantly, the claims do not instruct how the variables would need to be changed to produce the multiple frequencies required to achieve a dual-damping result, or to tune a liner to dampen bending mode vibrations.”).

<sup>11</sup>35 U.S.C. § 112; 35 U.S.C. § 101.

<sup>12</sup>*American Axle*, 939 F.3d at 1374.

<sup>13</sup>*Id.* at 1361 citing *Alice*, 573 U.S. at 217.

<sup>14</sup>*Id.* at 1363 (“The problem with AAM’s argument is that the solution to these desired results is not claimed in the patent.”)

<sup>15</sup>*Id.* at 1373.

<sup>16</sup>*Id.* at 1374.

The harm of patent eligibility confusion does not stop at the courthouse steps. Real people who would benefit from innovations incentivized by the U.S. patent system are adversely affected. Sadly, many lifesaving inventions will never be made because investors will not fund research if they cannot profit from patent protection. In view of the hydra's now numerous heads, the only real hope for correction is from Congress.

In May 2019 Senators Thom Tillis (R-NC) and Chris Coons (D-DE) released a promising draft bill that seeks to eliminate judicial exceptions to patent eligibility, mandating that patent eligibility determinations are to be made "only while considering the claimed invention as a whole, without discounting or disregarding any claim limitations."<sup>17</sup> In June, Senator Tillis chaired a three-day hearing of the Subcommittee on Intellectual Property addressing patent eligibility generally, and the draft bill in particular.<sup>18</sup> While seemingly productive, no bill has been introduced to date, possibly due to resistance from some stakeholders having a starkly contrary point of view, as shown in a joint letter from the American Civil Liberties Union and a list of co-signers including Mayo Clinic Laboratories and Susan G. Komen.<sup>19</sup> In part, the letter alleges that:

if enacted [the Tillis-Coons bill] would authorize patenting products and laws of nature, abstract ideas, and other general fields of knowledge. Most troublingly, the legislation would permit patenting of human genes and naturally-occurring associations between genes and diseases. Allowing these patents will prevent the discovery of novel treatments for diseases including cancer, muscular dystrophy, Alzheimer's disease, heart disease, and other rare and common diseases.

Undeterred, IP groups including members such as former Director of the USPTO, David Kappos, and retired Judge Paul Michel are reportedly working on a proposal "aimed at jump-starting talks on legislation".<sup>21</sup> In the meantime, innovators and investors continue struggling to operate in an unpredictable legal climate.

Dominic A. Frisina JD, MA  
600 Superior Ave. Suite 1400  
Cleveland, OH 44114  
(216)685-4736  
Frisina@BuckleyKing.com  
<http://www.buckleyking.com/attorney-bio-detail/frisina-dominic>

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<sup>17</sup>*Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act> (last visited Nov. 14, 2019).

<sup>18</sup>*The State of Patent Eligibility in America: Part I*, <https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i> (last visited Nov. 14, 2019).

<sup>19</sup>*Coalition Letter Opposing Draft Legislation of Section 101 of Patent Act*, <https://www.aclu.org/letter/coalition-letter-opposing-draft-legislation-section-101-patent-act> (last visited Nov. 14, 2019).

<sup>20</sup>*Id.*

<sup>21</sup>*IP Groups Developing Fresh Patent Eligibility Bill Proposal (2)*, <https://news.bloomberglaw.com/ip-law/ip-groups-developing-fresh-patent-eligibility-bill-proposal> (last visited Nov. 14, 2019).

## ANONYMOUS, NO MORE? DATA PRIVACY IN THE GENETIC AGE

By: Talia E. Sukol  
Flannery Georgalis, LLC

### Introduction: The Challenge of Truly Anonymizing Genetic Data

Recent developments in genetic research have brought to light certain challenges relating to the proliferation of data. In a study published in 2009, scientists revealed that they were successful in isolating and identifying the DNA of individuals from a highly complex genomic mixture, or a DNA composite comprised from the genes of many individuals.<sup>1</sup> The scientists did not prepare a mixture, or a DNA composite comprised from the genes of many individuals.<sup>1</sup> The scientist did not know the number of

individuals that comprised the mixture, but nevertheless were able to re-individualize pieces of DNA in a mixture that contained the genetic information of over a thousand individuals. The researchers' approach could "rapidly and sensitively" identify trace amounts (<1%) of an individual's DNA.<sup>2</sup>

Scientists have sought to balance the push for genetic research in medicine with a desire to keep the identity of research subjects private. This was the very premise of using genomic mixtures: by using genetic information from a large group of individuals, genomic mixtures should, in theory, mask individual-level information.<sup>3</sup> But this study revealed that individual-level information can still be discerned from these complex samples.

A second study in 2013 pushed identification even further. Researchers were successful in identifying the surnames of male individuals who had contributed purportedly anonymous genetic information for research purposes.<sup>4</sup> Using short genetic sequences on the Y chromosome and publicly available information on genetic genealogy databases, researchers triangulated this information with other metadata such as age and state of residence.<sup>5</sup> The technique relied on free and publicly accessible information on the internet, and researchers were successful in identifying multiple participants.<sup>6</sup> In this study, even more so than in the one discussed previously here, scientists deliberately sought to clarify the question of how private this allegedly de-identified information was in fact. And the answer was: not very private at all.

### Roadmap and Thesis

This paper discusses advances in genetic research, and in particular, how these advances relate to privacy matters. The paper examines how state, federal, and non-U.S. lawmakers have attempted to legislate on this question. The paper next considers the right to anonymity under the lens of genetic information. It then examines how other sectors have addressed privacy matters. This paper suggests that the proper contours of a legal regime on genetic privacy rights should reflect the growing realization that genetic information may not be truly anonymizable.

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<sup>1</sup> Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays; <https://journals.plos.org/plosgenetics/article/file?id=10.1371/journal.pgen.1000167&type=printable>.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Identifying Personal Genomes by Surname Inference; <https://science.sciencemag.org/content/sci/339/6117/321.full.pdf>.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

## The Tension Between Privacy and Progress

Society benefits greatly from genetic research. Scientists have been successful in advancing the treatment and prevention of cancer, treating heart disease, and selecting for embryos that lack genetic diseases.<sup>7</sup> Outside of the medical context, law enforcement have solved cases long gone cold and families have been reunited through the use of genetic testing.<sup>8</sup>

But the advances have not been strictly positive in the minds of some. Families have discovered unknown half-siblings.<sup>9</sup> Information about the genetic component of a blood relative's disease is not always welcomed. And now, individuals who generously donated their genetic information for research purposes could one day receive a notice that scientists many time zones away have identified them from among a pool of information previously thought to be anonymous.

## Privacy in the Law, Generally

As the Presidential Commission for the study of bioethical issues posited in their 2012 report, concerns about privacy are documented in the ancient Greek political writings.<sup>10</sup> The report also points out that although the word "privacy" does not appear in the United States Constitution, courts have recognized an implicit right of privacy in the Bill of Rights.<sup>11</sup> Furthermore, courts have used the Due Process Clause to protect individual privacy related to medical, marital, sexual, and family planning decisions.<sup>12</sup>

States have also legislated on issues of privacy. Some states have a privacy tort, some states have a breach of confidentiality tort, and some states even create a right to privacy in their state constitution.<sup>13</sup> These efforts, however, are largely piecemeal; in contrast to European privacy law, which applies broadly to all industries, U.S. privacy law is largely sector-specific.<sup>14</sup> State privacy law varies by jurisdiction and sector, and as such, there is little in the way of uniformity when it comes to protecting genetic privacy.

## Government Efforts to Protect the Proliferation of Genetic Information

### *Genetic Information Nondiscrimination Act*

In 2008, the U.S. Congress passed the Genetic Information Nondiscrimination Act (GINA). GINA protects individuals from employment and health insurance discrimination on the basis of genetic information.<sup>15</sup> However, GINA fails to protect against other forms of genetic discrimination, notably life and disability insurance determinations. A barrier to genetic testing for some individuals is a fear that this will make it more difficult, if not impossible, to have the life or disability insurance policies that would provide support to themselves or their families if such circumstances arise. If greater privacy protections were in place for genetic information, such as a right to withhold such information, individuals may be more willing to undergo genome sequencing. And if individuals could somehow be assured that their information would remain private and used only by scientists for research purposes, then more people may be willing to submit their genome sequencing for research. This would facilitate the medical advancement that increases public health.

<sup>7</sup> E.g., <https://www.cancer.gov/about-nci/organization/ccg/cancer-genomics-overview>.

<sup>8</sup> E.g., <https://www.nytimes.com/2018/04/27/health/dna-privacy-golden-state-killer-genealogy.html>.

<sup>9</sup> <https://www.npr.org/2019/04/26/717079333/part-of-my-dna-an-adopted-woman-learns-of-her-birth-mother-s-resilience>.

<sup>10</sup> Aristotle, *Politics*, (Benjamin Jowett trans., Dover first ed. 2000) (350 B.C.).

<sup>11</sup> "1) freedom of speech, freedom of religious, political and personal association, and related forms of anonymity (First Amendment); 2) freedom from government appropriation of one's home (Third Amendment); 3) freedom from unreasonable search and seizure of one's body and property (Fourth Amendment); 4) freedom from compulsory self-incrimination (Fifth Amendment); 5) freedom from cruel and unusual punishment, including unnecessarily extreme deprivations of privacy (Eighth Amendment); and 6) other personal freedoms (Ninth Amendment)" [https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508\\_1.pdf](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508_1.pdf).

<sup>12</sup> [https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508\\_1.pdf](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508_1.pdf).

<sup>13</sup> See, e.g., Alaska's Constitution [Ltgov.alaska.gov](http://legis.alaska.gov); Cal. Civil Code § 6267; Article I: Declaration of Rights, Section 23: Right of privacy". *Constitution of Florida*. Florida Legislature. November 5, 1968; Article II: Declaration of Rights, Section 10: Right of privacy". *Constitution of Montana*. Montana Legislative Services. March 22, 1972; "Privacy Protections in State Constitutions". National Conference of State Legislators. 2018-11-07.

<sup>14</sup> [https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508\\_1.pdf](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508_1.pdf).

<sup>15</sup> <https://www.eoc.gov/laws/statutes/gina.cfm>.

### *The Presidential Commission*

In the 2012 *Privacy and Progress in Whole Genome Sequencing* report issued by the Presidential Commission for the study of Bioethical Issues, the Commission addressed the ethical mandates that should drive policy around the need for genetic privacy.<sup>16</sup> Additionally, the Commission recommended specific legislation.<sup>17</sup> The Commission presented five goals. First, all handlers of data should establish policy practices and state and federal government should establish floor-level protections for this data.<sup>18</sup> Second, individuals who work with whole genome sequencing data should not intentionally, recklessly, or negligently access or misuse data. In cases when security lapses or breaches occur, data handlers should be accountable to federal and state laws' remedial or penal measures. Additionally, law enforcement and security or defense should not have access to biospecimens or whole genome sequence data for non-health related purposes without the consent of the individual. The guidelines, issued in 2012, recommended that whole genome sequencing data be stripped of identifiers in order to inhibit recognition or reidentification. But the 2013 study where researchers re-identified purportedly anonymous genetic data calls into question the basis of this particular recommendation.

Third, researchers should adopt robust consent processes that empower subjects to understand who will have access to their data and for what purposes it will be used at present as well as in the future. To this same effect, the federal Office for Human Research Protections (i.e., the governing body for human subject research, supported by the Department of Health and Human Services), should establish clear guidelines for informed consent that (1) describe whole genome sequencing, (2) describe how the data will be used now and how it might be used in the future, (3) describe the extent to which an individual will have future control over their data, (4) describe benefits, risks, and state that there may be unknown risks, and (5) state what data and information about the individual will be provided back to him or her.<sup>19</sup> Such protocols are crucial in light of the unique propensity for genetic research to produce incidental findings. For instance, sequencing data collected for research into genetic markers for heart disease may reveal a high likelihood of early-onset Alzheimer's disease. The report by the Presidential Commission makes clear that subjects should know about the possibility of incidental findings and should also know whether they will be notified of any such findings.

Fourth, progress should be facilitated with respect to research in whole genome sequencing. Interestingly, the report recommends that researchers pursue "participatory models that promote collaborative relationships" between scientists and study participants. Lastly, the Commission highlighted the importance of performing whole genome sequencing research such that it benefits all people. The federal government, the Commission stated, should invest in research that promotes this goal.

This report, issued in 2012, fails to address one of the most fundamental difficulties in this area of privacy law, however, because it assumes that researchers are able to remove identifiers from genetic information. As the 2009 and 2013 studies revealed, however, partial— and even trace amounts—of gene sequencing data can be used to reidentify individuals who submit genetic data for research purposes. Though the report marks a positive first step toward building a policy regime of genetic privacy rights, the Commission's glossing over the difficulty of anonymizing data demonstrates that the effort to develop a legal regime that is truly protective of genetic privacy remains in its infancy.

### **Recognition of a "right to anonymity" helps mitigate the harms of identification**

It is worth considering the areas in which rights to anonymity have been recognized. In the United Nations Report of the Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression, Frank La Rue espoused the importance of anonymous expression, particularly through the lens of State surveillance.<sup>20</sup>

Anonymity is threatened when individuals must present government-ID when (1) using a public computer, (2) buying a cell phone or SIM card, (3) making purchases, (4) commenting on online media sites or blogs, or (5) creating a social networking account.<sup>21</sup> Special Rapporteur La Rue chastised entities for creating "back doors," i.e., weakened security protections that allow for law enforcement access.

<sup>16</sup> [https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508\\_1.pdf](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508_1.pdf).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> [https://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A.HRC.23.40\\_EN.pdf](https://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A.HRC.23.40_EN.pdf).

<sup>21</sup> <https://www.eff.org/deeplinks/2013/06/anonymity-encryption-and-free-speech-what-nations-need-to-do>.

This concern applies in the realm of genetic information, too. Not only could the government make determinations based on genetic information, for instance, admittance to public higher education institutions, but private entities could surveil and benefit from commercial use of this information, for instance by selling drug manufacturers lists of individuals with certain genetic diseases. Accordingly, protections should be in place not only for keeping genetic information secure, but also for ensuring individuals are not adversely affected in the event of data breaches.

To combat the 2013 study that revealed that information about a purportedly anonymous genetic information donor could be triangulated to identify him, perhaps researchers should collect even less information to begin with on research subjects. Without information on age or collection location, researchers may be thwarted from making the identification. An alternative solution, though not recommended here, would be to ban public genealogy databases that allow entities to match purportedly anonymous genome sequencing with sequencing identifiable to a family.

The U.S. Supreme Court has also recognized the right to anonymity in other contexts. During the 1950's and 1960's, the Court protected anonymity by allowing members of controversial groups to remain unidentified in order to ensure the First Amendment right to free association.<sup>22</sup> More recently, the Court has protected anonymity by allowing individuals engaged in personal political activity, i.e. passing out leaflets or gathering petitions, to remain unidentified.<sup>23</sup> It is possible, then, that a party injured by a data breach of genomic information could bring a successful claim for violation of their right to be anonymous, particularly if the claim were tied into a newly-recognized right to genetic privacy.

### **Existing rules protecting privacy in credit reporting and health care can inform the development of genetic data privacy rights**

In light of the 2009 and 2013 studies that call into question whether genetic information can be truly anonymized, it is helpful to look to privacy law in sectors where information is by its very nature identifiable to an individual. Privacy with respect to genetic data presents similar issues as data privacy in other contexts, such as credit or medical information. Accordingly, rules existing in these sectors requiring information to be stored securely and confidentially, and only accessed for authorized purposes, can serve as a roadmap toward the development of policies that are similarly protective of genetic data.

#### *Fair Credit Reporting Act*

The Fair Credit Reporting Act (FCRA) creates a number of rights for individuals with respect to credit reporting.<sup>24</sup> First, there is a right to know what is in your credit file. All people are entitled to a free credit report on a yearly basis, and there is also an entitlement to information about your file in the event of identity theft, inaccurate information as a result of fraud, receipt of public assistance, adverse action taken because of information in a credit report, or unemployment with expectations to apply for employment within 60 days.<sup>25</sup> Under FCRA, individuals have a right to dispute incomplete or inaccurate information contained in their credit report, credit reporting agencies must make corrections to credit reports within 30 days, they may not report negative information that is more than 7 years old or bankruptcy information more than 10 years old, access to files is limited to those with a valid need, businesses must obtain an individual's consent before requesting a credit report on an employee or potential employee, and individuals can limit prescreened offers of credit.<sup>26</sup> In addition, individuals have rights to (1) obtain a security freeze such that express authorization is needed for the release of credit information on an individual, (2) obtain a fraud alert that requires businesses to take measures to verify a consumer's identity before extending credit, (3) seek damages from violators, and (4) additional measures designed to protect victims of identity theft as well as active duty military personnel.<sup>27</sup>

<sup>22</sup> *Watkins v. United States* (1957), *NAACP v. Alabama* (1958), *Bates v. Little Rock* (1960), and *Gibson v. Florida Legislative Investigation Committee* (1963); <https://mtsu.edu/first-amendment/article/32/anonymous-speech>.

<sup>23</sup> *Talley v. California* (1960), *McIntyre v. Ohio Elections Commission* (1995), *Buckley v. American Constitutional Law Foundation* (1999), and *Watchtower Bible and Tract Society of New York v. Village of Stratton* (2002); <https://mtsu.edu/first-amendment/article/32/anonymous-speech>.

<sup>24</sup> 15 U.S.C. § 1681.

<sup>25</sup> <https://www.consumer.ftc.gov/articles/pdf-0096-fair-credit-reporting-act.pdf>.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

These principles are helpful to consider and offer insight into how genome sequencing information could be protected. First, individuals should have a right to the information in connection with their genome sequencing data. This could take the form of a yearly report detailing the uses of their information and any incidental findings. Individuals should also receive notice when there is any breach of their privacy, and could possibly obtain additional protections when such an event occurs. For instance, when a data breach occurs, individuals could block access to their information absent express authorization. Anti-discrimination protections could be enacted to prevent life and disability insurers from making policy determinations based on this information. Individuals should also obtain a right to seek damages in the cases of violation or breach from the entity entrusted with protecting their data or from entities that wrongfully obtained their genetic data.

The challenge with applying FRCA controls is that credit reporting is by its nature very individualized, and it identifies information about a named person. In contrast, genetic information for research purposes seeks to be anonymous. Maintaining the kinds of records that would allow a person to have greater control over their genome sequencing information could make it even easier for entities to identify the individuals who donated the genetic information. Any attempt to install a regime of genetic privacy rights will necessarily need to navigate this tension between the enforceable protections that come with identifiability and the security of remaining anonymous.

### **Health Insurance Portability and Accountability Act**

The 1996 Health Insurance Portability and Accountability Act (HIPAA) established a set of standards that protect personally identifiable information (PHI) held by health providers and insurers.<sup>28</sup> In order to comply with HIPAA, any entity that comes into contact with PHI must maintain policies, procedures, and safeguards to protect the information's privacy. Failure to establish and comply with these procedures is itself a HIPAA violation, regardless of whether an unauthorized disclosure occurs. In addition, under HIPAA, patients have a right to request and receive a copy of their medical records within 30 days of the request. HIPAA also establishes a safeguards rule that applies to electronic PHI (for example, PHI must be encrypted if it extends beyond the entity's firewall) as well as physical realities (for example, work stations must be set up such that computer screens cannot be viewed from a public area).<sup>29</sup> HIPAA also requires the appointment of a Security Officer and Privacy Officer, and these officers must conduct annual risk assessments and audits.<sup>30</sup> Entities must notify the Office of Health and Human Services within 60 days of when a breach occurs, and must notify the media as well as individuals about whom information was revealed when breaches occur involving greater than 500 patients.<sup>31</sup> Finally, HIPAA establishes penal standards such as a fine of up to \$50,000 for negligence or fines of \$50,000 per offense for willful neglect.<sup>32</sup>

Similar safeguards should apply within the context of genetic information. For instance, entities that come into contact with genetic information should be required to maintain policies that safeguard this information, and they should be held strictly liable for breach simply by failing to do so. Similar to both HIPAA and FRCA, research subjects should have a right to make a request and receive a copy of their information within a timely period. It should establish similar electronic and physical safeguards. It should also require the appointment of officers who would conduct risk assessments and audits as well as establish notification rules for breach. It should set penal standards for failure to comply.

In some ways, HIPAA is a good model for genetic information privacy. Substantively, HIPAA concerns similar kinds of information, *i.e.*, health and medical data, that is at issue in genetic data used in scientific research. HIPAA involves similar parties, *i.e.*, patients and physicians or medical researchers. And the HIPAA protections as applied to genetic information would be helpful. The shortcoming of applying HIPAA protections is similar to the difficulty with FRCA application. In this instance too, personally identifiable health information is by its very nature identified, whereas genetic research information seeks to be anonymous. However, if current research reveals that it is not possible to truly anonymize genetic information, then creating protections that implicitly recognize that genetic information is not anonymous would be satisfactory (or at least an improved outcome.)

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<sup>28</sup> 110 Stat. 1936; PHI includes names or part of names, any other unique identifying characteristic, Geographical identifiers, dates directly related to a person, phone number details, fax number details, email addresses, Social Security details, medical record numbers, health insurance beneficiary numbers, account details, certificate or license numbers, vehicle license plate details, device identifiers and serial numbers, website URLs, IP address details, fingerprints/retinal/voice prints, complete face or any comparable photographic images.

<sup>29</sup> <https://www.hipaaguide.net>.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

### **A framework for genetic privacy depends upon the anonymizability of genetic data**

One of the essential questions in establishing a body of law around this area of genetic information privacy is whether information can truly be anonymous. As we have seen here, there is a recognition of the importance of anonymity and protecting it when possible. But if the answer is that this information cannot be truly anonymous, then there are several possible responses that arise out of this realization. One proposal from geneticists is that genetic information should be inaccessible unless a research entity obtains status as a trusted user.<sup>33</sup> Those entities that are trusted users, however, would gain access to an entire repository of genetic sequencing research.<sup>34</sup> The geneticists noted that there would be difficulties in implementing this approach.<sup>35</sup> Since researchers across the world do not use the same databases to store their information, compatibility across platforms would be a barrier.<sup>36</sup> Computational Biologist Eric Schadt at Mount Sinai Hospital disagrees, however.<sup>37</sup> He suggests that subjects should be notified that their privacy cannot be completely protected. His measure for protection is that legislation should be in place to protect subjects from exploitation.<sup>38</sup>

Another avenue to explore is the centralization of genetic data used in research applications. If all genome sequencing research data were stored in a single database, it would streamline the manner in which many concerns are addressed. For instance, someone's information from the database could be readily removed upon request, an individual could be notified when incidental findings are uncovered (such as a cancer predisposition), or researchers could easily request consent from donors for specific studies. This kind of centralization would lend itself to regulatory oversight. There are concerns here too, though. Centralizing all genetic data could make the database an appealing target for hackers. And a data breach here could operate on a scale much greater than if the information was decentralized. The advantages of allowing individuals greater control over their genetic information, though, makes a centralized database a potentially net-positive contribution.

Alternatively, this paper proposes that the government look to privacy measures established in other areas, notably FRCA and HIPAA, that enact a structure that seeks to protect the privacy of the information, while also establishing protections in cases of data breaches. Usefully, FRCA and HIPAA contain mandates that an individual's personal information may not be accessed or utilized for certain purposes, and (equally importantly) provide the individual a legal remedy in the event of data misuse. To the extent that genetic data becomes identifiable in the same way as credit or medical information, FRCA and HIPAA provide direct templates for the implementation of a new genetic privacy regime.

However, we should not be so quick to declare at this point that genetic data is never truly anonymizable. It should be clear that this paper's musings on the subject are based off of two studies, from 2009 and 2013, and that further advances in the development of genetic identification may in fact reveal that anonymization is truly possible. Nevertheless, in developing a regime of genetic privacy rights, one's right to be anonymous should not form a central part of that regime unless and until additional research makes it clear that anonymization is possible. In the event it is not possible, a better model for establishing privacy rights are those models in place with respect to identifiable information.

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<sup>33</sup> <https://www.nature.com/news/genetic-privacy-1.12238>.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> <https://www.nature.com/news/privacy-loophole-found-in-genetic-databases-1.12237>.

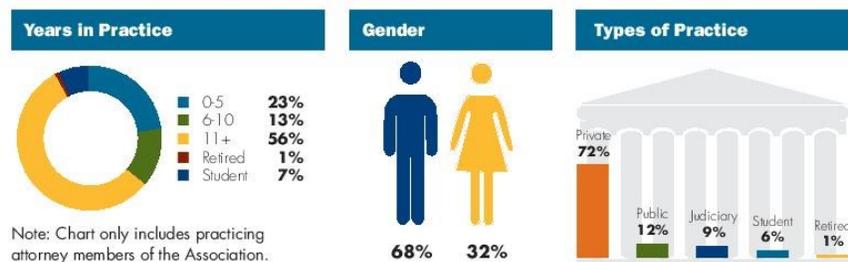
<sup>38</sup> *Id.*

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## ***Co-Editors for the Winter 2020 Newsletter:***



Stephen H. Jett  
Co-Chair, Newsletter Committee  
Jett Law LLC  
440-821-8515  
[sjett@jett.law](mailto:sjett@jett.law)  
[www.jett.law](http://www.jett.law)



Prof. Jonathan Entin  
Co-Chair, Newsletter Committee  
Case Western Reserve University  
216-368-3321  
[jonathan.entin@case.edu](mailto:jonathan.entin@case.edu)  
[www.case.edu.law](http://www.case.edu.law)

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