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WHAT YOUR TWEET DOESN'T SAY: TWITTER, NON-CONTENT DATA, AND THE STORED COMMUNICATIONS ACT

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ABSTRACT

A federal district court in Virginia recently held that Twitter users have no privacy rights regarding non-content information associated with their use of Twitter. The court thus affirmed that the government may obtain Twitter users' Internet Protocol (IP) addresses without notice to the users. The users in this case were alleged to be members of WikiLeaks. The government obtained an order of production in connection with grand jury proceedings, compelling Twitter to turn over IP address data to the government. After Twitter motioned to have the order unsealed, the alleged WikiLeaks members unsuccessfully attempted to intervene to quash the order of production. The district court found that the users lacked standing to challenge the order under the Stored Communications Act (SCA) because Twitter's terms of use negated any expectations of privacy and the nature of IP address data itself requires that users convey IP addresses and associated information in order to use the Internet. This Article examines the court's decision and analysis under the SCA and Fourth Amendment jurisprudence, and discusses the impact of expanded warrantless disclosures of non-content electronic records.

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INTRODUCTION

More Americans are using social media to communicate than ever before, and using a wide array of devices, from personal computers to cellular phones, to do so. Online social networking sites—such as Twitter, Facebook, MySpace, LinkedIn, and FourSquare—are ubiquitous. For example, Twitter use is increasingly prevalent among nearly every demographic group in the United States. A 2011 Pew Research survey found that 13 percent of adults that use the Internet use Twitter.[1] The survey also found pronounced growth in the number of non-white Twitter users, as well as significant growth in the number of Twitter users age 25-44.[2] Such trends appear consistent with the growth of online social media in general; as of 2011, 65 percent of online adults used social networking sites such as MySpace, Facebook, or

[1] Aaron Smith, *Twitter Update 2011*, PEW RESEARCH CENTER, June 1, 2011, http://www.pewresearch.org/pubs/2007/twitter-users-cell-phone-2011-demographics.

[2] *Id.*

LinkedIn.[3] Considering that in February 2005, only 8 percent of adult Internet users used social networking sites, the pace of growth for online social networking site is "staggering."[4]

Unlike email messages and other predecessors to modern social media, communications through online social media are often publicly available—at least to other members of the social network. The public nature of many online social networks reduces or eliminates any expectation of privacy as to the content of the messages themselves. Government entities pursuing evidence of criminal activity through the records of online social networking sites do not always seek the actual content of the communications, but rather seek the non-content data—including the identity and location of the user. As a result, questions regarding privacy and government access to electronic non-content records arise relating to the Stored Communications Act (SCA), 18 U.S.C. § 2701 *et seq.* (2010). Because non-content data,[5] such as an Internet Protocol (IP) address, is necessary for communication via the Internet, many social networking companies routinely retain such information.

A federal district court in Virginia recently held that the federal government may obtain Twitter users' Internet Protocol (IP) addresses without notice to the users. This decision represents a

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[3] Mary Madden & Kathryn Zickuhr, 65*% of Online Adults Use Social Networking Sites*, PEW RESEARCH CENTER, Aug. 26, 2011, http://pewinternet.org/Reports/2011/Social-Networking-Sites/Overview.aspx.

[4] *Id*.

[5] Non-content information has been described as "the envelope information needed to deliver a communication from one location to another." WAYNE R. LAFAVE, JEROLD H. ISRAEL, NANCY J. KING & ORIN S. KERR, 2 CRIM. PROC. § 4.4(D) (3d ed. 2011). Under the SCA, non-content information includes:

> (A) name; (B) address; (C) local and long distance telephone connection records, or records of session times and durations; (D) length of service (including start date) and types of service utilized; (E) telephone or instrument number or other subscriber number or identity, including any temporarily assigned network address; and (F) means and source of payment for such service (including any credit card or bank account number)."

18 U.S.C. § 2703(c)(2) (2010); *see also* WAYNE R. LAFAVE, JEROLD H. ISRAEL, NANCY J. KING & ORIN S. KERR, 2 CRIM. PROC. § 4.8(C) (3d ed. 2011).

natural application of existing Fourth Amendment jurisprudence applying the SCA. Further, the decision gives notice to both users and operators of social networks that there is no expectation of privacy for IP address data transmitted over the Internet—even when the data is transmitted from a personal computer located in a private space.

This Article examines the federal district court's decision and analysis under SCA and Fourth Amendment jurisprudence. Then, this Article discusses the impact of expanded warrantless disclosures of non-content electronic records on online social networking sites and users. The Article concludes by noting that the nature of online communication itself requires that non-content data be disclosed between machines, meaning that under the SCA, certain data required for using the Internet is inherently non-private.

I. TWITTER AND NON-CONTENT DATA

A. Twitter

Twitter is an online social media network that allows users to post short messages to one another or to the public. The company's website states, "Twitter is a real-time information network that connects [users] to the latest stories, ideas, opinions and news about what [users] find interesting."[6] Twitter users communicate using "tweets." Each tweet is up to 140 characters long; users can share photos, videos and conversations directly in tweets.[7] Twitter allows users to post tweets and read the tweets of other users via computers and other mobile devices that connect to the Internet. Users can monitor, or "follow," other users' tweets, and can permit or forbid access to their own tweets. In addition to posting their own tweets, users may send messages to a single user ("direct messages") or repost other users' tweets ("retweet"). Each Twitter user has a unique username, which is associated with that user's

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[6] *About Twitter*, TWITTER.COM, http://twitter.com/about (last visited Jan. 3, 2013).

[7] *Id.*

tweets, direct messages, and retweets.[8]

Twitter requires that users agree to a "clickwrap"[9] agreement that includes agreeing to Twitter's Terms of Service and Privacy Policy as a condition of creating a Twitter account.[10] The Privacy Policy includes a number of key terms and conditions that relate to retention of user data. For example, the Privacy Policy as of May 17, 2012 explained that, "We may preserve or disclose your information if we believe that it is reasonably necessary to comply with a law, regulation or legal request; to protect the safety of any person; to address fraud, security or technical issues; or to protect Twitter's rights or property."[11] Additionally, the Policy states that:

> Our servers automatically record information ("Log Data") created by your use of the Services. Log Data may include information such as your IP address, browser type, operating system, the referring web page, pages visited, location, your mobile carrier, device and application IDs, search terms, and cookie information. We receive Log Data when you interact with our Services, for example, when you visit our websites, sign into our Services, interact with our email notifications, use your Twitter account to authenticate to a third-party website or application, or visit a third-party website that includes a Twitter button or widget. Twitter uses Log Data to provide our Services and to measure, customize, and improve them. If not

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[8] *In re* Application of the U.S. for an Order Pursuant to 18 U.S.C. §2703(d), 830 F. Supp. 2d 114, 118 (E.D. Va. Nov. 10, 2011) (internal footnotes omitted); *see also* Rafe Needleman, *Newbie's guide to Twitter*, CNET, March 15, 2007, http://news.cnet.com/newbies-guide-to-twitter/.

[9] In computer software, hardware, and Internet transactions terms and conditions are often contained in a clickwrap agreement—terms and conditions that appear on the computer screen when the user attempts to install the software or use the website and require that a consumer agree to the license terms before being allowed to purchase or use the product or website. 15B AM. JUR. 2D *Computers and the Internet* § 105 (2012).

[10] *In re Application*, 830 F. Supp. 2d at 118.

[11] *Twitter Privacy Policy*, TWITTER.COM, May 17, 2012, http://twitter.com/privacy.

> already done earlier, for example, as provided below for Widget Data, we will either delete Log Data or remove any common account identifiers, such as your username, full IP address, or email address, after 18 months.[12]

Users must acknowledge and agree to this Privacy Policy as a condition of using Twitter.

B. 18 U.S.C. § 2703: Content or Non-Content Under the SCA

Enacted as Title II of the Electronic Communications Privacy Act of 1986,[13] the SCA largely governs the methods and requirements for government access to electronically stored communications and the data related to those communications. The SCA draws an important distinction between content and non-content information in Section 2703. In addition to establishing the procedures by which the government may obtain access to electronic communications and information, the section distinguishes between "contents" and non-content "records."[14]

The SCA distinguishes between content substance and form. When the government seeks "information concerning the substance, purport, or meaning of that communication" (in other words, content), paragraphs (a) and (b) apply.[15] If, on the other hand, the government seeks non-content records, paragraph (c) controls.[16] Section 2703, paragraph (c)(2) lists the type of non-content data subject to disclosure, including the subscriber or

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[12] *Id.*

[13] Pub.L. No. 99–508, 100 Stat. 1848 (1986) (codified as amended at 18 U.S.C. §§ 2701–2711 (2010)). The Electronic Privacy Act of 1986 was enacted in part to extend enhanced privacy protections to developing forms of telecommunications and computer technology, including cellular phones, pagers, and email. *See* S. Rep. No. 99–541 at 4 (1986), reprinted at 1986 U.S.C.C.A.N. 3555, 3559; *see generally* Orin S. Kerr, *A User's Guide to the Stored Communications Act, and a Legislator's Guide to Amending It*, 72 GEO. WASH. L. REV. 1208,1209-13 (2008).

[14] 18 U.S.C. § 2703 (2010); *see also* Smith v. Maryland, 442 U.S. 735, 743–44 (1979).

[15] 18 U.S.C. §§ 2510(8), 2703(a)-(b), 2711(1) (2010).

[16] 18 U.S.C. § 2703(c) (2010).

customer name, address, telephone connection records or records of session times and durations, length and type of service used, telephone number or temporarily assigned network address, and method of payment.[17] "Although the line between [content and non-content] occasionally blurs, in most cases the line is clear: it is the line between a message that a person wants to communicate and information about when and how he does so."[18] Under the SCA, data associated with a subscriber or customer is non-content, whereas information contained in the communication itself is content.

According to the SCA, a court order issued under 18 U.S.C. § 2703(c) for non-content records "shall issue only if the governmental entity offers specific and articulable facts showing that there are reasonable grounds to believe that the contents of a wire or electronic communication, or the records or other information sought, are relevant and material to an ongoing criminal investigation."[19] This court order is "something like a mix between a subpoena and a search warrant. . . . If the judge finds that the factual showing has been made, the judge signs the order. The order is then served like an ordinary subpoena . . ."[20] The order does not require notification to the customer or subscriber when the government requests non-content records under paragraph (c).[21]

II. *IN RE APPLICATION OF THE U.S. FOR AN ORDER PURSUANT TO 18 U.S.C. §2703(D)*[22]

In a memorandum opinion issued on November 10, 2011, a federal district court judge in Virginia addressed the limitations of

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[17] 18 U.S.C. § 2703(c)(2) (2010).

[18] Kerr, *supra* note 13, 1228.

[19] 18 U.S.C. § 2703(d) (2010).

[20] Kerr, *supra* note 13, 1219.

[21] 18 U.S.C. § 2703(c)(3) (2010). The requirements for accessing content information are far more complex and vary in part based on whether the content has been in "electronic storage" more or less than 180 days. *See* WAYNE R. LAFAVE, JEROLD H. ISRAEL, NANCY J. KING & ORIN S. KERR, 2 CRIM. PROC. § 4.8(D) (3d ed. 2011).

[22] 830 F. Supp. 2d 114 (E.D. Va. Nov. 10, 2011).

the Fourth Amendment right to privacy with regard to Internet communications. The opinion affirms a United States magistrate judge's rulings regarding an order of production issued under the SCA that allowed the government to obtain non-content records regarding Twitter users without a warrant. Petitioners, three alleged members of the WikiLeaks organization[23] facing potential criminal charges over public disclosure of classified information about the Iraq and Afghanistan wars, moved to quash the order, unseal the application seeking the order, and publicly docket other related information on a variety of grounds, including a constitutional claim based on the Fourth Amendment right to privacy. In denying petitioners' motions, the judge noted that gaining online access requires all Internet users to transmit IP address information associated with their personal computing devices out of private home spaces and onto online routers that then convey traffic to specific websites. Combined with Twitter's privacy policy, which resulted in application of the Fourth Amendment's third-party doctrine, the nature of Internet data transmission led the judge to conclude that Twitter users have no expectation of privacy regarding the numerical IP addresses that identify their computers, cellular phones, or other mobile devices that connect to the Internet when using Twitter.

A. Factual Context

As part of an ongoing criminal investigation into alleged leaks of classified United States military documents related to the Iraq and Afghanistan wars, the federal government sought a court order based on 18 U.S.C. § 2703(d) instructing Twitter, Inc. to turn over information pertaining to three individuals under grand jury investigation.[24] The government alleged that the three

[23] WikiLeaks is an international, online, self-described "not-for-profit media organisation" that seeks to publish original source material and news stories based on information leaked from a variety of anonymous sources. *About*, WIKILEAKS.COM, http://wikileaks.org/About.html (last visited Jan. 3, 2013).

[24] In re *Application*, 830 F. Supp. 2d at 117; Scott Shane & John F. Burns, *U.S. Subpoenas Twitter Over WikiLeaks Supporters*, N.Y. TIMES, Jan. 8, 2011, http://www.nytimes.com/2011/01/09/world/09wiki.html?pagewanted=all&_r=0.

individuals—Jacob Appelbaum, a resident and citizen of the United States and a computer security expert, Rop Gonggrijp, a Dutch citizen and a computer security expert, and Birgitta Jonsdottir, a citizen and resident of Iceland, and a member of the Icelandic parliament—acted as members of the Wikileaks organization and performed criminal acts related to the release of classified U.S. government documents.[25] The three were alleged to be subscribers and users of Twitter, and used the Internet to communicate with the Twitter social networking site.[26]

B. Procedural Posture

Upon *ex parte* application by the government, Magistrate Judge Theresa Carroll Buchanan issued an order instructing Twitter to produce specific electronic records to the government.[27] Twitter responded with a motion to unseal the order. On January 5, 2011, based on Twitter's motion and the government's consent, the magistrate judge unsealed the order, finding that it was in the best interest of the investigation.[28] The magistrate judge also authorized Twitter to disclose the order to Appelbaum, Gonggrijp, and Jonsdottir.[29]

In response, the three individuals filed a motion to vacate the order, and a motion to unseal certain other court records pertaining to the order and publicly docket all orders issued under 18 U.S.C. § 2703.[30] The individuals based their motions on a variety of grounds, including a constitutional claim based on the Fourth Amendment right to privacy.[31]

After briefing from both parties, Magistrate Judge Buchanan issued an order and memorandum opinion denying the motion to vacate, granting in part the motion to unseal, and keeping under

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[25] *In re Application*, 830 F. Supp. 2d at 117.
[26] *Id.*
[27] *Id.* at 121.
[28] *Id.* at 122.
[29] *Id.*
[30] *Id.*
[31] *Id.* at 127.

advisement the issue of public docketing.[32] In her memorandum opinion, Magistrate Judge Buchanan found that the individuals lacked standing to challenge the order, that issuance of the order was proper under the SCA, and that issuance of the order did not violate the Fourth Amendment.[33] Then, on June 1, 2011, Magistrate Judge Buchanan issued an order and memorandum opinion denying the request for public docketing.[34] Appelbaum, Gonggrijp, and Jonsdottir filed objections to both orders.[35]

C. Building on Prior Precedent

On November 10, 2011, Federal District Court Judge Liam O'Grady affirmed the rulings of Magistrate Judge Buchanan, finding that the individuals lacked statutory standing.[36] The judge further found that the order of production issued under the SCA that allowed the government to obtain non-content Twitter information was valid, did not require a warrant, and did not violate any Fourth Amendment right to privacy.[37]

In denying petitioners' motions, Judge O'Grady noted that gaining online access requires all Internet users to transmit IP address information associated with their personal computing devices out of private home spaces and onto online routers that then convey traffic to specific websites.[38] Combined with Twitter's privacy policy, which resulted in application of the Fourth Amendment's third-party doctrine, the nature of Internet data transmission led the judge to conclude that Twitter users have no expectation of privacy regarding the numerical IP addresses that identify their computers, cellular phones or other mobile devices that connect to the Internet when using Twitter.[39]

The court first addressed locational privacy issues raised by the

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[32] *Id.* at 122.
[33] *Id.* at 127.
[34] *Id.* at 122.
[35] *Id.*
[36] *Id.* at 128-29.
[37] *Id.* at 129-30, 138.
[38] *Id.* at 135.
[39] *Id.* at 138.

possible use of non-content data. The court distinguished *United States v. Karo*,[40] noting that the case at bar did not involve surveillance of something that had been withdrawn from view, but rather something that was transmitted from a private space into a public space, and that Twitter, not the government, recorded the information.[41] That such information could be used to pinpoint the location of the user did not worry the court, as "[t]he Fourth Circuit has explicitly approved the collection of non-IP subscriber information" to pinpoint the location of a party.[42] In essence, the court distinguished the facts of this case from those of *Karo*, focusing on the entity making the transmission and the entity recording the data. In addition, the court explained that, assuming *arguendo* that the government was able to track user movements based upon IP address data, "IP addresses are no more revealing about the contents of communication than are phone numbers."[43] Just as the government "may be able to make educated guesses about what was said, simply based on non-content information about the parties involved in the communication" using telephone numbers, so too may the government perform similar guesswork with IP addresses.[44]

The court then examined the impact of the third-party doctrine on the privacy claim. The court noted the history of the third-party doctrine, looking to *United States v. Miller*,[45] and *Smith v. Maryland*.[46] The court explained:

> Like the defendant in *Smith* [relied on the phone company to connect calls], Petitioners relied on Internet technology to access Twitter, indicating an intention to relinquish control of whatever information would be necessary to complete their communication. They knew that their communications with Twitter would be transmitted

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[40] 468 U.S. 705 (1984).
[41] *In re Application*, 830 F. Supp. 2d at 131-33.
[42] *Id.* at 133 (citing U.S. v. Bynum, 604 F.3d 161, 164 n.2 (2010)).
[43] *Id.* at 138.
[44] *Id.*
[45] 425 U.S. 435 (1976).
[46] 442 U.S. 735 (1979).

> out of private spaces and onto the Internet for routing to Twitter.[47]

Analogizing the defendant's voluntary disclosure of information to the phone company when dialing a phone from within his home in *Smith* to the act of the petitioners in the case at bar in disclosing their IP addresses to Twitter, the court concluded that "[b]oth phone numbers and IP addresses must be revealed to intermediaries as a practical necessity of completing communications over their respective networks."[48]

The court pointed to two prior cases to support its conclusion that IP addresses are analogous to telephone numbers. In *U.S. v. Christie*, the defendant was convicted of possession of thousands of images of child pornography and of various child-pornography-related offenses.[49] The defendant appealed, based in part on an argument that the government's acquisition of his IP address violated his Fourth Amendment rights and thus evidence gathered related to his activity on a child pornography website should have been suppressed.[50] The Third Circuit rejected this argument, analogizing an IP address to other subscriber information and holding that "no reasonable expectation of privacy exists in an IP address."[51] Likewise, in *United States v. Forrester*, a defendant convicted of conspiracy to manufacture ecstasy and various other offenses related to the operation of a large ecstasy-manufacturing laboratory challenged the validity of a government computer surveillance program that enabled the government to learn, among other things, the IP addresses of the websites that he visited.[52] Comparing the gathering of IP address data with the use of a pen register in *Smith*,[53] the Ninth Circuit concluded that the government's actions were not a search within Fourth Amendment purposes.[54]

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[47] *In re Application*, 830 F. Supp. 2d at 135.
[48] *Id.*
[49] 624 F.3d 558, 562 (3d Cir. 2010).
[50] *Id.* at 567.
[51] *Id.* at 574.
[52] 512 F.3d 500, 504 (9th Cir. 2007).
[53] 442 U.S. 735 (1979).
[54] *Forrester*, 512 F.3d at 510.

The court also distinguished the facts of the Twitter case from those of two other situations that courts have faced. First, the court noted that the petitioners reliance on *United States v. Warshak*[55] was misplaced because *Warshak* dealt with an order seeking emails—in other words, content.[56] In contrast, the government sought only non-content records in the case at bar.[57] Similarly, the Court concluded that *United States v. Heckenkamp*[58] was "inapposite because the intrusion at issue [in *Heckenkamp*] was a remote search of the defendant's computer, which included running commands and examining files stored on the defendant's personal computer."[59] Whereas "[p]ersonal computers are ordinarily treated like closed containers under the Fourth Amendment," the non-content data the users transmitted to Twitter moved from a private space into a public space.[60]

Thus, relying in large part on previous decisions, the Court determined Twitter users lack a reasonable expectation of privacy in the IP data transmitted as part of their communication with the website.

III. IMPACT ON ONLINE SOCIAL NETWORKING SITES AND USERS

A. Non-Content Data is Not Private or Protected

Application of the SCA to social networking sites appears to limit any privacy interests that end users have in information conveyed to the social media service providers, at least in non-content information. Under this court's analysis, it does not appear that the Fourth Amendment would ever protect non-content information contained in or associated with IP addresses. As the Court states, "[The Petitioners] also implicitly consented to disclosure of their IP address information to Twitter as a practical

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[55] 631 F.3d 266 (6th Cir. 2010).
[56] *In re Application*, 830 F. Supp. 2d at 137.
[57] *Id.*
[58] 482 F.3d 1142 (9th Cir. 2007).
[59] *In re Application*, 830 F. Supp. 2d at 137.
[60] *Id.*

necessity of using Internet technology."[61] IP addresses are necessary to route communications over the Internet. Such a result is consistent with prior decisions and represents a natural expansion of prior precedent.[62] The distinction between content and non-content, as well as the distinction between private and public spaces, remain firm.

The conclusions of others who have considered the application of the SCA to analogous situations also bolster this decision.[63] Because the nature of online communication requires disclosure of IP address data into public space and to a third party, even when transmitted from a personal computer located in a private space, social networking site users and operators should be on notice that no expectation of privacy exists in IP address data transmitted over the Internet.

B. Non-Content Data is Collected and Retained

Social networking sites will continue to track and retain non-content data, including IP address information. For example, both Twitter and Facebook include explicit messages about retaining IP address information in their respective privacy policies.[64] Twitter

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[61] *Id.* at 139.

[62] *See e.g.*, U.S. v. Christie, 624 F.3d 558, 574 (3d Cir. 2010); U.S. v. Forrester, 512 F.3d 500 (9th Cir. 2007).

[63] *See, e.g.*, Kerr, *supra* note 13, 1210 ("[B]y communicating with their ISPs, Internet users have revealed information to their ISPs and have relinquished their Fourth Amendment rights in that information."); People v. Malcolm Harris, 949 N.Y.S.2d 590 (N.Y. Crim. Ct. June 30, 2012).

[64] According to Twitter, "Our servers automatically record information (Log Data) created by your use of the Services. Log Data may include information such as your IP address, browser type, operating system, the referring web page, pages visited, location, your mobile carrier, device and application IDs, search terms, and cookie information." *Twitter Privacy Policy*, TWITTER.COM, June 23, 2011, http://twitter.com/privacy. Likewise, Facebook states, "We receive data from the computer, mobile phone or other device you use to access Facebook, including when multiple users log in from the same device. This may include your IP address and other information about things like your internet service, location, the type (including identifiers) of browser you use, or the pages you visit." *Data Use Policy*, FACEBOOK.COM, https://www.facebook.com/about/privacy/your-info (last visited Jan. 3, 2013).

informs users that in most cases it will only retain such data for 18 months, after which it will either delete it or remove "common account identifiers" (such as username, full IP address, or email address);[65] Facebook retains data until an account has been deleted.[66]

That private companies are retaining non-content data does not appear to worry the court in this case. After noting that IP addresses are necessary to route communications over the Internet, the court continued:

> The fact that Twitter chose to record IP address information pertaining to [the Twitter users], and the purpose for which it did so, makes no difference. . . . As the Supreme Court stated in *Smith* [*v. Maryland*], the meaning of the Fourth Amendment cannot be dictated by the record-keeping practices of a private corporation. ("We are not inclined to make a crazy quilt of the Fourth Amendment, especially in circumstances where (as here) the pattern of protection would be dictated by billing practices of a private corporation.").[67]

Non-content data is necessarily transmitted and routinely retained. Social networking companies collect and retain non-content data because users necessarily provide it—making it pervasive and uniform. Non-content data helps companies provide more personalized service, and can be used to monetize social networking sites through targeted advertising. And regardless of why non-content data is retained, privacy interests found in the Fourth Amendment or the SCA do not protect it.

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[65] *Twitter Privacy Policy*, TWITTER.COM, June 23, 2011, http://twitter.com/privacy.

[66] *Data Use Policy*, FACEBOOK.COM, https://www.facebook.com/about/privacy/your-info (last visited Jan. 3, 2013).

[67] *In re* Application of the U.S. for an Order Pursuant to 18 U.S.C. §2703(d), 830 F. Supp. 2d 114, 137-38 (E.D. Va. Nov. 10, 2011) (internal citation omitted).

CONCLUSION

In deciding *In re Application of the U.S. for an Order Pursuant to 18 U.S.C. §2703(d)*, a federal district court in Virginia affirmed that the federal government can legally obtain a Twitter user's IP address and other non-content information associated with the user without first providing notice to the user. This decision represents a natural expansion of existing Fourth Amendment jurisprudence applying the SCA, and gives both users and operators of social networking sites notice that there is no expectation of privacy for IP address data transmitted over the Internet—even when the data is transmitted from a personal computer located in a private space. The nature of online communication itself requires that machines disclose non-content data, meaning that under the SCA, the data required for using the Internet is inherently non-private. Internet users lack a reasonable expectation of privacy in the IP data and other non-content information they transmit as part of their communication with a website.

PRACTICE POINTERS

- All social networking companies should employ "clickwrap" agreements and/or privacy policies that put users on notice regarding the company's retention of non-content data.
- Internet users should be aware that social networking sites (as well as a host of other sites) retain non-content data for a variety of purposes.
- Courts will likely continue to analogize IP address information to telephone numbers when performing any Fourth Amendment analysis.

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WHEN IS A PHONE A COMPUTER?

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ABSTRACT

In United States v. Kramer*, the Eighth Circuit upheld a two-level sentence enhancement for a defendant who made calls and sent text messages from a cellphone to a minor in order to lure her across state lines for criminal sexual activity. This enhancement was based on a provision in the United States Sentencing Guidelines that incorporates the definition of "computer" from the Computer Fraud and Abuse Act. The broad language of that statute encompasses not only computers—in the plainest sense—and cellphones, but also a myriad of other devices such as automobiles equipped with GPS navigation. In contrast to the sentencing context, this conception of many electronics devices as "computers" does not extend into issues related to searches. There, courts tend to permit broader examination of cellphones and other electronic devices in searches incident to arrest, despite the general protection computers are usually afforded under the Fourth Amendment.*

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[*] J.C. Lundberg, University of Washington School of Law, Class of 2013. Many thanks to Lauren Guicheteau, Jane Winn and Peter Winn for all their input on this Article.

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INTRODUCTION

In a recent case, *United States v. Kramer*,[1] the Eighth Circuit held that a two-level sentencing enhancement was appropriate when a defendant used a cellphone to induce a minor to cross state lines for criminal sexual activity. This enhancement applied because Kramer's cellphone was deemed to qualify as a computer under the relevant statutory definition of the Computer Fraud and Abuse Act.[2] This definition is so encompassing that Steve Wozniak's somewhat flippant claim, "[e]verything has a computer in it nowadays,"[3] becomes a troubling reality for many criminal defendants. Given the realities of how this class of crimes is committed and the sweeping definition above, effectively all defendants sentenced for such crimes will be eligible for the sentence enhancement. In contrast, computers—as traditionally conceived—are offered unique protection from searches under the Fourth Amendment. Under searches incident to arrest and those pursuant to a warrant, computer searches must be narrowly tailored. This double reading of the word "computer"—expansive for sentencing purposes and narrow for Fourth Amendment purposes—reflects the fog which plagues courts trying to apply

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[1] 631 F.3d 900 (8th Cir. 2011).

[2] 18 U.S.C. § 1030 (e)(1) (2006).

[3] Mark Millian, *Apple's Steve Wozniak: 'We've lost a lot of control'*, CNN TECH (Dec. 8, 2010, 12:16 PM), http://articles.cnn.com/2010-12-08/tech/steve.wozniak.computers_1_computer-whiz-computer-history-museum-apple-shares?_s=PM:TECH.

traditional principles or older statutes to our rapidly evolving technology.

I. THE WORD "COMPUTER" AND SENTENCING

A common dictionary definition of "computer" is any "device that computes, especially a programmable electronic machine that performs high-speed mathematical or logical operations or that assembles, stores, correlates, or otherwise processes information."[4] This definition encompasses essentially all portable electronics—including iPods, smartphones, e-readers and iPads—as well as many microwaves and televisions. However, in common usage, "computer" generally intends either a laptop or desktop PC. Generally, most people think a computer is a device with a full QWERTY keyboard designed to be typed on at length.[5] Considering a more expansive definition than the intuitive one outlined above, the borders of where a modern device stops being a computer in any meaningful sense of the word is when a user cannot use the device to connect to the Internet.

The United States Sentencing Guidelines (USSG) include an enhancement of two levels if the "offense involved the use of a computer . . . to (A) persuade, induce, entice, coerce, or facilitate the travel of, the minor to engage in prohibited sexual conduct; or (B) entice, encourage, offer, or solicit a person to engage in prohibited sexual conduct with the minor."[6] The U.S. Sentencing

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[4] AMERICAN HERITAGE DICTIONARY.

[5] The increasing adoption of tablet devices, including the iPad and Microsoft Surface, shows some of the difficulty in defining "computer" in a way that is acceptable everyone. Some call these products halfway between a laptop and a smartphone. Michael Arrington, *The Unauthorized TechCrunch iPad Review*, TECHCRUNCH (Apr. 2, 2010), http://techcrunch.com (calling the iPad a "New category of device"). Others deride them as oversized smartphones. Matthew Shaer, *iPad nothing more than an oversized Apple iPhone: Motorola*, THE CHRISTIAN SCIENCE MONITOR: HORIZONS (Dec. 21, 2010), http://www.csmonitor.com/Innovation/Horizons.

[6] United States Sentencing Guidelines § 2G1.3 (b)(3) (2013). Similar enhancements—albeit not always with identical language—appear in USSG §§ 2A3.1 ("Criminal Sexual Abuse" or Attempt), 2A3.2 (Statutory Rape or Attempt), 2A3.3 ("Criminal Sexual Abuse of a Ward" or Attempt), 2A3.4 ("Abusive Sexual Contact" or Attempt), 2G2.1 (Creation of Child Pornography),

Guidelines incorporate the definition of "computer" in the Computer Fraud and Abuse Act (CFAA). "'Computer' has the meaning given that term in 18 U.S.C. § 1030(e)(1)."[7] In turn,

> the term 'computer' means an electronic, magnetic, optical, electrochemical, or other high speed data processing device performing logical, arithmetic, or storage functions, and includes any data storage facility or communications facility directly related to or operating in conjunction with such device, but such term does not include an automated typewriter or typesetter, a portable hand held calculator, or other similar device.[8]

A cellphone is not a typewriter, calculator, or similar device. The deciding factor in the CFAA analysis has to do with the storage capacity. Some typewriters have a one line memory and most four function calculators can remember a single number but beyond that they rely on the user to supply data and processing power. Even the most rudimentary cellphone available on the market today qualifies as a computer under the CFAA due to its ability to, at a minimum, store a call history and list of contacts. The Seventh Circuit adopted this reasoning and spoke in even broader terms, stating that "[e]very cell phone and cell tower is a 'computer' under this statute's definition; so is every iPod, every wireless base station in the corner coffee shop, and many another gadget."[9] One commentator expands on the category of "many another gadget [sic]" which "can include coffeemakers, microwave ovens, watches, telephones, children's toys, MP3 players, refrigerators, heating and air-conditioning units, radios, alarm clocks, televisions, and DVD players, in addition to more traditional computers like laptops or desktop computers."[10]

2G2.2 (Trafficking in Child Pornography), 2G2.6 ("Child Exploitation Enterprises"), 2G3.1 ("Importing, Mailing, or Transporting Obscene Matter"), and 2H3.1 ("Interception of Communications").

[7] United States Sentencing Guidelines § 2G1.3 (2012), Note 1, Definitions.

[8] 18 U.S.C. § 1030 (e)(1).

[9] U.S. v. Mitra, 405 F.3d 492, 495 (7th Cir. 2005).

[10] Orin S. Kerr, *Vagueness Challenges to the Computer Fraud and Abuse Act*, 94 MINN. L. REV. 1561, 1577-1578 (2010) (footnote omitted).

As a practical matter, there is a question of how some of the broader instances above could actually trigger the USSG computer-use enhancement. How, for example, could a coffeemaker be used to lure a child across state lines for immoral purposes? Some hypotheticals, however, are not so farfetched. One not addressed in any published case thus far would be the use of a modern automobile to transport a minor across state lines, absent the use of any other computer. The myriad of computerized controls, not to mention built-in GPS devices, inherent in a newer vehicle renders it a "computer" under the CFAA. As such, the individual who used such a car to transport a child across state lines for immoral purposes could be subject to the 2-level enhancement of USSG § 2G1.3 (b)(3) as was the defendant in *Kramer*. If an attempt were made by a U.S. Attorney to seek the enhancement, the intuitive understanding that cars and computers differ significantly, is likely to prevail, causing the enhancement to be denied.

II. COMPUTERS AND THE FOURTH AMENDMENT

There are two general streams of jurisprudence addressing searches: searches pursuant to a warrant and searches incident to arrest. The latter—searches performed in the context of an arrest—generally offer far less protection for suspects than the former. In both situations, however, computers are treated very differently from cell phones and similar devices.

A. Warrant Searches

The general rule governing searches is that a search of a person's effects or papers requires a warrant.[11] The Fourth Amendment requires that warrants are written "particularly describing the place to be searched, and the persons or things to be seized."[12] This protection ensures that warrant searches are strictly limited to the scope of the warrant, even going so far to limit what

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[11] *See generally* U.S. CONST. amend. IV.
[12] *Id.*

sort of data the police can search for on a computer.

Some courts attempt to resolve the limits of warrant computer searches by utilizing traditional ideas in Fourth Amendment law, especially the closed container doctrine, which prohibits warrantless searches of a closed container.[13]

In applying these traditional ideas to computers, a prosecutor in the case *U.S. v. Crist* argued that a defendant's entire computer should be treated as a single closed container. The Middle District of Pennsylvania did not accept the U.S. Attorney's reasoning. "A hard drive is not analogous to an individual disk. Rather, a hard drive is comprised of many platters, or magnetic data storage units, mounted together. Each platter, as opposed to the hard drive in its entirety, is analogous to a single disk as discussed in *Runyan*."[14] The court relied on the technical aspects of hard drive construction, which offered an avenue of limiting the search.

With advents in data storage technology, however, this limit will do little good going forward. The storage on many newer computers, and on all cellphones, is flash-based rather than platter-based.[15] While similar reasoning may be applied—multiple chips in a flash hard drive and multiple platters in a traditional hard drive—some smaller devices, like cellphones, use flash chips for their storage. *Crist*'s reasoning could also protect, for example, a car's GPS history information if the warrant is only written to permit searching the interior of the car for specific items or classes of items. For that matter, a warrant authorizing a search for any kind of item—that is, physical object—may not permit any search of the car's computer systems or GPS history since digital data is not an object.[16]

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[13] See generally U.S. v. Monghur, 588 F.3d 975 (9th Cir. 2009).

[14] U.S. v. Crist, 627 F.Supp.2d 575, 586 (2008, M.D. Penn.) (citing U.S. v. Runyan, 275 F.3d 449 (5th Cir. 2001)).

[15] One example is Apple's Macbook Air which, since 2010, is only available with flash hard drives. As time goes on, the list of potential examples of this kind of storage in laptops grows prodigiously.

[16] Courts addressing GPS data generally do so in the context of tracking units placed on cars by police officers. *See, e.g.*, United States v. Jones, 132 S.Ct 945 (2012). As such, courts have not addressed this information/object distinction directly but it could be leveraged by defendants seeking to exclude some information.

A better rubric under which to analyze warrant searches of computers is offered by *U.S. v. Carey*.[17] In that case, an officer searching a computer came upon an image of child pornography. Instead of stopping for a modification of the warrant, the officer continued to search the computer for child pornography. "The warrant authorized the officer to search any file because 'any file might well have contained information relating to drug crimes and the fact that some files might have appeared to have been graphics files would not necessarily preclude them from containing such information.'"[18] When the search was challenged, the court found that the first incidence of child pornography was a licit find because it was in digital plain view, but the remainder resulted from the officer's indifference to the warrant. "The Supreme Court has instructed, 'the plain view doctrine may not be used to extend a general exploratory search from one object to another until something incriminating at last emerges.'"[19] Warrant searches must be limited not only to the places the warrant allows but also to the thing to be found.

Despite the use of more traditional categories, including the plain view and closed container doctrines, some courts have attempted to extend general search protections over computers and other electronics. In *United States v. Arnold*, the district court held:

> [T]he information contained in a laptop and in electronic storage devices renders a search of their contents substantially more intrusive than a search of the contents of a lunchbox or other tangible object. A laptop and its storage devices have the potential to contain vast amounts of information. People keep all types of personal information on computers, including diaries, personal letters, medical information, photos and financial records.[20]

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[17] 172 F.3d 1268 (10th Cir. 1999).

[18] *Id*. at 1272.

[19] *Id*. at 1272 (quoting Coolidge v. New Hampshire, 403 U.S. 443, 466 (1971)).

[20] United States v. Arnold, 454 F.Supp.2d 999, 1003–1004 (C.D.Cal. 2006) reversed by U.S. v. Aronld, 523 F.3d 941 (9th Cir. 2008). The appeal was

The decision in *Arnold* shows that some judges are increasingly aware of the broad sweep permissive electronics searches would make into the private lives of individuals who may well have done nothing wrong.

B. Automobile Exception

Despite the traditional protection against searches of closed containers, cell phones may be "opened" under the automobile exception.[21] The jurisprudence addressing searches of cellphones is generally centered on phones found in automobiles, where longstanding rules permit their search despite the special protection generally afforded to computers. The limits of this exception are drawn by probable cause and "not defined by the nature of the container in which the contraband is secreted. Rather, the exception is defined by the object of the search and the places in which there is probable cause to believe that it may be found."[22]

This automobile exception is similar to the general exception to the privacy right that is triggered when an individual is arrested.

> [T]he police may also examine the contents of any containers found within the passenger compartment, for if the passenger compartment is within reach of the arrestee, so also will containers in it be within his reach. Such a container may, of course, be searched whether it is open or closed, since the justification for the search is not that the arrestee has no privacy interest in the container, but that the lawful custodial arrest justifies the infringement of any privacy interest the arrestee may have.[23]

The application of this exception, however, treats cellphones and computers quite differently. While both have been shoehorned into the legal framework of the closed container doctrine, computers

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decided on the grounds that the search occurred at a border where warrantless searches are widely permitted.

[21] United States v. Ross, 456 U.S. 798 (1982).

[22] *Id.* at 824.

[23] New York v. Belton, 453 U.S. 454, 460–61 (1981) (footnotes omitted).

have been exempted from the automobile exception but cellphones have not.

The Tenth Circuit has explicitly exempted computers from the automobile exception. In *U.S. v. Burgess*,[24] the Court analyzed a search of a defendant's motorhome, which revealed marijuana, cocaine, a laptop, and an external hard drive.[25] In analyzing whether the discovery, and subsequent search, of the computer was licit, the court refused to follow the government's simple "syllogism": (1) the expected privacy of the contents of a computer is like that of a briefcase; (2) the automobile exception permits searches of briefcases, even if locked, found in automobiles given probable cause; hence (3) police may—given probable cause—search computers found in automobiles.[26]

The *Burgess* court did not disagree that the syllogism was formally valid, but clarified that the treatment of computers as closed containers was done "to emphasize the high expectation of privacy for" computers and "not to permit promiscuous searches under the automobile exception."[27] In dicta, the court emphasized that computers hold much information about an individual's life, very little of which would be relevant for criminal investigation. Accordingly, a warrantless search of a computer would be like a warrantless search of "relevant documents so intermingled with irrelevant documents that they cannot feasibly be sorted at the site."[28] While officers may seize such papers for evaluation pursuant to a search warrant granted by a magistrate when they cannot feasibly search them on site, "[t]he magistrate should then require officers to specify in a warrant which type of [documents] are sought."[29] Under similar reasoning, computers would be exempted from the automobile exception.[30]

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[24] 576 F.3d 1078 (10th Cir. 2009).

[25] *Id*. at 1082-83.

[26] *Id*. at 1088 citing California v. Acevedo, 500 U.S. 565, 580 (1991) (confirming the applicability of the automobile exception to locked briefcases).

[27] U.S. v. Carey, 172 F.3d 1268, 1275 (10th Cir. 1999) (quoted in *Burgess*, 576 F.3d at 1089).

[28] *Id.*

[29] *Id.*

[30] The Tenth Circuit ultimately punted on the issue, despite much discussion, because "[i]nteresting as the issue may be, we need not now resolve

Implicit in some courts' dicta is the idea that computers are not subject to the automobile exception. For example the U.S. District Court for the Western District of Missouri ruled, in an unpublished opinion, on a criminal defendant's motion to suppress information found on his cellphone after it was discovered in an automobile search an officer conducted after the defendant's arrest. "The Court concludes that the automobile exception to the Fourth Amendment's warrant requirement gave Officer Hilburn's [sic] latitude to search defendant's cell phone and camera, like it would allow the search of other closed containers in the vehicle."[31] This conclusion was followed immediately by a footnote distinguishing *Kramer*—on which the defendant relied—because it did not consider the Fourth Amendment implications of the computer/cellphone unification.

This double standard has not gone unnoticed by Fourth Amendment scholars. "If current Fourth Amendment jurisprudence is extended to its logical conclusion, officers who arrest drivers for traffic infractions will be permitted to search the call histories, text messages, email, photos, movies, and Internet browsing history on iPhones with no suspicion of wrongdoing whatsoever."[32] In fact, the same line of reasoning would also permit the examination of the history of a GPS device found in, or built into, a car. Because this area of jurisprudence is currently growing and developing, it remains to be seen whether these concerns will come to fruition, but they certainly mark one possible trend of the unfolding interface of the Fourth Amendment and portable technology.

C. Searches Incident to Arrest

Outside the context of automobiles, the permissibility of searches incident to arrest centers on the safety of officers. Because this standard is narrower than the automotive exception, it will be much less likely to cover the search of a cellphone, and its

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it because the search of Burgess' hard drives was authorized by a warrant." Burgess, 576 F.3d at 1090.

[31] U.S. v. Stringer, 2011 WL 3847026, *9 (W.D. Missouri July 20, 2011).

[32] Adam M. Gershowitz, *The iPhone Meets the Fourth Amendment*, 56 UCLA L. REV. 27, 27 (2008).

bounds generally preclude a search of an arrestee's cellphone's memory.

The Supreme Court has clearly delineated the reasons for warrantless searches incident to arrest. "The exception [to a general requirement for a warrant] derives from interests in officer safety and evidence preservation that are typically implicated in arrest situations."[33] The dangers in both categories are clear. A weapon in an arrestee's control can harm the arresting officer, other officers, or other arrestees, and evidence left in an arrestee's possession can easily be damaged or destroyed before recovered during booking. Neither category offers purchase for a warrantless search of either computers or cellphones conducted incident to arrest.

Courts place extreme importance on the intent of the officer in searches incident to arrest. If the search was conducted for officer safety, the evidence will likely be permitted. In other circumstances, the Northern District of California struck down a search of defendants' cellphones conducted subsequent to arrest because the "[o]fficers did not search the phones out of a concern for officer safety, or to prevent the concealment or destruction of evidence. Instead, the purpose was purely investigatory. Once the officers lawfully seized defendants' cellular phones, officers could have sought a warrant to search the contents of the cellular phones."[34] As a practical matter, it is unlikely that officer safety would ever justify a search of a cellphone's memory.

Similarly, cellphone memory is generally long-lasting and robust, thereby preserving evidence which does not offer sufficient reason to protect a warrantless search of an arrestee's cellphone. In *State v. Smith*[35], the Supreme Court of Ohio rejected a search of a cellphone made subsequent to arrest on the grounds that the Government failed to show that any of its data faced imminent deletion or destruction and that it could not be found any other way.[36] Much like the Supreme Court of Ohio, the Northern District

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[33] Arizona v. Grant, 556 U.S. 332, 338 (2009).

[34] U.S. v. Park, 2007 WL 1521573, *8 (N.D. California May 23, 2007).

[35] 920 N.E. 2d 949 (Ohio 2009)

[36] See THOMAS K. CLANEY, CYBER CRIME AND DIGITAL EVIDENCE: MATERIALS AND CASES 187 (2011). There are potential situations where

of California placed cellphones outside the reach of warrantless searches incident to arrest; "a cellular phone should not be characterized as an element of individual's clothing or person, but rather as a 'possession[ ] within an arrestee's immediate control [that has] fourth amendment [sic] protection at the station house.'"[37]

CONCLUSION

The word "computer" has a myriad of meanings depending on the context in which it is used. The choice of the meaning has a substantive effect on the legal framework applied to the object in question. In the sentencing context, for example, "computer" has the broad meaning under the Computer Fraud and Abuse Act, which can then result in the use of a simple cellphone rendering a defendant eligible for a sentencing enhancement. On the other hand, sometimes courts look past terminology to the functional aspects of the device in question, often traditional doctrines such as the closed container doctrine. Even in these contexts, however, some courts treat cellphones and computers much differently, typically to a defendant's detriment.

What devices can be searched, in what manner, and when are evolving areas of the law. One can only "speculate whether the Supreme Court would treat laptop computers, hard drives, flash drives or even cell phones as it has a briefcase or give those types of devices preferred status because of their unique ability to hold vast amounts of diverse personal information."[38] In the meantime, the mixed judicial reactions to the evidentiary implications of the word "computer" can offer advantage to both sides in criminal cases.

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evidence on a cellphone could be destroyed if not investigated at the time of arrest, they are not identifiable ex ante by an officer at the scene. One would be an iPhone that can be remotely wiped by someone with its associated iCloud account password. Determining whether such data will be deleted is impossible to tell before it begins.

[37] U.S. v. Park, 2007 WL 1521573, *8 (N.D. California May 23, 2007) (quoting U.S. v. Monclavo-Cruz, 662 F.2d 1285, 1290 (9th Cir. 1981)).

[38] U.S. v. Burgess, 576 F.3d 1078, 1090 (10th Cir. 2009).

PRACTICE POINTERS

- Prosecutors: Point to instances where courts have been widely permissive of searches of new technologies, especially cellphones.
- Defenders: Point to the fact that a cellphone or other pieces of new technology often hold as much intimate information about an individual as a computer. They should, therefore, be extended the same protection.

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UNCHAINING E-DISCOVERY IN THE PATENT COURTS

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ABSTRACT

This Article analyzes the Federal Circuit's Model Order Regarding E-Discovery in Patent Cases (the "Model Order"). The Article briefly describes the purpose behind the Model Order, describes its key provisions, analyzes the Model Order to identify some areas of continuing concern, and defines predictive coding to examine the impact, or lack thereof, on the Model Order. The Author concludes that, while it is beyond refute that the Model Order is an appropriate step toward controlling and managing e-discovery, the Model Order is only the first step. In this regard, several problems, as set forth below, can potentially arise when counsel or the courts use the Model Order. It is hoped that this Article will encourage judges, litigants, and other interested parties to continue trying to solve the continuously troubling aspects of e-discovery and e-discovery abuse.

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INTRODUCTION

The Model Order Regarding E-Discovery in Patent Cases[1] ("Model Order") is the Federal Circuit's response to the exponential growth of e-discovery and related costs in cases before it.[2] As noted in the Introduction to the Model Order, patent cases tend to suffer from disproportionally high discovery expenses—one study determined that the costs of Intellectual Property cases run almost 62 percent more than other litigation.[3] Moreover, the exponential growth in electronic documents and communications has, intentionally or otherwise, led to what the Federal Circuit considers to be excessive e-discovery.[4] Broad and unfettered e-discovery—particularly email-related discovery—facilitated litigation where the time and cost of electronic production far outweighed the minimal benefits of marginal and cumulative disclosure, thus threatening to derail the judicial promise of just, speedy, and affordable dispute resolution:

> As technology and knowledge play an increasingly important role in our economy, litigation must not become an intolerably expensive way to resolve patent disputes. Specifically, litigation costs should not be permitted to unduly interfere with the availability of the court to those who seek to vindicate their patent rights. The enforcement of such rights is both an obligation of the legal system and important to innovation. Likewise, disproportionate expense should not be permitted to force those accused of infringement to acquiesce to nonmeritorious claims.[5]

The Model Order provides the courts and counsel with a

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[1] Fed. Cir., E-Discovery Committee, Model Order Regarding E-Discovery in Patent Cases, available at http://www.cafc.uscourts.gov/images/stories/the-court/Ediscovery_Model_Order.pdf [hereinafter Model Order].

[2] Fed. Cir., E-Discovery Committee, Introduction to Model Order Regarding E-Discovery in Patent Cases, 2, available at http://www.cafc.uscourts.gov/images/stories/the-court/Ediscovery_Model_Order.pdf [hereinafter Introduction to Model Order].

[3] *See id.* at 1 (citing Emery G. Lee III & Thomas E. Willging, *Litigation Costs in Civil Cases: Multivariate Analysis* 8 (Fed. Judicial Ctr. 2010)).

[4] *Id.* at 2.

[5] Introduction to Model Order at 2.

framework to manage the e-discovery process, particularly for the responsible and targeted use of e-discovery in patent cases. It seeks to "promote economic and judicial efficiency by streamlining e-discovery, particularly email production, and requiring litigants to focus on the proper purpose of discovery—the gathering of material information . . . ."[6]

I. A REVIEW OF THE KEY PROVISIONS OF THE MODEL ORDER

The Model Order attempts to initiate mutual targeted e-discovery by placing presumptive limits on e-discovery. In this regard, the Model Order patterned itself after Federal Rule of Civil Procedure 30, which limited deposition practice by presumptively limiting each side to ten depositions of seven hours each.[7] Specifically, the Model Order requires the parties exchange the type of core documentation key to every patent litigation—i.e., documents concerning (i) the patent, (ii) the accused product, (iii) the prior art, and (iv) the relevant finances—before propounding email requests.[8] Even then, the Model Order presumptively limits the number of custodians and search terms for all email production requests, such that any email production requests remain focused on appropriate e-discovery issues.[9] These limits are presumptive only, and may be modified by the parties or the court for good cause shown.[10]

Where a party seeks more discovery than agreed upon by the parties, or allowed by the court, the requesting party bears the reasonable cost of that discovery.[11] By shifting costs, the Model Order seeks to ensure that a party carefully balances the cost and value of the additional discovery.[12]

The Model Order also seeks to lower the cost of e-discovery by

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[6] *Id.*; *see also* Model Order ¶ 1 ("This Order . . . streamlines Electronically Stored Information ('ESI') production to promote a 'just, speedy, and inexpensive determination' of this action.").

[7] *See id.* at 3; FED. R. CIV. P. 30.

[8] Model Order ¶ 8.

[9] *Id.* ¶¶ 6, 7, 10, 11.

[10] *Id.* ¶ 2.

[11] *Id.* ¶¶ 10, 11.

[12] *Id.*; Introduction to Model Order at 3-4 .

addressing a large source of that cost—pre-production document review by attorneys or other human reviewers. To minimize this pre-production review, the Model Order expressly provides that the inadvertent production of work product or attorney-client privileged work during the e-discovery period may not be used in the pending case. Moreover, these protected works neither constitute a waiver in the pending case, nor in any other federal or state proceeding.[13]

II. THE MODEL ORDER: AREAS OF CONTINUING CONCERN

The Model Order is a good first step toward addressing the major problem with e-discovery: ever-increasing complexity and expense. However, the Model Order solutions raise several concerns, four of which are identified and discussed below.

A. The Model Order's Cost-Shifting Triggers Allow the Parties to "Game" the System and May Offer Disincentives to More Economical Alternatives in E-Discovery

The first potential area of concern regarding the Model Order arises from the Model Order's reliance on disproportionate costs that trigger cost-shifting.[14] It is possible for the producing party's counsel to manipulate the discovery process so as to increase costs and force the requesting party to bear those costs. Specifically, the costs of performing data collection or execution may sometimes be substantially less costly if done in-house than if a third-party vendor collected and performed the search. For example, a large technology firm might have a proprietary document-tracking platform that runs on legacy hardware and an in-house IT team managing this system. In such cases, it would be substantially more costly to retain a third-party vendor than to use the in-house IT department. Yet, that expense arguably could still be presented

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[13] Model Order ¶¶ 12-14; Introduction to Model Order at 4.

[14] Model Order ¶ 3. The Model Order also provides that discovery tactics that delay or prolong the process will be considered by the court in determining which party should bear the costs of the discovery process. *Id.*

to the court and opposing counsel as a true cost in e-discovery, consequently deterring, narrowing, or shifting e-discovery costs. Indeed, the producing party can contend that using a third-party vendor is appropriate because doing so will avoid any concern that in-house IT staff will inevitably skew the production results in favor of the producing party. The end result is that a party can, or at least can try, to intentionally trigger cost-shifting as a litigation tactic.

Courts and litigants should be aware of this tactic, and raise the issue during the initial discovery conference mandated by Federal Rule of Civil Procedure 26. One solution involves the courts encouraging parties to utilize their own IT departments when possible to collect and produce documents, as long as "best practices" are followed by the in-house IT department in collecting and producing those documents.

B. The Model Order Default Standard That Metadata is not to be Produced Absent a Showing of Good Cause Ignores the Critical Value Metadata Provides When Issues Exist Around Authenticity or Authorship

The second area of concern with the Model Order is its default standard allowing no metadata (i.e., "data about data") absent a showing of good cause.[15] In patent-related disputes focusing on the patent creator's identity, filing date, or general priority, metadata is likely to be a critical element in the discovery process; metadata access can yield critical information regarding such key points as dates, times, authorship, and other related elements.[16] Although the Model Order does allow parties to request metadata upon a showing of good cause, it is an uphill effort for counsel to establish good cause because litigants may not have enough information to specifically determine what metadata they need in order to make the necessary showing.

One solution is for a court to maintain a lenient standard for

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[15] Model Order ¶ 5.

[16] *See* DANIEL B. GARRIE & YOAV M. GRIVER, DISPUTE RESOLUTION AND E-DISCOVERY (2012).

good cause, and allow relevant facts to emerge early in the case to reserve litigation time and cost.

C. The Model Order Only Allows Email Production to Occur After the Parties Have Exchanged Initial Disclosures of Basic Documents and Information on the Critical Systems Storing the Email

The Model Order attempts to force the parties to hold off on email production until after initial disclosures regarding relevant financial information, prior art, and patents.[17] However, to encourage focused and reasonable e-mail production, the Model Order also should require the parties to define their respective technology systems involved with email. This information is critical to drafting reasonable and narrowly tailored email requests required by the Model Order.[18]

For example, a party might craft an e-mail request that is narrowly tailored and appears reasonable,[19] but that request may be unreasonable if the party seeks email that is five years old and remains stored on disk backup in Germany. In this example, the cost of production, given the medium and location, makes an apparently narrow and reasonable request unreasonable in practice, and may require an even more refined request.

The parties should be required to identify and disclose their respective technology systems involved with email as a preliminary matter, so that such issues may be identified before

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[17] Model Order ¶ 8.

[18] *See* Model Order ¶ 6 ("To obtain email parties must propound specific email production requests."); ¶ 7 ("Email production requests shall only be propounded for specific issues, rather than general discovery of a product or business.").

[19] *See*, *e.g.*, McGrath v. United States, No. 11–318C, 2012 WL 726423 (Fed. Cl. March 6, 2012). In *McGrath*, the United States Court of Federal Claims considered a proposed discovery order that contained some, but not all, of the provisions from the Model Order. Among other things, the parties were eventually ordered to cooperate to identify the proper custodians, proper search terms, and proper timeframe before producing email, and "encouraged" to use narrowing search criteria (e.g., "and," "but not," "w/x") to limit email production.

each party issues email requests. Thus, one possible solution is a Model Order amendment requiring the parties to exchange information about their IT systems at the earliest litigation stage, enabling both sides to effectively organize their forthcoming search requests.

D. The Model Order Should Consider Requiring the Parties to Perform Email Sampling Before Limiting the Number of Search Terms and Custodians to Five People and Terms

The Model Order presumptively limits the number of custodians and search terms for all email production requests to five terms and custodians per producing party.[20] The intent is to control exorbitant production costs by minimizing what parties can request.[21] Although well-intentioned, this presumptive limit presents a challenging paradigm; it is impossible for parties to be 100 percent accurate on terms and custodians, especially when they do not control the data. Consequently, prior to selecting terms or custodians, the court or parties should filter the available field with common sense:

1. Both parties should group search terms into high-, medium-, and low-value groups.
2. The parties should then take each group of search terms and identify applicable timeframes and custodians.

For example:

> High Group
> Dates: 02/2010 to 05/2011; 03/2005 to 04/2006
> Custodians: D. Smith; M. Jane
> Terms: Apple, Democrat, Republican, Libertarian

3. The opposing party should then sample each of the custodians using the search terms and dates for the group.
4. The proposing party may then re-order the terms and custodians.

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[20] Model Order ¶¶ 10, 11.
[21] Introduction to Model Order at 2; Model Order ¶¶ 6, 7.

Of course, the court should mandate applying the Model Order's strict number requirements if the parties fail to mutually agree on a protocol, or if the terms the parties propose are inappropriate or indiscriminate in nature. Under such circumstances, ¶ 11 of the Model Order provides for cost-shifting to the requesting party.

III. IMPACT OF PREDICTIVE CODING ON THE FEDERAL CIRCUIT MODEL ORDER

Currently, there is a debate over the effectiveness and reliability keyword searching,[22] as many contend that there are superior ways to return the most responsive documents in a litigation matter.[23] Bolstering this contention is predictive coding, or technology-assisted review,[24] which increasingly strengthens

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[22] *See* Victor Stanley, Inc. v. Creative Pipe, Inc., 250 F.R.D. 251, 259-60 (D. Md. 2008). *See generally* Da Silva Moore v. Publicis Groupe, 868 F. Supp.2d 137 (S.D.N.Y. 2012) (order approving use of computer-assisted review). While there is a great deal of debate, condemning keyword search technology is unfair in this context, as it is akin to saying tape players are inferior to MP3 players, and predictive coding at various stages heavily relies upon the selection of the proper keywords.

[23] Technologies like de-duplication and keyword searching are used to limit the volume of documents reviewed in the discovery process and predictive coding software is just another piece of software; it just so happens that predictive coding limits the volume of documents by a greater multiple than other solutions available in the marketplace. Maura R. Grossman & Gordon V. Cormack, *Technology-Assisted Review in E-Discovery Can Be More Effective and More Efficient Than Exhaustive Manual Review*, XVII RICH. J.L. & TECH. 11 (2011). *See generally*, Bruce Hedin et al., Conference Report, *Overview of the TREC 2009 Legal Track*, SP 500-278 NIST Special Publ'n: 18th Text REtrieval Conf. Proc. (2009), http://trec.nist.gov/pubs/trec18/papers/LEGAL09.OVERVIEW.pdf.; Douglas W. Oard et al., Conference Report, *Overview of the TREC 2008 Legal Track*, SP 500-277 NIST Special Publ'n: 17th Text REtrieval Conf. Proc. (2008), http://trec.nist.gov/pubs/trec17/papers/LEGAL.OVERVIEW08.pdf.

[24] There is no agreement today as to what is the proper nomenclature for predictive coding technology. *See* Sharon D. Nelson and John W. Simek, *Predictive Coding: A Rose by any Other Name*, SENSEI ENTERPRISES, INC., http://www.senseient.com/storage/articles/Predictive_Coding.pdf (last visited Jan 24, 2013).

prospective alternatives to keyword search efficacy. While still somewhat contentious, courts have recognized that predictive coding software improves document review quality and efficiency and is a defensible means of facilitating discovery.[25] With these new tools in mind, the Model Order already requires amendment, as predictive coding mechanisms do not currently align with the Model Order's provisions.

A. What is Predictive Coding? How Does Predictive Coding Work?

Predictive coding is software trained by a user to predict which documents in a document set will be responsive and which will be non-responsive. In recent history, predictive coding has distinguished itself as an alternative to keyword searches for finding relevant documents within the ever-increasing document sets produced during discovery.[26] Predictive coding aims to reduce the number of documents reviewed by ranking available documents according to a calculated level of responsiveness.[27] Instead of looking at every email written by a custodian over a three-year time period, predictive coding uses numerous factors including subject matter, punctuation style, writing style, and

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[25] Moore v. Publicis Groupe SA, 2012 WL 1446534, *3 (S.D.N.Y. Apr. 26, 2012) ("Manual review with keyword searches is costly, though appropriate in certain situations."). Computer-assisted review need not be used in all cases. Moore v. Publicis Groupe, 18 Wage & Hour Cas. 2d (BNA) 1479, 2012 WL 607412, *12 (S.D.N.Y. 2012), *adopted*, 2012 WL 1446534 (S.D.N.Y. 2012); *see also* A.N.S.W.E.R. Coal. v. Salazar, 258 F.R.D. 36, 38 (D.D.C. 2009) (ordering parties to confer on "a methodology for [keyword] searches [and] . . . a list of search directives that are likely to result in [relevant] documents"); Am. Family Mut. Ins. Co. v. Gustafson, No. 08-cv-02772-MSK-MJW, 2009 WL 641297, *3 (D. Colo. Mar. 10, 2009) (ordering parties to "meet, confer, and agree upon the search terms that will be used" to search imaged hard drive).

[26] *See generally* Jason R. Baron, *Law in the Age of Exabytes: Some Further Thoughts on 'Information Inflation' and Current Issues in E-Discovery Search*, XVII RICH. J.L. & TECH. 9 (2011); Daniel B. Garrie & Edwin A. Machuca, *E-Discovery Mediation & the Art of Keyword Search*, 13 CARDOZO J. CONFLICT RESOL. 467 (2012).

[27] *See generally Moore*, 2012 WL 607412 (describing function and use of predictive coding software).

keywords to determine the chain of documents most relevant to the particular issue or topic.[28] The underlying programmable algorithms will vary between software brands.[29]

Technically speaking, predictive coding is a computerized process that uses "sophisticated algorithms to enable the computer to determine relevance, based on interaction with (i.e., training by) a human reviewer".[30] In other words, the software is trained by a senior attorney or partner to look for documents similar to documents that the training attorney deems responsive. This is done by the attorney reviewing a relatively small "seed set" of documents, and coding the documents as either responsive or not responsive.[31] "The computer identifies properties of those documents that it [then] uses to code other documents" until the "system's predictions and the reviewer's coding sufficiently coincide," at which point "the system has learned enough to make confident predictions for the remaining documents."[32]

Typically, this procedure allows a set of hundreds of thousands of documents (or more) to be coded for responsiveness by the software, even though only a few thousand have actually undergone examination by a senior attorney or partner.[33] In a common implementation of the technique, documents coded "non-responsive" by the software—typically the bulk of any document collection—may never be examined again, except for quality-control sampling to ensure that the software's responsiveness interpretation matches that of the attorney running the software.[34] Those documents coded by the software as "responsive" are reviewed by attorneys for a final responsiveness determination, as

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[28] *Id.*

[29] Alaap B. Shah, *Use of "Predictive Coding" to Limit Cost and Improve Efficiency in Healthcare E-discovery: The Light Is Green, But Proceed With Caution*, AHLA HEALTHCARE LIABILITY & LITIGATION, Jan. 13, 2012.

[30] *Moore*, 2012 WL 607412, *2.

[31] *Id.*

[32] *Id.*

[33] *See generally* Monique da Silva Moore v. Publicis Groupe, 868 F. Supp.2d 137 (S.D.N.Y. 2012); Daniel B. Garrie, *Effective Keyword Selection Requires a Mastery of Storage Technology and the Law*, 32 PACE L. REV. 400 (2012).

[34] *See generally Moore*, 2012 WL 607412.

well as for potentially privileged information.

When using predictive coding, counsel should understand how the software addresses recall, precision, and accuracy, as early computer-assisted review projects likely will require additional education for the reviewing court.[35] Counsel should understand the following concepts when assessing predictive coding technology:

- *Recall*[36] = Number of Documents Predicted to be Responsive / Total Number of Actually Responsive Documents.
- *Precision*[37] = Number of Actually Responsive Documents / Number of Documents Predicted to be Responsive.
- *Accuracy*[38] = (True Relevant Documents Retrieved + True Non-Relevant Documents Not Retrieved) / Total Documents.

There is a give-and-take relationship between Recall and Precision.[39] If recall is high (very broad search criteria), precision will be low (over-inclusive results). Conversely, if precision is high (stringent search criteria), recall will be low (under-inclusive results).[40] Richness is another concept to be aware of when looking at predictive coding statistics.[41] Richness is simply the percentage of relevant documents in the total population. It is a measure

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[35] Da Silva Moore v. PUBLICIS GROUPE & MSL GROUP, No. 11 Civ. 1279 (ALC)(AJP) (S.D.N.Y. Feb. 24, 2012).

[36] Daniel B. Garrie, *Predictive Coding Endorsed by the Southern District of New York – People Plus Technology Equals Smart Search*, DAILY JOURNAL, May 1 2012.

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] *Id.* The F-score is intended to account for this trade-off. It is a statistical measure used in text retrieval applications specifically to measure the compromise between precision and recall. $F = 2(P*R)(P+R)$.

For example, if our recall is 80 percent, but our precision is only 10 percent, the F-score is 17 percent. This is sometimes known as the Balanced F-score or F_1 measure because it gives equal weight to both recall and precision. The F-score can be weighted if more emphasis needs to be placed on recall (the F_2 measure) or on precision (the $F_{0.5}$ measure), according to user requirements.

[41] *Id.*

related to the population, not to the computer's overall document review performance. Thus, in a collection containing few relevant documents across a large document population, such as evidence of well-hidden corporate criminal activity, the richness will be low because only a few relevant documents are returned. Conversely, in, for example, a medical malpractice suit, almost all of the documents produced by the medical facility regarding a particular patient will be responsive, which will result in a higher richness score.

B. Impact of Predictive Coding on the Bar

While predictive coding software may lead to disappointment for those first-year attorneys enamored with the excitement and challenges of document review, it will be the savior to many others.[42] The effectiveness of predictive coding software hinges on the initial software training performed by either a senior associate or a partner who is intimately aware of the underlying facts and litigation strategies accompanying a particular case.[43] While the notion of learning how to train associates on such a system may be overwhelming, training concerns are misplaced, as some predictive coding software is operationally intuitive. In the end, predictive coding lowers costs, saves times, and, if done properly, generates revenue while increasing the quality of professional life for partners and associates.[44]

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[42] *See, e.g.*, Ralph Losey, *Bottom Line Driven Proportional Review*, E-DISCOVERY TEAM (Nov. 1, 2012), http://e-discoveryteam.com/2012/01/15/bottom-line-driven-proportional-review/ ("[Y]ou *cannot* just dispense with final manual review. . . . [W]e are not going to turn that over to the Borg anytime soon. I've asked around and no law firms do that now. No experts advocate that approach either, even the most extreme advocates for automation (of which I'm one). . . . You use predictive coding to speed up the final manual review to be sure, but only a fool (or con artist trying to get at a producing parties [sic] secrets) trusts coding software today without human verification.").

[43] *See generally* Alaap B. Shah, *Use of "Predictive Coding" to Limit Cost and Improve Efficiency in Healthcare E-discovery: The Light Is Green, But Proceed With Caution*, AHLA HEALTHCARE LIABILITY & LITIGATION, Jan. 13, 2012.

[44] Predictive coding will likely transform the economics of discovery in patent litigation. *See* Daniel B. Garrie, *Change is Coming: The Evolution of E-*

C. The Federal Circuit Should Modify the Model Order to Allow Parties to Work with Predictive Coding and Similar Technologies

Since the Model Order presumptively limits the number of custodians and search terms for all email production requests, the Model Order isolates the e-discovery focus on permissible keywords and custodians, which substantially decreases the benefits afforded by predictive coding.

The Model Order, while useful for limiting keyword search discovery demands, is not framed for other technologies like predictive coding. While predictive coding uses keywords, it does not utilize them in the same manner as keyword-driven technology. Consequently, Model Order's value in limiting keywords and custodians hinders any ability to use predictive coding technologies.

CONCLUSION

Courts and counsel should utilize the Model Order as a starting point for assessing the e-discovery process in patent disputes, but should also consider the potential pitfalls that the Model Order presents. As a few cases have shown since implementing the Model Order, the court is willing, within reason, to allow parties to produce their own mutually agreeable protocol.[45] However, it remains to be seen what will happen in a case involving unwilling parties whose case demands more than what the Model Order allows.

Discovery Economics, THE METROPOLITAN CORPORATE COUNSEL, Nov. 28, 2012, http://www.metrocorpcounsel.com/articles/21299/change-coming-evolution-e-discovery-economics; Corinne L. Giacobbe, Note, *Allocating Discovery Costs in the Computer Age: Deciding Who Should Bear the Costs of Discovery of Electronically Stored Data*, 57 WASH. & LEE L. REV. 257, 282-83 (2000); AAB Joint Venture v. United States, 75 Fed. Cl. 432, 438, 442-43 (2007) (ordering discovery of storage tapes defendants conceded might have relevant information despite $150,000 restoration cost).

[45] *See, e.g.*, McGrath v. United States, No. 11–318C, 2012 WL 726423 (Fed. Cl. March 6, 2012) (modifying a proposed discovery order submitted by the parties that was based, in part, on the Model Order).

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PERSONALIZED MEDICINE, GENETIC EXCEPTIONALISM, AND THE RULE OF LAW: AN ANALYSIS OF THE PREVAILING JUSTIFICATION FOR INVALIDATING BRCA1/2 PATENTS IN *ASSOCIATION OF MOLECULAR PATHOLOGY V. USPTO*

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ABSTRACT

As medicine advances toward a more personalized model, the significance of genetic information is growing exponentially. While unlocking the genetic code has advanced the state of medicine, it has also reinvigorated the debate over the boundaries of patentable subject matter. The potential clash between having access to state-of-the-art medicine and protecting intellectual property investments came to a head in the case, Association of Molecular Pathology v. USPTO *("*Myriad*"). This Article analyzes the legal opinion rendered by the district court through the unique lens of genetic exceptionalism—a concept previously reserved to social science and public policy. Then, this Article analyzes Judge Sweet's unprecedented incorporation of genetic exceptionalism into the Patent Act by first tracing the historical roots of the exceptionalism doctrine and then dissecting the* Myriad *decision through that historical lens. As it stands at publication, it has yet to be seen whether the Supreme Court will similarly adopting a novel interpretation of the*

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Patent Act that incorporates genetic exceptionalism into the Act's subject matter restrictions.

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INTRODUCTION

Judge Sweet's decision in *Association of Molecular Pathology v. USPTO* ("*Myriad*")[1] has reinvigorated the longstanding debate of whether genes qualify for patent protection and whether granting such protection does more harm to patients than good for innovation. In a health care system moving more toward personalized medicine, the resolution of these questions is vital for the stability—and possibly the survival—of genetic innovation. *Myriad* has the potential to greatly impact the way personalized medicine is administered to patients by increasing access to more at-risk patients and decreasing the cost of genetic testing. On the other hand, the decision could be a potential setback to genetic innovation that results in more harm to patients by stifling research incentives. Regardless, stakeholders on both sides of the debate are eagerly awaiting the appeal that will provide some stability in an unsettled area of patent law.

There is no disagreement that since its discovery, DNA has captivated audiences from the science, medical, ethical, and legal fields, at times rising DNA to a near-reverent status. Despite the promise that genetic science holds, the science is susceptible to abuse, as has been demonstrated by the history of eugenics and

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[1] 702 F. Supp. 2d 181 (S.D.N.Y. 2010). The procedural history of this case—following Judge Sweet's opinion in district court—is complicated. The Federal Circuit first affirmed in part and reversed in part the lower court's decision in Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (reversing the lower court's decision on gene patentability by holding, among other things, that human genes are eligible patent matter). Certiorari was granted by the United States Supreme Court, only to have the case remanded back to the Federal Circuit for reconsideration. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012). After the Federal Circuit reviewed the case, the Supreme Court again granted certiorari, limiting the issue to whether human genes are patentable. *See* Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) *and* Ass'n for Molecular Pathology v. Myriad Genetics, Inc, 133 S. Ct. 694 (Nov. 30 2012) (certiorari granted in part). As it stands, the parties have until March 2013 to file their briefs on the merit. For an up-to-date status of the case as it proceeds through the Supreme Court, visit the case on the Scotus Blog, available at http://www.scotusblog.com/case-files/cases/association-for-molecular-pathology-v-myriad-genetics-inc/.

ethnically targeted genetic screening programs. It is this unharnessed power to do both good and bad that has directed scientists, academia, and policy makers alike to treat genetic information differently than other scientific knowledge, resulting in "genetic exceptionalism." Until the *Myriad* decision, however, genetic exceptionalism did not exist as a legal principle under the Patent Act, but was instead relegated to areas of discrimination, privacy, and insurance.

To better understand *Myriad*'s impact on personalized medicine and the progeny of gene patents flowing from the genome, it is helpful to first understand basic genetic science, the development of genetic exceptionalism in other contexts, the various types of gene patents, and the existing law on subject matter patentability. Part I of this Article begins with an overview of personalized medicine and its relation to genetic science. Parts II and III discuss the impact of patenting these genetic tools and the types of patent protection falling within the catch-all category of "gene patents." In Part IV, the Article provides a summary of the precedent governing the subject matter patentability requirement. Finally, Part V addresses Judge Sweet's incorporation of genetic exceptionalism into the Patent Act by first tracing the historical roots of the exceptionalism doctrine and then dissecting the *Myriad* decision through that historical lens. After doing so, the Article concludes that the court in *Myriad* inappropriately adopted genetic exceptionalism as a legal principle on patentability instead of leaving the gene patent policy decision to Congress.

I. CHANGING THE FACE OF MEDICINE ONE STRAND AT A TIME: HOW GENETIC INFORMATION IS ALTERING THE PRACTICE OF MEDICINE

A. Defining Personalized Medicine

What does the ambiguous phrase "personalized medicine" actually mean? After all, doctor-patient relationships have traditionally been of a personal nature. New advances in technology have altered this traditional doctor-patient approach to

treatment[2] and solidified "personalized medicine" as a term of art. Building on the traditional doctor-patient relationship, personalized medicine moves health care one step further by providing physicians with a more precise tool to evaluate, diagnose, and treat patients. Beyond promising better health outcomes for individual patients, personalized medicine also has the potential to transform the entire health care delivery infrastructure into a more efficient, cost-effective system.[3]

Despite being a recognized term of art, "personalized medicine" has multiple definitions. On the literal end of the spectrum, personalized medicine refers to the development of stem cell based therapies that are specifically tailored to an individual.[4] In this context, doctors would use cloned stem cells—embryonic or adult—to generate additional cells, tissues, or organs to circumvent the inherent risks associated with individual transplantations.[5]

On the other end of the spectrum, personalized medicine is cast more broadly, referring to technologies and treatments that can be administered to a subset of the population based on common characteristics found in DNA and environmental factors. More in line with this broader definition, the Personalized Medicine

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[2] *See, e.g.*, Kent Bottles, *The Doctor/Patient Relationship for the 21st Century*, THE PHYSICIAN EXECUTIVE 10-14 (Sep.-Oct. 2001), available at http://www.kentbottles.com/pdfs/Doctor-Patient-Relationship-for-the-21st-Century.pdf (discussing different views of the doctor/patient relationship).

[3] *See generally* James P. Evans et. al., *Preparing for a Consumer-Driven Genomic Age*, 363 NEW ENG. J. MED. 1099 (2010) (discussing personalized health care in the direct-to-consumer genetic testing context); Eric D. Green & Mark S. Guyer, *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204 (February 2011) (discussing a 2011 vision for moving towards an era of genomic medicine); Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301 (2010) (discussing the hurdles in moving from concept to clinical use); The Case for Personalized Medicine, PERSONALIZED MEDICINE COALITION, http://cllcanada.ca/2010/pdfs/TheCaseforPersonalizedMedicine_5_5_09.pdf (discussing the benefits of personalized medicine and the necessary steps for widespread implementation).

[4] *See* Matthew Herder, *Patents & the Progress of Personalized Medicine: Biomarkers Research as Lens*, 18 ANNALS HEALTH L. 187, 190-91 (2009).

[5] *Id.* at 190. Currently embryonic stem cell therapy is in its nascent stage and not a realistic therapeutic option.

Coalition describes the emerging practice as follows:

> Personalized medicine uses new methods of molecular analysis to better manage a patient's disease or predisposition toward a disease. It aims to achieve optimal medical outcomes by helping physicians and patients choose the disease management approaches likely to work best in the context of a patient's genetic and environmental profile. Such approaches may include genetic screening programs that more precisely diagnose diseases and their sub-types, or help physicians select the type and dose of medication best suited to a certain group of patients.[6]

Other definitions go even further to dispel the potential misunderstanding surrounding the term "*personalized*." For instance, the President's Council of Advisors on Science and Technology stressed that personalized medicine "does not literally mean the creation of drugs or medical devices that are unique to a patient but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment."[7]

In other words, personalized medicine interpreted broadly enables physicians to provide better diagnoses and earlier interventions, to engage in more effective drug development, and to implement more effective therapies for various subsets of patients who share the same genetic variations.[8]

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[6] *Personalized Medicine: An Introduction*, PERSONALIZED MEDICINE COALITION, http://www.personalizedmedicinecoalition.org/sites/default/files/personalmed_backgrounder.pdf.

[7] Priorities for Personalized Medicine, President's Council of Advisors on Science and Technology (September 2008), http://www.whitehouse.gov/files/documents/ostp/PCAST/pcast_report_v2.pdf.

[8] *Id.* Because this paper focuses primarily on gene patents, the term personalized medicine should be understood in the broader context as defined by the Coalition and the President's Council.

B. The Science Underlying Genetics and Personalized Medicine

Genetic science continues to revolutionize the practice of medicine by enabling treatment tailored to individual patients and providing insight to better therapeutic approaches. Although many patients utilize personalized medicine at some point over the course of their medical treatment, not all patients understand the science behind such treatment. While understanding the basics of genetic science and the types of patents currently available for the countless discoveries in the field would aid the reader's understanding of the genetic impact on medicine, an in-depth discussion of this complex science is beyond the scope of this paper.[9] Instead, this Article will provide a basic explanation from a patient's perspective: what are genes and how are they patented? This section will define the key terms and introduce the basic scientific foundations of genetics, moving into an overview of the various categories of patents that collectively are referred to as "gene patents."

The genomic structure is best understood by explaining the different parts of DNA and how its components direct the formation of proteins.[10] DNA (deoxyribonucleic acid) is a double helix structure created by two chemically-bonded strands that

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[9] *See, e.g.*, Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine – A Primer*, 347 N. ENG. J. MED. 1512-20 (2002); W. Gregory Feero & Alan E. Guttmacher, *Genomic Medicine – An Updated Primer*, 362 N. ENG. J. MED. 2001-11 (2010); Wylie Burke, Genetic Testing, 347 N. ENG. J. MED. 1867-75 (2002).

[10] Many articles go into great detail on the structure of DNA and its corresponding science. *See, e.g.*, Eric D. Zard, Note, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology's Clash with the Public Good*, 6 U. ST. THOMAS L.J. 486-490 (2009); Lorelei Perez Westin, Note, *Genetic Patents: Gatekeeper to the Promised Cure*, 25 T. JEFFERSON L. REV. 271, 276-79 (2002). Similarly, the Federal Circuit has discussed molecular genetics in greater depth. *See, e.g.*, In re Deuel, 51 F.3d 1552, 1554-56 (Fed. Cir. 1995); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1207-08 (Fed. Cir. 1991); In re O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988). This Article will not rearticulate the scientific foundation in as great detail, but will rather provide sufficient background to understand the gene patents and their relationship with genetic exceptionalism.

stores and encodes an organism's genetic information.[11] Each DNA strand contains four base molecules (A, G, C, and T) that serve as the building blocks.[12] Before the cell can make the protein, the DNA strand must undergo three processes: (1) copying the DNA strand into RNA (transcription); (2) removing or splicing of the inactive regions (introns) and connecting the active regions (exons); and (3) translating the RNA (ribonucleic acid) into its corresponding amino acids.[13] When joined together, these amino acids fold into unique three-dimensional shapes that determine the property and function of the protein in the body.[14]

While the human genome contains more than three billion base pairs,[15] only two percent of these base pairs represent the 20,000 to 25,000 genes present in the human genome.[16] In comparing human

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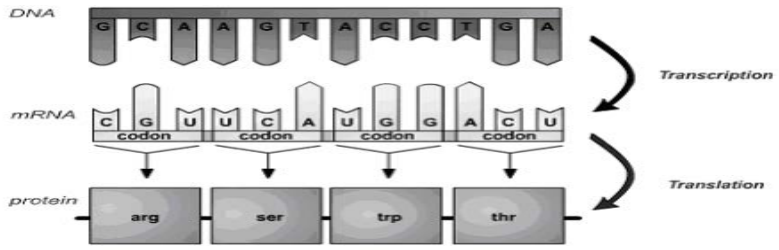
[11] Wylie Burke, *Genetics Primer*, NATIONAL ASSOCIATION OF WOMEN JUDGES, GENOME JUSTICE, September 2005, 1-14.

[12] *Id.*

[13] The following figure, a reproduction of Figure 14.5 from DAVID KROGH, BIOLOGY: A GUIDE TO THE NATURAL WORLD 249 (5th ed., 2005), depicts the two processes for decoding genetic information:



[14] There are typically three regions that are relevant to genetic patents: (1) the exon region (coding region of the gene); (2) the promoter and terminating regions of a gene (which mark the beginning and the end of gene); and the (3) intron region (non-coding regions that are spliced or removed during the transcription phase). See Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means*, 7 COMPUTER L. REV. & TECH. J. 255, 256 (2003).

[15] The human genome refers to the complete set of DNA from the combined chromosomes. *See The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, HUMAN GENOME PROJECT INFORMATION (Mar. 26, 2008) http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml.

[16] *How Many Genes Are in the Human Genome?*, HUMAN GENOME PROJECT INFORMATION (Sept. 19, 2008) http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml. Currently, the average gene is

genomes, scientists have discovered that humans share approximately 99.9 percent of the same code, resulting in only .01 percent variation between human genomes.[17] Scientists have identified 1.4 million locations where these single-base variations occur.[18] These variations are referred to as single nucleotide polymorphisms, or "SNPs."[19]

Depending on where the variation occurs, the mutation(s) may result either in minor changes that account for the normal range of characteristic like hair color, height, or medication response, or in more profound changes that are responsible for various forms of genetic diseases.[20] While a single mutation may cause a handful of diseases, the majority of diseases are multifactorial, depending on a complex interaction of multiple genes and numerous environmental factors.[21]

II. PATENTING THE TOOLS OF PERSONALIZED MEDICINE: A LOOK AT THE IMPACT OF GENETIC PATENTS ON PATIENT CARE

Each step towards understanding the human genome fortifies the bridge between DNA code and a patient's bedside by creating new possibilities in personalized medicine. With the completion of the Human Genome Project, researchers have unlocked the key to a wealth of genetic information. But discovering the function and relationship of genes and translating these discoveries into

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approximately 3,000 bases, with the largest known gene having 2.4 million. And of the known genes, scientists can identify the function for only approximately 50 percent.

[17] Burke, *supra* note 9, at 4.

[18] *Id.*

[19] *Id.*

[20] *Id.* SNPs help determine the likelihood that a person will develop a disease during his or her lifetime.

[21] *See id.* at 7, 12. The media coverage has influenced the public's perception of genetic diseases, often oversimplifying the causation between a mutation and a disease and overemphasizing the determinative effect of a genetic mutation. Diseases caused by single gene mutations can be broken down into autosomal dominant, autosomal recessive, and X-linked recessive disorders. Chromosomal conditions, another subset of genetic diseases, are caused by a deficiency or excess of chromosomal material. *Id.* at 9-11.

beneficial treatment is an ongoing, complex endeavor. Currently, there are over 6,000 diseases that can be traced to a single gene,[22] while there are thousands of other conditions that are linked to genetic variations in multiple genes and interactions with environmental factors. As scientists better understand these complex genetic interactions, further progress can be made in the development of diagnostic tools, prevention techniques, and therapeutic treatments.[23]

With the progress in personalized medicine comes the desire to protect the intellectual property associated with such advancements. The impetus behind the U.S. patent law system has always been the careful balancing between the competing interests of incentivizing innovation, encouraging the disclosure of inventions for the public good, and fostering competition. The framers of the U.S. Constitution were mindful of these tradeoffs in drafting Article I § 8, which provides that Congress shall have the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[24] America's founding fathers understood that granting an exclusive right for a period of time may justify an otherwise undesired monopoly so long as the exclusive right provided sufficient incentives to invest in research and development that would otherwise not come to fruition absent the incentive. In exchange for this period of exclusivity, however, the patentee must contribute to the public a useful, novel, non-obvious invention–disclosing sufficient information for a person skilled in the arts to practice the invention.[25]

Understanding that innovation and ongoing discovery is

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[22] Melissa Conrad Stoppler, *Genetic Diseases Overview*, MEDICINENET.COM (May 11, 2010), http://www.medicinenet.com/genetic_disease/article.htm.

[23] Eric D. Green & Mark S. Guyer, *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204 (2011); see also Ethical, Legal & Social Issues: Gene Testing, HUMAN GENOME PROJECT INFORMATION (July 7, 2010) http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[24] U.S. CONST. art. I, § 8, cl. 8.

[25] *See* 35 U.S.C. §§101-103, 112 (2003).

imperative to personalized medicine's success, numerous stakeholders have raised concerns that granting genetic patents may substantially impede necessary scientific research and block access to therapeutic treatments.[26] As a basis for these public policy concerns, critics argue that the twenty years of protection provided to the patent holder from the date of filing enables the patent holder to prevent others from researching the patented gene and from performing diagnostic testing procedures on patented variations of the gene.[27] Critics maintain that even if a patent holder is willing to license the patent(s), researchers have a difficult time locating the owner of the patent rights.[28] Moreover, because U.S. patent law permits patent issuance for gene fragments and single nucleotide variations (see discussion on the types of gene patents, *infra*), critics argue that licensees incur higher transaction costs to obtain multiple licenses associated with one gene.[29]

In an effort to assess whether gene patents truly inhibit research, health and science researcher David Blumenthal[30] conducted several surveys that targeted both academics and commercial scientists involved with genetic research. He found that "[o]ne of every five medical scientists has delayed publication of research results for at least half a year in order to protect

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[26] *See* Marisa Noelle Pins, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics' Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377 (2010).

[27] *See* Eric Zard, Comment, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology's Clash With the Public Good*, 6 U. ST. THOMAS L.J. 486, 504 (2009).

[28] *Id.*

[29] *Id.*

[30] David Blumenthal, M.D., M.P.P., was appointed on March 20, 2009, by the Obama Administration to serve as the National Coordinator for Health Information Technology. In this capacity, Dr. Blumenthal will lead "the implementation of a nationwide interoperable, privacy-protected health information technology infrastructure." U.S. Dept. of Health & Human Services, *HHS Names David Blumenthal As National Coordinator for Health Information Technology* (March 20, 2009), available at http://www.hhs.gov/news/press/2009pres/03/20090320b.html.

financial interests."[31] He also found that "twenty-eight percent of the geneticists surveyed reported that they were unable to duplicate published research because other academic scientists refused to share information, data, or materials,"[32] thereby preventing scientists from verifying the studies.

Further compounding the problem of gene patents is the "patent thicket"—a term critics use to refer to the multiple patents on various components of a gene—which, according to some critics, "may be stifling life-saving innovations further downstream in the course of research and product development."[33] In other words, if research scientists must acquire multiple licenses from multiple parties to conduct research on any given gene, then the cost of researching gene therapy is greater and the research itself is at risk of being derailed by a patent holder who refuses to license a necessary input to the research.[34]

While some critics concede that a level of patent protection is necessary for incentivizing research, they suggest that the patent system is offering protection at the wrong stage in the development process.[35] By issuing patents early in the development process when little is understood about the role the gene plays, a patent holder can assert the patent against later discovered mutations or genetic associations when more is understood about the gene's role in genetic diseases.[36] Arguably, the patent system grants the equivalent of a "hunting license" to the pioneering scientist, rewarding the search without compensating later discoveries that

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[31] Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives With Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 81 (2002) (summarizing findings in David Blumenthal et al., *Withholding Research Results in Academic Life Sciences*, 277 JAMA 1224, 1224 (1997)).

[32] *Id.* (citing David Blumenthal et al., *Data Withholding in Academic Genetics*, 284 JAMA 473, 477 (2002)).

[33] *Id.* at 85 (quoting Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 701 (1998)).

[34] *See id.* at 85-86.

[35] *See id.*

[36] *See id.* at 87-88. But consider that some people, including Steven Shavell, argue that awarding patents early in the process prevents excess duplicative investment.

result in a useful application.[37] As Justice Abraham Fortas once summarized, "a patent may confer power to block off whole areas of scientific development, without compensating benefits to the public."[38]

Finally, gene patents arguably deprive patients the access to reliable genetic tests and therapies that would otherwise be available. Because some patent holders exclusively license their patent, a genetic test may be permitted at one laboratory, leaving the patient with no means for getting a second opinion.

III. GENE PATENTS: DOES ONE SIZE FIT ALL?

This Article's genetic primer has focused thus far on how DNA works in its natural, non-patentable state. To be patentable, an inventor must "transform" genetic information into a non-natural form to circumvent the rule against patenting products of nature.[39] After taking steps to isolate, purify, or modify the genetic information, the inventor can claim the resulting product as an invention because the resulting product is chemically different from the product in nature.[40] In other words, the patent is not issued on the gene found in the body, but rather on man-made DNA molecules.[41]

Generally, genetic patent claims relate to one of the following four categories found to satisfy the patentability standards prior to *Myriad*:

> (1) Whole genes or parts of them, (2) proteins that the genes encode as well as their function in organisms, (3) vectors used for the transfer of genes

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[37] *Id.* at 88.

[38] *Id.* at 88 (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966)).

[39] *See, e.g.*, Parker v. Flook, 437 U.S. 584 (1978); Diamond v. Diehr, 450 U.S. 175 (1981).

[40] *Id.* Isolating DNA refers to the process of removing the DNA from its natural environment in the body, while purifying DNA refers to removing the non-coding regions of the DNA (e.g. cDNA). *See* John Conley & Dan Vorhaus, *When the Grass Eats the Cows*, 23 GENEWATCH 8 (Oct.-Dec. 2010).

[41] *See* Sharon Terry, *Why Banning Patents Would Hurt Patients*, 23 GENEWATCH 24 (Oct.-Dec. 2010).

> from one organism to another, or (4) genetically modified cells or organisms, processes used for the making of genetically modified products and the uses of genetic sequences or proteins for genetic tests.[42]

The patents are generally issued as "compositions of matter" or "method-of-use" patents, and although sometimes erroneously interpreted as patenting the gene itself, the patent only covers genetic information that has been isolated and purified.[43]

A. cDNA Patents

Complementary DNA (cDNA) is a synthetic copy of an isolated section of DNA that includes only the coding-region for a protein as opposed to the entire gene as it is found in the body.[44] Scientists take the mRNA (which is copied DNA minus the non-coding regions) and convert it into a new DNA molecule through reverse transcription (cDNA).[45] Structurally and functionally different from genes found in nature, cDNA molecules can be used to produce large quantities of human protein in non-human species, to identify disease-causing mutations for diagnostic testing, to treat genetic disorders (gene therapy), and to enable new discoveries with their use as chemical reagents and research tools.[46] Although critics of cDNA patents assert that the information contained in cDNA is identical to naturally occurring DNA, even those critics acknowledge that naturally occurring DNA cannot be used for commercial diagnostic testing and research.[47]

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[42] E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Political Storm*, http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad_Legal.pdf (working document).

[43] *Id.*

[44] *See* Kevin Noonan, *Why Genes Must Remain Eligible for Patenting*, 23 GENEWATCH, 24, 30 (Oct.-Dec. 2010).

[45] *Id.*

[46] *See* Terry, *supra* note 41.

[47] See Magdalina Gugucheva, *The Physical Embodiment of Information*, 23 GENEWATCH 26-27 (Oct.-Dec. 2010). Vectors, which are larger molecules with integrated cDNA, that can be used to insert genes into other cells, are also patentable.

B. EST Patents

Expressed sequence tags (ESTs) are fragments of the cDNA molecule that are approximately 300-500 base pairs long, representing approximately 10 to 30 percent of the average cDNA molecule.[48] In practice, ESTs are used as research tools to map and discover entire genes in a fraction of the time it would take without the aid of these markers. Advocates for EST patenting claim that there are several uses for ESTs, which include: (1) serving as a molecular marker for mapping genomes; (2) measuring the level of mRNA in a tissue sample; (3) providing primers for polymerase chain reaction processes; (4) identifying polymorphisms; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.[49] In 2005, the Federal Circuit addressed the patentability of ESTs in *In re Fisher*.[50] Focusing on the utility requirement under § 101 of the Patent Act, the court invalidated the patent for lacking "specific and substantial utility."[51] Without digressing into a utility discussion, it is sufficient for this Article's purpose to understand that EST patents must claim a known correlation between the EST and an identified underlying gene to be patentable.[52] Strictly speaking, the EST must be more than a mere research intermediary with no immediate, well-defined benefit to the public.[53]

C. SNP Patents

Of the patents that are collectively referred to as "gene patents," SNP patents are arguably the most controversial because

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[48] *Genetics and Patenting*, HUMAN GENOME PROJECT INFORMATION (July 7, 2010) http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[49] *See* In re Fisher, 421 F.3d 1365, 1369-74 (Fed. Cir. 2005) (discussing the uses for ESTs proffered by Fisher).

[50] *Id*.

[51] *Id*.

[52] *See id.* at 1372-73.

[53] *Id.*

SNP patents permit the patentee to claim one "letter" of a sentence. As previously discussed, SNPs are unlike cDNA and EST fragments because they represent a genetic mutation (or variation) in only one nucleotide base in a genetic sequence.[54] These minor variations can have a major impact on the way that humans respond to disease, environmental factors, or pharmaceuticals and medical treatment.[55] Typically, SNP patents include claims for the method of determining a patient's susceptibility to a disease by detecting a particular SNP in a known gene and for the isolated SNP molecule itself.[56]

D. Patents on DNA Tests

The relationships between genetic mutations and diseases allow practitioners to tailor medical diagnoses and treatment to individual patients. Once a gene is discovered, scientists then work to develop a complementary test to screen individuals for the genetic mutation associated with a disease.[57] Genetic tests offer a window to a person's genetic make-up, making it possible to confirm suspected diagnoses, to predict likelihood of future illness, to detect carrier status in unaffected individuals, and to evaluate a person's response to medical treatment.[58] The tests differ in the manner by which they identify genetic variations. For example, some tests utilize short pieces of DNA, called probes, to seek out a complementary sequence to the mutated gene which then binds to the sequence if present.[59] Another type of genetic testing directly compares the patient's DNA sequence to a normal version of the sequence, looking for any differences between the two sequences.[60] Finally, other genetic tests detect gene products, such

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[54] *See* Genome Project Information, *Ethical, Legal & Social Issues: Gene Testing*, HUMAN GENOME PROJECT INFORMATION (July 7, 2010) http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[55] *Id.*

[56] *Id.*

[57] *Genetic Testing*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Jan. 10, 2013), http://www.genome.gov/10002335.

[58] *Id.*

[59] *Id.*

[60] *Id.*

as an enzymes or proteins, for determining whether a gene variation is present.[61] Beyond method patents for analyzing a person's DNA, genetic testing patents may also cover the physical testing kits that contain the necessary materials to perform the test.[62]

E. Patents on DNA Diagnostic Algorithms

Genetic patents have also been issued for algorithms that compare known risks with multiple genetic variations.[63] These method patents straddle the line between an abstract idea and an invention.[64] When the algorithm uses information derived from multiple variations and gives different weight to known risks, the algorithm is likely to be patentable subject matter.[65] In this case, scientists can invent around the patented algorithm by creating a different model of analysis.[66] The issue of patentability is more questionable when the diagnostic algorithms use an "assay-and-correlate" model, which analyzes simple levels of physiological substances.[67] For these algorithms, it much more difficult—if not impossible—to design around the patented method.

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[61] *Id.*

[62] Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 846 (2008).

[63] Michael J. Shuster & Pauline Farmer-Koppenol, *Patent Strategy for Personalized Medicine in Light of* Bilski, BILSKYBLOG.COM (2010), http://www.bilskiblog.com/files/07-19-10_patent-strategy-for-personalized-medicine-bilski-3.

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.* Algorithms are also used in developing synthetic DNA with computer software and are patentable. For example, "patents have already been granted on many of the processes and products involved in synthetic biology, including patents on methods for building synthetic DNA, synthetic genes and DNA sequences, synthetic pathways, synthetic proteins and amino acids, and novel nucleotides that replace the letters of DNA." Eric Hoffman & Jaydee Hanson, *Synthetic Biology: The Next Wave of Patents on Life*, 23 GENEWATCH 39, 40 (Oct.-Dec. 2010).

IV. GENETICS AND THE LAW: AN OVERVIEW OF SUBJECT MATTER PATENTABILITY PRECEDING *MYRIAD*

The watershed case invalidating Myriad Genetics' gene patents was not the first to address gene patents, albeit perhaps the first to directly attack the patents under the subject matter requirement.[68] Patent law's history is fraught with cases that courts can draw on for the gene patentability analysis, dating as far back as the late 1800s.[69] The earlier cases addressing biotechnology patents focused primarily on the novelty and obviousness prongs of patentability.[70] It was not until after the Patent Act of 1952, however, that courts recognized the requirements of subject matter, novelty, and non-obviousness were wholly separate inquiries.[71]

The purification doctrine[72] has long been the linchpin for justifying gene patents. In 1874, the Supreme Court addressed the validity of a patent on purified cellulose used to make paper.[73] The Court reasoned that because the product was not substantially different than the naturally occurring product either in form or substance, the patent was invalid for lack of novelty.[74]

Subsequent courts interpreted this decision to mean that inventors could potentially patent purified or isolated products of nature with a new commercial or therapeutic use. In the early 1900s, *Parke-Davis & Co. v. Kalo Inoculant Co.*, decided whether purified adrenaline could be patented.[75] In upholding the validity

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[68] Myriad Genetics is the company that holds the patents on BRCA1/2, which are the patents the plaintiff sought to invalidate in the case referred to herein as *Myriad*.

[69] *See* Ashley McHugh, *Invalidating Gene Patents: Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 62 HASTINGS SCI. & TECH. L.J. 185, 191-92 (2010).

[70] *See id.*

[71] *See id.*

[72] The purification doctrine states that naturally occurring substances may still be patentable, despite being products of nature, if the substance can be isolated and purified from its naturally occurring state. *See, e.g.*, Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911).

[73] American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566 (1874).

[74] *Id.* at 593-96.

[75] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911).

of the patent, the court reasoned that although the product was naturally occurring, the purified version of adrenaline was "a new thing commercially and therapeutically."[76]

Despite the trend of expansive subject matter, the Supreme Court reigned in the scope of patentable subject matter for naturally occurring products in its 1948 opinion in *Funk Brothers Seed Co. v. Kalo Inoculant Co*.[77] At issue in *Funk Brothers* was the validity of a patent held for a mixture of isolated bacterium, which unlike its predecessor products, could be mixed without the inhibitory effects owing to the inventor's method of testing and selecting noninhibitive strains.[78] The Court evaluated the patent under the requirements set forth in 35 U.S.C. § 31, which permitted issuance of a patent to, "[a]ny person who has *invented or discovered* any new and useful *art, machine, manufacture, or composition of matter* . . . ."[79] Interpreting the requirement of "invention or discovery," Justice Douglas provided that "[t]he qualities [of the invention at issue] are the work of nature. Those qualities are, of course, not patentable. For patents cannot issue for the discovery of the phenomena of nature."[80] The Court focused on the properties of the bacterium, namely that they performed no new function when mixed together and merely provided a more efficient means of packaging for the purchaser.[81]

Although seemingly supporting the position that genes (and fragments) are entirely outside the scope of patentability as products of nature, Justice Douglas' oft-quoted statement for this proposition must be narrowly read in light of the limited question presented: whether the mixture was an "invention or discovery" within the meaning of 35 U.S.C. § 31. The way the act was written, the "invention or discovery" requirement stands separate from the patentable subject matter requirement, which is embodied in the

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[76] *Id.* at 103.

[77] 333 U.S. 127 (1948).

[78] *Id.* at 130-31.

[79] 35 U.S.C. § 31 (2000) (emphasis added).

[80] *Funk Brothers*, 333 U.S. at 130.

[81] *Id.* at 131-32 ("[T]he packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like.").

"art, machine, manufacture, or composition of matter" language. The Court also provided additional language that suggests it was not deciding the case on the subject matter prong of patentability:

> Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a *different use*. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the *range of their utility*. . . . Their use in combination does not *improve in any way their natural functioning*.[82]

Because the *Funk Brothers* analysis was directed at the invention or discovery prong—not the subject matter prong—the holding should be narrowly construed in subsequent cases.[83] Opponents of gene patents should not be quick to conclude that the case prohibits patenting naturally occurring biological products since the likely correct interpretation invalidates only those patents that fail to apply the naturally occurring substance in a non-obvious way.[84]

Indeed, *Funk Brothers* did not foreclose the door for patents on naturally occurring substances despite Justice Douglas' "phenomena of nature" reasoning.[85] In 1980, the Supreme Court

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[82] *Id.* at 131 (emphasis added).

[83] *See id.* at 132 ("[W]e conclude that the product claims do not disclose an invention or discovery within the meaning of the patent statutes, we do not consider whether the other statutory requirements contained in 35 U.S.C. § 31, R.S. § 4886, are satisfied.") (emphasis added).

[84] *See* John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301 (2003).

[85] *See, e.g.*, Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156, 164 (4th Cir. 1958). In 1958, the Fourth Circuit Court of Appeals upheld a patent on purified vitamin B-12 based on the therapeutic and commercial value of the biological product, noting that nothing in the language of the Patent Act of 1952 prohibited the patenting of naturally occurring substances. *Id.* The court found that compositions of matter necessarily included products of nature, stating:

> All of the tangible things with which man deals and for which

decided the question whether a *genetically modified* organism was patentable subject matter under the current Patent Act, 35 U.S.C. § 101.[86] Drawing from the purification doctrine, the Supreme Court held that a genetically altered organism was patentable as a "nonnaturally occurring" biological product.[87] The Court reasoned that the genetically engineered bacterium—developed to break down oil—was patentable under § 101 as a "manufacture" or "composition of matter" because the altered product had characteristics that did not exist in its native environment.[88] Specifically distinguishing *Funk Brothers*, the *Chakrabarty* Court held that the bacterium had "markedly different characteristics from any found in nature and one having the potential for significant utility."[89] Unlike in *Funk Brothers*, the *Chakrabarty* decision clearly speaks to the subject matter requirement.

Marking a turning point for the biotechnology industry, *Chakrabarty* has since provided gene patent advocates with fodder in the patentability debate.[90] By the close of the 20th century, the patentability of isolated (or purified) naturally occurring products was well-established, providing the biotechnology industry with much-needed assurance that its emerging discoveries would be protected by the U.S. patent system.[91] The USPTO issued numerous gene patents under the purification doctrine without dispute as to whether the subject matter was beyond the scope of patentability, granting over 5,000 DNA patents and 16,000 relating

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> patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed are composed necessarily includes naturally existing elements and materials.

Id. at 161-62.

[86] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[87] *Id.* at 303.

[88] *See id.* at 308-09.

[89] *Id.* at 310.

[90] *See* Gold, *supra* note 42; DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 1 (2004).

[91] *See id.*

to DNA in the two decades that followed this revolutionary decision.[92]

Despite the proliferation of DNA patents, none have been invalidated for lack of subject matter. Instead, challenges to gene patents focus primarily on the novelty, utility, and non-obviousness requirements for patentability.[93]

V. BEGGING THE QUESTION: DOES GENETIC EXCEPTIONALISM HAVE A PLACE IN THE PATENT ACT?

A. The History of Genetic Exceptionalism in Social Science and Public Policy

Several bioethicists and legal commentators have discussed the role of genetic exceptionalism in the areas of privacy, insurance, and discrimination laws, with some questioning whether the special treatment of genetic information is necessary or even beneficial.[94] Despite the body of literature replete with arguments for and against gene patentability, genetic exceptionalism is conspicuously absent from the debate. The recently decided case invalidating Myriad's BRCA1/2 patents, however, arguably opened the door to a more nuanced application for genetic exceptionalism: invalidating gene patents based primarily on a gene's unique function in nature as an information carrier. To better understand how Judge Sweet's legal analysis effectively directs gene patents down the road to exceptionalism, it is first

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[92] *Id.*

[93] Because this Article focuses solely on genetic exceptionalism's influence on the subject matter requirement for gene patents, the court decisions regarding utility, novelty, obviousness, and enablement will not be discussed here. Recognizing these requirements are equally important to gene patentability, the Author suggests reading Lauren M. Nowierski, Note, *A Defense of Patenting Human Genome Sequences Under U.S. Law: Support For the Patenting of Isolated and Purified Substances*, 26 CARDOZO ARTS & ENT. L.J. 473 (2008), for an in-depth overview of genetic patent challenges under these patentability prongs. *See also* Conley, *supra*, note 40.

[94] *See, e.g.*, Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L.Q. 669, 671 (2001).

necessary to understand the principle of genetic exceptionalism and its historical development in American culture.

Genetic exceptionalism is a term that refers to the idea that genetic information is qualitatively different from other health information and raises separate social, ethical, and legal issues.[95] Both a fascination with the inherent power of genetic information and the historical fear from genetics' role in eugenics arguably spawned the principle of genetic exceptionalism.

Despite its potential for providing improved patient care, genetic information can be both "uniquely threatening and susceptible to misuse."[96] In an article assessing its allure, Professor Sonia M. Suter traced genetic exceptionalism's development from its historical roots through the eyes of four key stakeholders: the public, the media, scientists, and policy makers.[97] Since the discovery of genes, the public and media have together elevated genes' status to an arguably overstated position of the "Holy Grail" of predictive traits and patient well-being. Since the early 1960s, the media has run rampant with coverage that suggests single genes alone determine characteristics ranging from everything like aggression to homosexuality, while often understating the role of multi-gene and environmental interactions.[98]

In the 1980s, popular culture was fixated on the advent of gene therapy that promised to treat or prevent disease altogether, but three decades later the public and medical community are still

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[95] *Id.* at 671.

[96] *Id.*

[97] *Id.* at 674-75.

[98] *See, e.g.*, Robert Wring, *Our Cheating Hearts*, TIME MAGAZINE, Aug. 15, 1994 ("[Genes] affect behavior by creating feelings and thoughts--by building and maintaining the brain."); DOROTHY NELKIN & M. SUSAN LINEE, THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON 85 (1995) (quoting a New York Times reporter as having said "evil is 'embedded in the chromosomes that our parents that our parents pass to us at conception.'"). In their book, authors Nelkin and Linee suggest that popular culture's "love affair" with the gene draws from scientific principles, but fails to confine itself to DNA's technical boundaries. The authors detailed the debate over the criminal gene, which gained traction in the early 1960s and continued throughout the decades in media's coverage of seemingly unexplainable crimes. *See id.* at 83-86.

waiting for the promise to come to fruition.[99] As one author comments, "Science reporters must first and foremost attract readers, a difficult task when competing with more attention-grabbing topics like war and pop culture. Likely in response to this pressure, two trends have emerged in media coverage of genetics: oversimplification and sensationalism."[100]

Prior to 1993, media coverage focused on newly discovered genes, but as these discoveries became "old news," the stories lost their luster.[101] The media responded by shifting their angle to the pitfalls and perils of genetics, reporting on cautionary tales of discrimination and the proliferation of designer babies.[102] Regardless of whether the undulating media coverage currently paints genetics with a brush or negative, the public's impression that genetics deserves a unique, tailored discourse has already been solidified in the collective mind.

Throughout the ongoing discourse, the public and media have not ignored the other side of the proverbial genetic coin. Simultaneous with genetics' elevation to its "Holy Grail" status was the emergence of a historically-based distrust of genetics' misuse. While the majority of the public most readily identifies the eugenics movement's apex with the Nazi experiments of World War II, the principles of reproductive selection have existed since the days of Darwin.[103]And as evidenced by the oft-reviled United

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[99] See *Gene Therapy*, HUMAN GENOME PROJECT INFORMATION (Aug. 24, 2011), http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml. Gene therapy remains in the experimental stage and has yet to have a solidly successful clinical trial. The technology has not overcome the difficulties presented by the short-lived nature of gene therapy, immune responses in recipients, problems with viral vectors, and the complex nature of multigene disorders.

[100] Ellen Dupont, *Diagnosing the Geno-Hype: Genetic Determinism in the Mass Media*, 5 THE SCI. IN SOC'Y REV. 20, 21 (Spring 2009).

[101] Suter, *supra* note 94, at 678 n.1.

[102] *See* Dupont, *supra* note 100; *see also* David A. Hyman, *Lies, Damned Lies and Narrative*, 73 IND. L.J. 797 (1998) (discussing the power of anecdotal evidence to shape public opinion); Mike Snider, *How Genetics Can Be Used Against You*, USA TODAY, Nov. 17, 1993, at 9D, available at 1993 WL 6726460; Lisa Goldstein, *If You Knew Your Child Would Be Born Deaf*, S.F. CHRON., Feb. 1, 1999, at A19.

[103] Although deemed most prolific implementation of eugenics practice, the

States Supreme Court case *Buck v. Bell*,[104] the eugenics movement did not culturally confine itself. In fact, eugenics' principles manifested themselves as the underpinning rationale for the Court's upholding of compulsory sterilization in America.[105] Not only did courts promulgate eugenics principles, so too did the legislatures at both the federal and state level. In 1924, Congress adopted the Federal Immigration Restriction Act to curb the migration of persons thought to have defective genes.[106] States, on the other hand, began implementing mandatory genetic screening programs for African Americans in the 1970s, resulting in the unintended, yet harmful stigmatization of the African American population.[107] This brief history of the eugenics movement serves only to illustrate the imbedded distrust present in the public's perception of genetic science.

Many scholars, researchers, and law makers alike have been influenced by the media and the history of genetics as an exceptional science in their quest for solutions to social issues and policy making. As early as the 1970s, legislatures have crafted laws that regulate genetic information separate and apart from other medical information,[108] the most recent genetic-specific legislation being the Genetic Information Nondiscrimination Act signed into law by President Bush in 2008.[109] Contributing to the

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Nazi regime by no means created the practice. The word "eugenics" was coined in 1883 by Francis Galton to refer to the practice of improving the human race by controlling reproduction. Martin S. Pernick, *Eugenics and Public Health in American History*, 87 AM. J. PUB. HEALTH 1767 (1997). In 1922, the American Society for Eugenics was founded in the United States to "stem the tide of threatened race degeneracy," and in 1927, the Supreme Court of the United States justified the use of compulsory reproductive eugenics to sterilize those deemed unfit for reproducing. *Id.* at 1769.

[104] 274 U.S. 200 (1927).

[105] *See id.*

[106] Paul Lombardo, *Medicine, Eugenics, and the Supreme Court*, 13 J. CONTEMP. HEALTH L. & POL'Y 2 (1996).

[107] Howard Markel, *The Stigma of Disease: Implications of Genetic Screening*, 93 AM. J. MED. 209, 210-11 (1992).

[108] Suter, *supra* note 94 at 670 n.1.

[109] Genetic Information Nondiscrimination Act, H.R. 493 (110th Cong. 2008). GINA prohibits health insurance companies and employers from discriminating against individuals based on genetic information, which includes

driving force of the exceptionalism movement was the dedication of "the largest expenditure of money for biomedical ethics and health law in the country" to the study of the ethical, legal, and social issues (ELSI) in genetic research.[110] This unprecedented expenditure generated a vast body of literature and countless studies dedicated exclusively to genetic issues, and "even if much of the scholarship is not explicitly premised on notions of genetics exceptionalism, . . . [it] intensifies the media's attention to genetics issues and public fear about genetics."[111] While many of the same threats for misuse and potential social consequences exist in other disciplines, no other science has captivated the public with equal pervasiveness as genetic science.[112]

The confluence of lofty promises for cures, the trendy appeal of the ethical issues, and the sordid history of misuse can explain genetic exceptionalism in American culture. Traditionally, scholars have analyzed genetic exceptionalism in the areas of employment discrimination, insurance discrimination, and privacy laws.[113] The

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family medical histories and information pertaining to an individual or family member's genetic tests and genetic services. Although several states had already acted to protect against genetic discrimination, GINA served to set the minimum level of protection afforded to individuals.

[110] Suter, *supra* note 94, at 685 n.1 (quoting Robert Weir, *Why Fund ELSI Projects?*, *in* GENES AND HUMAN SELF KNOWLEDGE: HISTORICAL AND PHILOSOPHICAL REFLECTIONS ON MODERN GENETICS 189 (Robert F. Weir et al. eds., 1994)).

[111] Suter, *supra* note 94, at 685-86.

[112] *See* Thomas H. Murray, *Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information*, *in* GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 60, 61 (Mark A. Rothstein ed., 1997); Suter, *supra* note 94. *But see* Eric T. Juengst, *FACE Facts: Why Human Genetics Will Always Provoke Bioethics* 32 J.L. MED. & ETHICS 267 (2004) (arguing that genetic information's intrinsic moral value justifies the continued prominence of genetic exceptionalism in bioethics).

[113] *See* Suter, *supra* note 94; see also Trudo Lemmens, *Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?*, 45 MCGILL L.J. 347 (2000) (discussing the desirability of genetic-specific legislation in the insurance context); Douglas H. Ginsburg, *Genetics and Privacy*, 4 TEX. REV. L. & POL. 17 (2000); Mark A. Rothstein, Genetic Exceptionalism and Legislative Pragmatism, 35 J.L. MED. & ETHICS 59 (2007); Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetic Exceptionalism*, 40 JURIMETRICS J. 21 (1999) (arguing that there

literature is silent, however, on whether genetic exceptionalism applies with equal force to the patentability of genes debate. In other words, assuming that the statutory requirements for patentability can otherwise be satisfied, should the law reject gene patents based solely on genetic exceptionalism's justification that genes unique characteristics warrant different protections than do other fields of science?

B. Power Play from the Bench: Myriad*'s Insertion of Genetic Exceptionalism into the Patent Act*

The previous sections provide background information to the reader with regard to the law on gene patents and the story of genetic exceptionalism's impact on insurance, discrimination, and privacy laws. In the recent controversial case on gene patents, *Association for Molecular Pathology v. U.S. Patent and Trademark Office*,[114] patentable subject matter collides with genetic exceptionalism for the first time, transforming genetic exceptionalism into a legal principle. In the opinion, Judge Sweet singles out DNA from other isolated products based purely on DNA's information carrying characteristics, while attempting to invalidate DNA patents under a "product of nature" analysis.[115] The court falls short in its explanation of why other purified or isolated products of nature continue to be patentable subject matter. Perhaps influenced by DNA's mystique, the court reasoned that genetic patents differ from patents on antibodies, antibiotics, hormones, metabolites, biologic drugs, and the like, because DNA is solely the "physical embodiment of information."[116] Rather than purely focusing on the chemical makeup of DNA (after all, DNA is comprised of chemically bound strands of molecules), the court

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is no clear demarcation between genetic data and other health information).

[114] 702 F. Supp. 2d 181 (S.D.N.Y. 2010); referred to herein as "*Myriad*."

[115] *See id.*

[116] *See* Noonan, *supra* note 44, at 30 n.17. As Noonan points out, these naturally occurring, isolated products are in "substantially homogenous form, are structurally unchanged from their sources in blood and other bodily fluids, and are less altered than the cDNAs that are the subject of the claims to isolated human DNA invalidated by the district court." *Id.*

embraces the genetic exceptionalism ideals by finding that genes are *inherently different* and thus deserving of unique treatment under the Patent Act.[117] Despite whether genetic information should be treated differently in other contexts—for example with insurance, discrimination, and privacy laws—Judge Sweet overlooks the fact that the genetic information itself is not patented. As such, researchers are able to utilize the genetic information disclosed in the patent for purposes such as performing sequence comparisons or detecting genetic polymorphisms.[118] This section dissects the law on patentable subject matter from the opinion's genetic exceptionalism components, and then evaluates whether the holding can stand based purely on the legal arguments that remain.

1. Background of BRCA1/2 and the *Myriad* Litigation

In 1990, a team of geneticists discovered that a mutation in the BRCA1 gene was linked to an increased risk for developing breast and ovarian cancers.[119] Of the patients with hereditary breast cancer, five to ten percent have a substituted allele that inactivates the BRCA1 gene, leading to an abnormal cellular gene expression of the protein.[120] If a patient has a mutated gene, she has a lifetime risk of 40 to 85 percent for developing breast cancer and a risk of 16 to 40 percent for developing ovarian cancer.[121] Other known factors, such as the type of mutation (e.g., insertion, deletion, or rearrangement of codons) and family history can impact the lifetime risk of developing cancer, as well as the likely interaction

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[117] Some philosophers have viewed genes as more than the "common heritage of mankind," arguing that genes are an "un-encloseable commons-by-necessity . . . . free for use by any and all." David Koepsell, *Naturally Occurring Genes and the Commons by Necessity*, 23 GENEWATCH 32, 34 (Oct.-Dec. 2010).

[118] *Id.* at 31.

[119] Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 131 (2002).

[120] *Id.* at 127.

[121] *Id.*

with other genes.[122] The BRCA2 gene is also thought to be a similar acting tumor-suppressing gene.[123]

Mark Skolnick, the co-founder of Myriad, sequenced the BRCA1 gene in August 1994 with the help of a team of researchers from NIH, the University of Utah, and McGill University.[124] Following this discovery, Skolnick and Myriad filed for a U.S. patent claiming the isolated sequence and the associated mutations as both a "composition of matter" and a "method-of-use."[125] The USPTO was quick to issue the patents to Myriad, but further complicated the patentability of BRCA1 by issuing a similar patent to OncorMed.[126] OncorMed's BRCA1 patent differed only slightly with respect to the mutations claimed, overlapping in both the diagnostic and therapeutic applications of the patent.[127] As a result, both patent owners filed infringement suits against the other, but instead of litigating the issue, OncorMed settled by selling Myriad its patent on BRCA1 in 1998.[128]

Understanding the importance of locating and patenting BRCA2, Myriad embarked on a race to discovery against a group of U.K. scientists who were also highly invested in locating the sequence. On December 21, 1995, the day before the U.K. scientists were scheduled to publish its discovered BRCA2 sequence in *Nature* magazine and the day of the U.K.'s planned press conference, Myriad notified the public that they had sequenced BRCA2 and had filed for a U.S. patent.[129] Having now secured patents to both the isolated BRCA1 and BRCA2 genes, Myriad was poised to control the testing market for breast and

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[122] *Id.*

[123] *Id.*

[124] *Id.* at 131. The founders of Myriad were "focused on the discovery and commercialization of genes involved in major common disorders including cancer and heart disease." *Id.* at 129 (citation omitted). Myriad now offers an array of services, ranging from research and development to diagnostics.

[125] *Id.*

[126] *Id.* at 132.

[127] *Id.*

[128] Williams-Jones, *supra* note 119, at 132.

[129] Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 202 (S.D.N.Y. 2010).

ovarian cancer and the market for developing therapeutics to treat patients with one of the mutations.[130]

Over the course of the 1990s, Myriad did not assert its exclusivity rights over its BRCA1/2 patents, but instead allowed researchers to use the tests under certain circumstances. Myriad offered to license its patents to the University of Pennsylvania Genetic Diagnostic Laboratory so that the laboratory could continue its screening program on BRCA1 and BRCA2.[131] Not satisfied with the scope of the license, the University and its physicians rejected the licensing proposal.[132] Myriad subsequently sent cease-and-desist letters to the University of Pennsylvania and on August 26, 1998, sent notice that the physicians were infringing Myriad's patents and filed the infringement suit in November of the same year.[133] Although the laboratory was forced to stop performing tests, Myriad informed the University that it was free to continue academic research on the genes.[134] A similar course of conduct—Myriad offering a license and the plaintiffs rejecting the license—occurred with the other plaintiffs in the case.[135]

Myriad asserted seven patents against the plaintiffs, identifying fifteen claims within those patents that the plaintiffs allegedly infringed.[136] The claims fell into one of two categories: composition claims or method-of-use (or process) claims.[137] Because there were several composition claims within the patent,

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[130] In the years following the issuance of the patents, Myriad developed a host of tests to screen and diagnose patients with an increased risk for breast cancer. Among the tests (listed from least to most expensive) include: (1) a single site test for patients having a family history of the mutation, designed to identifies carriers; (2) a multisite test that searches for three common mutations in the Ashkenazi Jewish population; (3) a comprehensive test identifying the full gene sequence; and (4) a rapid test designed to return the full gene sequence within seven days. Williams-Jones, *supra* note 119, at 133-34. Myriad's tests were arguably more sensitive than other tests offered at the time because Myriad's tests identified each base-pair within the gene. *Id.*

[131] *Myriad*, 702 F. Supp. 2d at 205.

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *Id.* at 212.

[137] *Id.*

the court provided one composition claim as the categorical representative, which read: "An *isolated DNA* coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2."[138]

Similarly, the court provided a representative methods-of-use claim for Myriad, which reads: "A method for detecting a germline alteration in a BRCA1 gene . . . in a human which comprises *analyzing a sequence* of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA . . . ."[139] In layman's terms, the first category of claims at issue covers any use of the isolated gene itself and the second category of claims at issue covers methods used to analyze mutations in the gene that correlate with a predisposition for breast and ovarian cancer.[140]

The plaintiffs brought an action for summary judgment against the USPTO & Myriad asking the court to declare these patents relating to BRCA1/2 invalid for lack of patentable subject matter.[141] The plaintiffs urged the court to find that the patents were improperly issued to cover products of nature, laws of nature, physical phenomena, and abstract ideas, which offend Article I, § 8, Clause 8 of the United States Constitution.[142]

2. A Closer Look at Judge Sweet's Analysis in the *Myriad* Decision

Judge Sweet crystallized the issue before the court as whether "isolated human genes and the comparison of their sequences [are] patentable."[143] He embarked on his legal inquiry by first constructing the claims at issue to determine the scope of the patent protection. The first claim dispute to be resolved involved the terms "DNA" and "isolated DNA."[144] The plaintiffs argued

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[138] *Id.* (emphasis added).
[139] *Id.* at 213 (emphasis added).
[140] *See id.* at 211-17.
[141] *Id.* at 184.
[142] *Id.*
[143] *Id.* at 185.
[144] *Id.* at 216. In construing a patent claim, the court applies several cannons of construction to arrive at a final interpretation. These canons can be broken

that the term "DNA" should be construed to mean "a sequence of nucleic acids, also referred to as nucleotides."[145] As Myriad pointed out, this definition implies that DNA refers to a description of the sequence of nucleic acids (i.e., information only).[146] Myriad contended that "DNA" encompasses a "real and tangible molecule, a chemical composition made up of deoxyribonucleotides linked by a phosphodiester backbone."[147] In resolving this dispute in Myriad's favor, the court looked at the specification of Myriad's patent, which explicitly referred to DNA as a *physical manifestation* of the nucleotides such that the DNA *could be separated* from the other components of the cells that naturally accompany DNA.[148] Similarly, the court adopted Myriad's definition of "isolated DNA" as set forth in the specification, which defined isolated DNA as "a DNA molecule which is substantially separated from other cellular components which naturally accompany a native human sequence . . . ."[149]

The second claim concerned the definition of BRCA1 and BRCA2. The plaintiffs argued that each meant "a particular fragment of DNA found on chromosome 17 [13 for BRCA2] that relates to a person's predisposition to develop breast and ovarian cancer."[150] Once again, however, Myriad acted as its own lexicographer, defining in the patent specification each gene as "a human breast cancer predisposing gene . . . some alleles of which

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down into two categories, intrinsic and extrinsic evidence, with more weight given to the former. Some of the intrinsic evidence considered by a court includes: words of the claims themselves, the written description, and the prosecution history of the patent. *Id.* at 214-15. In looking at this evidence, the court will not read a limitation in a dependent claim into the independent claim, nor will the court read a limitation from the specification into the claim (but does read the claim "in light of" the specification). Finally, if the patentee acts as its own "lexicographer," then the court will use the patentee's definition for a disputed term. The court may also look at the extrinsic evidence available: dictionaries, treatises, and expert testimony. Usually, extrinsic evidence is used to inform the judge of the field of science and technology. *Id.* at 215-16.

[145] *Id.*

[146] *See id.*

[147] *Id.*

[148] *Id.* at 216.

[149] *Id.* at 217.

[150] *Id.*

cause susceptibility to cancer, in particular breast and ovarian cancer."[151] While noting that BRCA1 and 2 are genes normally integrated into chromosomes 17 and 13 respectively, the court again adopted Myriad's construction of the definition.[152]

Having construed the claim language, the court moved into the heart of the analysis: subject matter patentability under § 101 of the Patent Act, which provides, "Whoever invents or *discovers* any new and useful *process*, machine, manufacture, or *composition of matter*, or any new and useful improvement thereof, may obtain a patent . . . ."[153] Although Congress intended to grant patent protection broadly, § 101 is not without limits. Specifically, the Supreme Court has carved out three categories of non-patentable subject matter: laws of nature, natural phenomena, and abstract ideas. The reasoning behind these exclusions is that although each may be "discovered" in a sense, each comprises the basic tools of science and technological work.[154]

Under the heading, "Patentable subject matter must be 'markedly different' from a product of nature," Judge Sweet emphasized that questions of utility and statutory subject matter patentability are wholly separate inquiries, and only cases decided on subject matter grounds are binding on the court.[155] Judge Sweet relied on *Funk Brothers*, which he described as holding that the mixture of bacteria was not patentable subject matter because it "did not create a state of inhibition or of non-inhibition," but rather maintained qualities that were a work of nature.[156] Despite ample

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[151] *Id.*

[152] *Id.*

[153] *Id.* at 218 (emphasis added).

[154] *Id.* at 218-219 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)). Recall from discussion *supra*, *Chakrabarty* held that a genetically altered bacterium was patentable subject matter because it had "markedly different characteristics from any found in nature and one having the potential for significant utility."

[155] *Id.* at 219, 222.

[156] *Id.* (citing Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 128-31 (1948)). Recall that *Funk Brothers* was deciding the issue whether the mixture was an "invention or discovery," not necessarily whether the mixture was patentable subject matter. Prior to the Patent Act of 1952, "invention or discovery" was interpreted as the non-obvious prong for patentability. *See* Brief

evidence that *Funk Brothers* was decided on grounds other than subject matter patentability,[157] however, the court interpreted the case as standing for the exclusion of natural phenomena from subject matter patentability.[158]

The court next turned in passing to *Chakrabarty*, which is arguably more controlling in *Myriad* since it was decided under § 101 of the current Patent Act.[159] While he included some of the language of the opinion, Judge Sweet omitted any meaningful discussion on the analysis underlying the Court's holding. For instance, he seemingly glossed over the part of the *Chakrabarty* opinion that states that without a specifically designed exception from Congress, § 101 should be construed broadly and in such a way that includes living things.[160] Since the decision, *Chakrabarty* has supported patenting living products that have "markedly different characteristics from any found in nature and one having the potential for significant utility."[161]

Throughout the next several pages of the *Myriad* opinion, Judge Sweet proffered a litany of cases that essentially require "something more" than merely isolating or purifying a substance from its native state to fall within the scope of statutory subject matter.[162] Read collectively, these cases require that a patentable product have qualities or characteristics that were absent in its

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for Alnylam Pharmaceuticals, Inc. as Amici Curiae Supporting Defendants-Appellants, Ass'n for Molecular Pathology v. Myriad Genetics, Inc. 133 S.Ct. 694 (2012) (No. 12-398) at 8 ("Debunking myths of Funk Bros. Seed Co. v. Kalo Inoculant Co."), available at http://patentdocs.typepad.com/files/alnylam-amicus-brief.pdf. There is ample language in the *Funk Brothers* opinion that suggests the mixture was not patentable because the proffered "invention" conferred no new quality or use (i.e., obvious) for any one bacterium in the mixture or for the collective whole. Rather, the mixture merely provided consumers with a more convenient way to purchase the component bacteria.

[157] *See id.* For a discussion on this very issue, visit the 37 Thoughts legal blog, available at http://37thoughts.wordpress.com/2010/03/30/save-the-funk-brothers/.

[158] *Myriad*, 702 F. Supp. 2d at 222.

[159] *Id.* at 223.

[160] *Chakrabarty*, 447 U.S. at 318.

[161] *Id.* at 310.

[162] *Myriad*, 702 F. Supp. 2d at 223-28.

natural form.[163] As examples, the court cited to refined cellulose, artificial alizarine dye, purified tungsten, and isolated pine needle fibers, all of which were rejected as non-patentable subject matter.[164]

Turning to precedent relied on by Myriad, Judge Sweet summarily rejected the applicability of *Parke-Davis*, which Myriad asserted as establishing that the purification of a naturally occurring product (i.e., adrenaline) was patentable subject matter.[165] He noted that *Parke-Davis* was decided on novelty—not subject matter—grounds and was therefore not applicable to the present case being decided under § 101.[166] In so doing, he cast the language in *Parke-Davis*, which stated that "even if [adrenaline] were merely an extracted product without change, there is no rule that such products are not patentable," as dicta.[167] Judge Sweet went on to distinguish other cases cited by Myriad based on similar reasoning.[168]

Finally, almost as an afterthought, Judge Sweet briefly addressed *Merck & Co., Inc. v. Olin Mathieson Chem. Corp.*,[169] which held that a higher concentration of purified Vitamin B12—capable of treating anemia—was a patentable composition of matter.[170] The purified B12 was created through an artificial fermentation process that allowed for the production of a greater concentrated product than the naturally occurring B12 produced by cows.[171] Because of the different concentration and effectiveness as a therapeutic agent, the *Mathieson* court reasoned that the new product was not the same as the old naturally occurring product, but rather a "new and useful composition entitled to the protection

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[163] *See id.*

[164] *See id.*

[165] *See id.* at 225.

[166] *Id* at 225-26.

[167] *Id.* at 226 (quoting Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911)).

[168] *Id.* at 225-27.

[169] 253 F.2d 156 (4th Cir. 1958).

[170] *Myriad*, 702 F. Supp. 2d at 227.

[171] *Mathieson*, 253 F.2d at 165.

of the patent."[172] Without scratching the surface of the case, Judge Sweet merely pointed out the court's conclusion that purified Vitamin B12 was more than a "mere advance in the degree of purity of a known product."[173]

3. Genetic Exceptionalism Transcribed into Legal Principle: Isolated DNA is not "Markedly Different" from Native DNA

After setting forth the legal precedent, Judge Sweet identified the applicable test for determining the subject matter patentability of Myriad's isolated BRCA1 and BRCA2 gene patents. Namely, whether the isolated DNA claimed in the patent possesses "markedly different characteristics" from the native (or genomic) DNA.[174] Focusing on the chemical make-up of DNA, Myriad argued that the isolated DNA *is* markedly different because it differs both structurally and functionally from genomic DNA.[175] Instead of looking at the similarities and the differences between the two compositions, Myriad argued the court should look exclusively at the differences.[176] Judge Sweet rejected this approach, citing Supreme Court precedent that requires claims be considered as a whole.[177] While a correct statement of the law, the law may be misapplied; reading the claim as a whole means looking at the entire claim regarding *isolated* DNA, not the genomic DNA that falls outside the scope of the patent.[178]

At this point in the opinion, Judge Sweet diverges from a purely legal argument into what is viewed by some as carving out an exception for gene patents based on the inherent information carrying function of genes themselves. He explained that focusing on the chemical nature of DNA "fails to acknowledge the unique characteristics of DNA that differentiate it from other

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[172] *Id.*
[173] *Myriad*, 702 F. Supp. 2d at 227 (quoting *Mathieson*, 253 F.2d at 164).
[174] *Id.* at 227-28.
[175] *Id.* at 229.
[176] *Id.*
[177] *Id.*
[178] *See id*. at 228.

compounds."[179] Without citing any legal authority justifying why DNA *should* be considered differently under the Patent Act, he goes on to explain that even if other chemical compounds contain information, the information encoded in DNA reflects its primary biological function: "[DNA] direct[s] the synthesis of . . . proteins, biological molecules of enormous importance, which catalyze biological chemical reactions and constitute the major structural materials of the animal body."[180] Thus, DNA could be seen as the "physical embodiment of laws of nature."[181]

Given the unique nature of DNA, Judge Sweet reasoned that the structural and functional differences raised by Myriad were not "markedly different."[182] Rather than explaining why the differences are not relevant to an inquiry into the nature of native versus isolated DNA, he jumped to the conclusion that neither is relevant because of the "overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form."[183] In other words, because isolated DNA preserves the important characteristics of native DNA, isolated DNA can never be "markedly different."[184] He goes on to state that the "defining characteristic of DNA in its native and isolated forms *mandates the conclusion* that the challenged composition claims are directed to unpatentable products of nature."[185]

In its attempt to persuade the court, Myriad delineated several distinctions between isolated DNA and native DNA. First, they argued, there are structural differences because isolated DNA is

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[179] *Id.* In response to biotech's assertion that invalidating gene patents will lead to invalidating pharmaceuticals, Judge Sweet states: "The conclusions reached in this opinion concerning the subject matter patentability of isolated DNA . . . are based on the unique properties of DNA that distinguish it from all other chemicals and biological molecules found in nature." *Id.* at 228 n. 51 (emphasis added).

[180] *Id.* (internal quotations omitted).

[181] *Id.*

[182] *Id.* at 229.

[183] *Id.*

[184] *See id.*

[185] *Id.* (emphasis added).

not associated with chromosomal proteins.[186] The court rejected this argument, stating it was only a matter of purity.[187] Next, Myriad asserted that native DNA contains introns (noncoding regions) that are absent from the isolated or purified DNA, which only contains the exons (coding regions).[188] However, Judge Sweet found that because the isolated DNA contains *some* of the same gene fragments (e.g., the same fifteen nucleotide sequence), the two are not sufficiently different.[189] Judge Sweet stated that the claims covering the compositions of matter for BRCA1/2 (i.e., cDNA molecules) cover the same product that is produced by naturally-occurring splicing within the cell.[190] Yet he failed to recognize that the isolated DNA—as a chemical molecule—is much smaller, not three dimensional, and lacks the chemical complexity of genomic DNA, all properties which permit novel and innovative uses.[191]

Arguably, Myriad's strongest argument rested with isolated DNA's ability to be practically applied in ways that native DNA cannot. By extracting and significantly altering native DNA, scientists are able to use the isolated molecules to improve patient health care.[192] With the adapted DNA, scientists are able to perform diagnostic tests using the molecule as a probe, primer, or template for sequencing genes.[193] Likewise, isolated DNA opens the door to medical treatment options ranging from preventative care to gene therapy.[194] Without the isolated DNA molecules, none of these health care innovations would be possible.[195]

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[186] *Id.* at 228-29.
[187] *Id.* at 229.
[188] *Id.* at 230.
[189] *Id.*
[190] *Id.* at 229-230.
[191] *See* Brief for Am. Intellectual Prop. Law Ass'n as Amici Curiae Supporting Neither Party, Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010–1406) at 14, available at http://www.aipla.org/Advocacy%20Shared%20Documents/AIPLA-Myriad-Amicus-filed.pdf [hereinafter "AIPLA Brief"].
[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] *Id.* at 14-15.

Finally, Judge Sweet hypothesized that a "time may come when the use of DNA for molecular and diagnostic purposes may not require such purification."[196] This consideration runs contrary to patent law, which requires the evaluation for patentability to take place at the time of the invention, regardless of any subsequent innovations.[197]

Notwithstanding the newly derived capabilities of isolated DNA, the court erroneously rejected these differences, instead electing to focus on the information carrying characteristics of inherent in the nucleotide sequence. In so doing, Judge Sweet elevates DNA to a greater status than other chemical molecules—excepting genetic science from other fields of discovery. There is nothing in precedent or the Patent Act that demands DNA be treated differently than the molecules which comprise it. It follows that if Judge Sweet had not cast DNA as an elite chemical substance, the decision may have fallen more in line with that of the Court of Customs and Patent Appeals in *In re Bergy*.[198]

In *Bergy*, the court was presented with the question whether the discovery of a biologically pure bacterium for pharmaceutical use, providing an indispensable medical tool, was patentable.[199] The court reasoned,

> [M]icroorganisms have long been important tools in the chemical industry, especially its pharmaceutical branch, and when such a *useful, industrial tool* – [the tools used by chemical manufacturers in the same way as they use chemical elements, compounds, and compositions] – is invented which is new and unobvious, so that it complies with those conditions for patentability, we see no reason to deprive it or its creator or owner of the protection

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[196] *Myriad*, 702 F. Supp. 2d at 232.

[197] *See* 35 U.S.C. § 103 (stating the time for evaluating obviousness against prior art is at the time of invention, not the time of the patent application's evaluation).

[198] 596 F.2d 952 (C.C.P.A. 1979) (affirmed sub nom Diamond v. Chakrabarty, 447 U.S. 303 (1980)).

[199] *Id.*

> and advantages of the patent system by *arbitrarily excluding* it at the outset from the § 101 categories of patentable invention on the *sole ground that it is alive*. It is because it is alive that it is useful. . . .[200]

By analogy, DNA's chemical characteristics enable it to be used as a medical tool, but not unless it is isolated and purified. Without the man-made changes, the DNA molecule is unable and unreliable as a diagnostic tool. Thus, neither law nor fact supports arbitrarily excluding isolated DNA from patent protection owing to the fact that it carries the same information as genomic DNA. As an *Amicus Curie* brief eloquently summarized, "By selectively assigning dispositive importance to one shared characteristic of the claimed purified/isolated DNA molecules and discounting all the differences, the District Court adopted precisely the rationale that *Bergy* rejected."[201]

CONCLUSION

After reviewing Judge Sweet's 152-page opinion, the Author would argue that there is no legal or factual basis for declaring isolated DNA outside the scope of patentable subject matter. Instead, it appears that the impetus behind the *Myriad* decision is rooted in genetic exceptionalism. By adhering to the principles of genetic exceptionalism, the opinion tends to overlook legal precedent to arrive at a conclusion that the nature of DNA as information carriers naturally exempts itself from patent protection absent an express exclusion from Congress. One could conclude that the *Myriad* decision was largely influenced by the societal, moral, and ethical issues—not by the legal precedent—raised by the plaintiffs. The opinion devoted several pages to the negative impacts that gene patents have on costs and access to health care as well as the possible chilling effect on research innovation. While these are important considerations in determining patent *policy*, they are not factors to be applied under the Patent Act. If such was the case, patented and statutorily permissible subject matter—such

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[200] *Id.* at 975 (emphasis added) (internal citations and quotations omitted).
[201] AIPLA Brief at 17 (citing *Bergy*, 596 F.2d at 975).

as pharmaceuticals example—could be invalided solely based on similar policy concerns. Whether one agrees that genetic information should be treated different, almost reverently, deciding whether to adopt genetic exceptionalism is a matter of public policy rather than legal principle.[202] Thus mandating that the Patent Act subject matter patentability requirement be interpreted through the lens of genetic exceptionalism is a power not conferred to the bench, but rather to Congress.

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[202] Perhaps Chief Justice Burger stated it best in *Chakrabarty*, when addressing the judicial branch's place in making policy decisions:

> The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

447 U.S. at 317.