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THE COPYRIGHT & DIGITAL MISMANAGEMENT CHASM: FAIR USE IMPLICATIONS OF DIGITAL RIGHTS MANAGEMENT TECHNOLOGIES UPON THE DIGITAL VERSATILE DISK MEDIUM

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"Technological progress is like an axe in the hands of a pathological criminal." – *Albert Einstein*.[1]

I. INTRODUCTION

A new border fence has been erected, albeit almost unnoticed to the casual observer. Yet this fence, unlike the hotly debated concrete and wire fence at the southern border currently before Congress, is a unique creature indeed. This fence contains encryption methods and technologies to facilitate its ubiquitous dissemination. This new fence has its agents, too. However, unlike those that patrol the desert, these agents are in the form of Digital Video Disc ("DVD") optical disc manufacturers, DVD players, encryption licensing associations, and backers in the entertainment industry.

While consumers of audiovisual and audio works fixed in Video Home System ("VHS"), DVD, and Compact Disc ("CD") formats have become accustomed to certain privileges regarding uses of their purchased content, such niceties may soon be a thing of the past. To illustrate, an individual who owns DVDs may want to transfer the content to a portable digital player for an upcoming trip in order to avoid traveling with bulky discs and risking damage to them. However, certain technologies within the DVD prevent such a transfer.[2] Likewise, if an individual wanted to "rip" DVD content to a portable player, in order to preserve a back-up copy in the event the DVD becomes corrupt, access will be blocked. The only option will be to buy a new DVD.[3] Similarly, if a movie critic wished to take excerpts from various DVDs to present a point of view, she too, would be prevented from doing so.[4] These "privileges" fall under a legal doctrine called Fair Use and the Technologies, while the mechanisms that prevent such freedoms fall under the rubric of Digital Rights Management ("DRM").

This article suggests that the fair use rights of commentators, critics, and the everyday consumer are slowly being eroded by a two-pronged threat posed by technological and legal measures, namely

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[1] Brainy Quote, http://www.brainyquote.com/quotes/authors/a/albert_einstein.html (last visited Oct. 1, 2006).

[2] Center for Democracy and Technology, Evaluating DRM: Building a Marketplace for the Convergent World 4 (2006), http://www.cdt.org/headlines/931 (follow "Evaluating DRM Paper" hyperlink).

[3] *Id.* at 5.

[4] *Id.*

DRM systems and the Digital Millennium Copyright Act ("DMCA"), respectively.

In furtherance of the instant proposition, this article will elucidate how actions that were within the ambit of time-honored fair usage rights are now under attack. Such traditional freedoms have included: creating commentary and parody, time-shifting, having unfettered access to and copying of ideas, facts, and public domain materials, and copying for personal use. This article proposes that such restraint upon DVD content usage frustrates a basic tenet of fair usage: balancing the protections and incentives provided by copyright's constitutional push to reward authors, while simultaneously safeguarding First Amendment free speech rights as delineated by the Fair Use Doctrine and the Idea/Expression Dichotomy.

A. The Controversy

Public interest groups, associations, scholars, and critics, exercising their rights relating to accessing and copying DVD content blocked by DRM, all voiced fair use concerns to the United States Copyright Office ("Copyright Office") in its triennial review.[5] For instance, to comment on or criticize the content of a DVD is well within the Fair Use Doctrine; however, the use of DRM systems with DVDs prevents commentators from critiquing ancillary portions of DVDs by preventing clips from being excised for criticism.[6] Similarly, newsworthy material is also within the bounds of fair use; however, even with "thin copyright"[7] public domain works, once DRM is put into place upon a DVD, such access is denied and this is backed by the DMCA.[8]

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[5] United States Copyright Office, Rulemaking on Exemptions from Prohibition on Circumvention of Technological Measures that Control Access to Copyrighted Works (2006), http://www.copyright.gov/1201.

[6] *Id.* at 12; *see also* David H. Holtzman, *The DVD War AgainstConsumers*, BUSINESS WEEK ONLINE, May 30, 2006, http://www.businessweek.com/technology/content/may2006/tc20060526_680075.htm.

[7] United States Copyright Office, Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies 10 (2003), http://copyright.gov/fedreg/2003/68fr2011.html. "Thin copyright" refers to works where the copyrightable expression is limited in relation to the amount of subject material which is not in the particular work. *Id*.

[8] *Id.*

Although the DMCA only protects copyrighted works,[9] DRM technology is not sophisticated enough to distinguish protected expression from underlying quotes, theories, facts, ideas, and *de minimis* takings, which are free to sample. Before giving a full exposition as to why such elements contained in works of authorship are free for the taking while others require a more nuanced analysis, which will be addressed in Part III.A *infra*, it is crucial to comprehend the themes underlying the controversy.

While the Copyright Office's triennial review commented upon the DMCA's inapplicability to public domain works, this is of no consequence to the non-sophisticated DVD user. In other words, while the technologically-savvy may be able to circumvent a particular DRM technology, those without such a background are unable to access that to which they have every right.

To date, it is not clear that one may create tools to access DRM, even if the work is in the public domain and one is simply exercising her fair use rights.[10] Another annoyance consumers of legally purchased DVDs endure is the blocking methods that prevent skipping advertisements at the beginning of movies.[11] While the Copyright Office technically found such blocking is not anti-access, but rather a User Operation Prohibition ("UOP"), it declined to adopt an exemption and found such impediment to be of little concern.[12] Interestingly, while UOP blocking received a comprehensive discussion in the 2003 triennial report, the latest triennial review released by the Copyright Office on November 27, 2006, relegates UOP blocking to a footnote citing the 2003 report.[13] Although the Copyright Office does not see UOP blocking as anti-access, there are several commentators that do, suggesting that the definition of "access" is partially open to interpretation.

What in times past used to be an absolute right to access such building blocks and "engine[s] of free expression"[14] is now shrouded

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[9] 17 U.S.C. § 1201(a)(1)(A) (2006) "No person shall circumvent . . . *to a work protected under this title."* (emphasis added).

[10] Pamela Samuelson, Towards More Sensible Anti-Circumvention Regulations 4, http://www.ischool.berkeley.edu/~pam/papers/fincrypt2.pdf (last visited May 1, 2007).

[11] Marybeth Peters, *Recommendation of the Register of Copyrights in RM 2005-11, Rulemaking on Exemptions from Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies* 21, Nov. 17, 2006, http://www.copyright.gov/1201/docs/1201_recommendation.pdf.

[12] *Id.*

[13] *Id.*

[14] Harper & Row Publishers, Inc. v. Nation Enters., 471 U.S. 539, 558 (1985);

in a legal and technological morass in order to accommodate a concentrated, but powerful class. To suggest that one may copy, in order to appease those who argue for the undeniable right to ideas and facts, while concurrently denying access via encryption, is analogous to suggesting that one may speak in public to exercise her free speech rights, while at the same time denying the speaker an audience.

It is worth noting at the outset that the piracy of digital content on DVDs merits focused attention, using tailored means to combat the piracy via technological tools and legal methods. Assuming the end sought is the protection of expression through copyright laws in the United States and elsewhere in the world, the means employed are too broadly sweeping to accomplish this end.

To combat piracy of digital content utilizing DRM, at this stage of its development, is inappropriate because it is overly broad and its scope too restrictive on end-users. Not only does the technology block items which should be free for the taking (such as underlying commentary, facts, ideas, and quotes), but the legal force behind it, the DMCA, is just as far-reaching, if not more, in its breadth of coverage than its technological counterpart, DRM.

B. Why the Digital Rights Management Push

In order to gain a better understanding of why DRM protection of DVDs is on the rise, it is important to view the issue from the perspective of the distributor. Piracy of copyrighted movies and other information stored on DVDs is a serious issue and a growing epidemic.[15] The escalation can be largely attributed to the digitalization of media content, Internet access, and devices to play and copy such content. The focus herein is limited to DVDs, DVD players, and the Internet. To illustrate, International Data Corporation ("IDC"), a subsidiary of the International Data Group, a global provider of market intelligence for the information technology [16] and

See also Eddan Katz, Yale ISP, "Regulating Search?" Symposium, Dec. 3, 2005, http://www.library.yale.edu/~llicense/ListArchives/0511/msg00087.html. For an interesting read, this article discusses regulating searches on search engines with a legal-policy oriented approach.

[15] *See generally* Candace S. Friel, *The High Cost of Global Intellectual Property Theft: An Analysis of Current Trends, the TRIPS Agreement, and Future Approaches to Combat the Problem*, 7 WAKE FOREST INTELL. PROP. L.J. 209 (2007).

[16] Interoperability Clearinghouse (ICH), http://www.ichnet.org/glossary.htm (last visited Feb. 15, 2007); The Science Coalition, http://www.sciencecoalition.org (last visited Feb. 15, 2007). Information technology is essentially an integrated,

telecommunications industry, projects that by 2007 the information equivalent of the Library of Congress will be accessed and downloaded more than 64,000 times per day.[17] Just as staggering are some of the projected losses estimated by the Motion Picture Association of America, which represents giants such as 20th Century Fox, Warner Brothers Entertainment, Universal Studios, Sony Pictures, and Buena Vista Pictures.[18] In 2005, over $18.2 billion was lost to various forms of piracy worldwide, with $6.1 billion in losses attributable to studios represented by the Motion Picture Association of America.[19] In that same year, approximately eighty-one million DVDs were seized by enforcement agencies globally; in addition, there was a 113% increase in confiscated DVD burners from the previous year.[20]

Also noteworthy is the global profile of the typical pirate: a young male between the ages of sixteen and twenty-four, predominantly domiciled in an urban environment.[21] Additional studies have shown that in the United States alone, over 44% of losses are attributable to piracy by college students.[22] Further, as a result of the lower costs associated with hard goods, optical disc piracy, which includes not only piracy of DVDs but also of Laser Discs and Video Compact Discs, is very much on the rise.[23]

The phenomenon most responsible for the escalation in piracy seems to be the wider availability of the Internet, which makes downloading and streaming media possible on a much larger scale than in years past.[24] The World Intellectual Property Organization ("WIPO") estimates that over 600,000 copies of movies are

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functional system with the goal of creating a framework, which manipulates, transmits, and utilizes business data in meaningful ways. *Id.*

[17] Colin C. Haley, *Traffic Jam Could Lift Telecom*, ISP-PLANET, Mar. 3, 2003, http://www.isp-planet.com/research/2003/idc_traffic_030303.html.

[18] Motion Picture Association of America, http://www.mpaa.org/AboutUs Members.asp (last visited Feb. 18, 2007). The aforementioned companies, among others, have members on the MPAA's board of directors.

[19] Motion Picture Association of America, 2005 U.S. Piracy Fact Sheet, http://www.mpaa.org/USPiracyFactSheet.pdf (last visited Feb. 18, 2007).

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] World Intellectual Property Organization Frequently Asked Questions: Counterfeiting and Piracy, Which Products Are Typically Affected?, http://www.wipo.int/enforcement/en/faq/counterfeiting/faq03.html (last visited Feb. 21, 2007).

[24] *Id.*

downloaded illegally every day.[25] The Business Software Alliance suggests the escalation in piracy is due not only to the increased availability of the Internet, but also to the simplicity of making copies, which even a non-technically oriented user can accomplish.[26]

A simple scenario of one person buying a legally authorized copy of a DVD, downloading it onto his or her computer, and permitting others to download, vastly diminishes prospective sales. Thus, it is easy to see why DVD movie distributors, among others in the supply chain, have gone beyond raising an eyebrow to taking affirmative action to stop piracy through legal, technological, and lobbying methods.

C. Plotting a Course Through the Morass

Part II of this article provides a foundation by defining DRM technologies and how they interrelate with DVDs. Part III then addresses the DMCA and how courts have grappled with the tension between right of access via fair use under the Copyright Act, and the author's right to protect his or her expression. Likewise, this part will present this author's suggestions, in conjunction with other commentators' thoughts, on how precedent should guide the courts in navigating the murky waters left in the wake of the DRM/DVD merger. Finally, Part IV concludes with recommendations for various options that may be available to ensure a more balanced approach by courts, which will maintain the inherent spirit of copyright law, both as it was first envisioned and as it has evolved in the face of emerging new technologies.

II. DRM/DVD 101: WHAT DRM IS AND HOW IT RELATES TO DVDS

DRM may best be described as an umbrella of technologies and solutions that allows digital media content providers to manage or restrict (depending on one's viewpoint) not only who uses the provider's products, but also when and how many times access will be permitted.[27] Further, DRM's implementation is varied, as it can

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[25] *Id.*

[26] Business Software Alliance (BSA): Anti-Piracy Information, Internet Piracy, http://www.bsa.org/usa/antipiracy/Internet-Piracy.cfm (last visited Feb. 21, 2007). Estimates show that over 100 million Americans have Internet access. *Id.* Further, what used to be an involved process of understanding source code and object code has been relegated to the simple click of the mouse button. *Id.*

[27] United States Public Policy Committee of the Association for Computing

encompass encryption of both methods and tools, digital broadcast flags[28] transmitted via video signal, and cross-licensing agreements between digital content providers and manufacturers of hardware devices such as DVD players.[29] DRM technology is a relative newcomer to the digital media market. This is due in large part to the explosion of the Internet, and the latest media devices which allow the expeditious and effortless transfer of digital content across the web, as well as from disc to disc in DVD and CD formats.[30] As initially envisioned, the DVD was a win-win product for consumers, distributors, and manufacturers alike. Hitting the market in 1996,[31] DVDs provide seven times the storage capacity of CDs and are capable of displaying movies, outtakes, director's notes, and various factual underpinnings related to the digital content.[32] Unfortunately, at least from the distribution and manufacturing side of the aisle, once such content is put into digital form, it becomes very easy for consumers to make unlicensed copies to share with others.

A. Early and Current DRMs

In order to deter piracy of digital content, Content Scramble System ("CSS"), an encryption form of DRM protection, was put into

Machinery, *USACM Policy Recommendations on Digital Rights Management* (Feb. 2006), http://www.acm.org/usacm/PDF/DRM.pdf.

[28] Mark Hackman, *New DRM Scheme Could Make Current DVD Players Obsolete*, Jan. 5, 2005, EXTREMETECH, http://www.extremetech.com/article2/0,1558,1748511 ,00.asp. This article explores the DVD encryption method Video Content Protection Scheme, which evaluates Broadcast Flags working in concert with DVD players and optical discs to deny users the ability to copy digital television, thereby making current players obsolete.

[29] *See generally* Center for Democracy and Technology, *Evaluating DRM: Building A Market Place for the Convergent World*, Sept. 2006, http://www.cdt.org/copyright/20060907drm.pdf.

[30] *See generally id.*; Electronic Frontier Foundation, Sony BMG Litigation Info, http://www.eff.org/IP/DRM/Sony-BMG/#docs (last visited Feb. 21, 2007) (On December 28, 2005, Sony-BMG, First 4 Internet, and SunnComm International entered into a settlement agreement in a class action in the U.S. District Court for the Southern District of New York [In re Sony BMG CD Technologies Litigation No 1:05-cv-09575 (NRB)] Sony had distributed CDs with flawed DRM, which restricted music transfer by way of XCP and Media Max, which when installed, precipitated security vulnerabilities to viruses and made the systems unstable).

[31] TIMOTHY B. LEE, CIRCUMVENTING COMPETITION: THE PERVERSE CONSEQUENCES OF THE DIGITAL MILLENNIUM COPYRIGHT ACT, CATO INST. POL'Y ANALYSIS 7 (2006), http://www.cato.org/pubs/pas/pa564.pdf.

[32] WGCU Public Media, http://www.wgcu.org/hdtv_glossaryofterms.html#D (last visited Feb. 15, 2007).

place. A CSS blocks would-be pirates by allowing only CSS-enabled DVD players to play the DVDs.[33] The DVD Copy Control Association is the group responsible for the licensing of this dual-pronged system, by which manufacturers of DVD players and those who produce the discs purchase licensing agreements from each other.[34] Essentially, the Copy Control Association licenses the DRM scheme (CSS encryption) to DVD manufacturers. With discs so encrypted, DVD device manufacturers come to the DVD Copy Control Association to enter into licensing agreements (providing the decryption tools) so as to allow those CSS-enabled discs to play on their respective DVD players.[35]

One particular aspect of storing content on DVDs is the capability of manufacturers to "region code," which is another form of digital rights management. Region coding allows the manufacturer to restrict a particular DVD, sold in a particular region, to be played only on DVD players from that region.[36] As with any cat and mouse game, soon enough there were DVD players being manufactured with the capacity to play DVDs from any region. To combat this progression, a new form of region coding dubbed Regional Coding Enhancement, an upgraded DRM scheme, has developed to stop DVDs manufactured in the United States, its territories, and Canada from playing on region-free DVD players.[37] As with CSS and region coding, such restricted usage has sparked debate about consumer rights, as well as many of

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[33] Technicolor Encyclopedia, http://www.technicolor.com/Cultures/En-Us/Support/Encyclopedia/C/CSS+(Content+Scramble+System).htm (last visited Feb. 15, 2007). This method scrambles the data on the master disc so that only CSS-enabled DVD players can decrypt the code. *Id*.

[34] DVD Copy Control Association, Frequently Asked Questions, http://www.dvdcca.org/faq.html (last visited Feb. 15, 2007); *see also*, http://www.dvdcca.org/css/ (last visited Feb. 15, 2007). The Copyright Control Association is a not-for-profit association which has various pricing schemes for the licensing of CSS, depending on where in the chain a particular product and/or service falls. *Id*.

[35] *See generally* http://www.dvddemystified.com/dvdfaq.html#6.1 (last visited Feb. 15, 2007). No single entity claims sole ownership of "DVD," rather the specification (a term of art in patent law) was developed by JVC, Mitsubishi, Pioneer, Time Warner, Philips, Hitachi, Toshiba, Thomson, Matsushita, and Sony. *Id*.

[36] DVD Talk, Regional Coding Enhancement, http://www.dvdtalk.com/rce.html (last visited Feb. 15, 2007).

[37] *Id*. (explaining that the world has been divided into 8 regions with the United States, its territories, and Canada comprising Region 1; Regional Coding Enhancement is currently being implemented onto DVDs by Warner Brothers and Columbia Pictures).

the legal underpinnings which give supplemental support to these DRM schemes.[38]

The DVD Copy Control Association suggests, at least implicitly, that region coding benefits consumers.[39] Due to the fact that movies are released in theatres at different times around the world, if region coding were not available, movie makers would hesitate to release a DVD format until all the theatre releases worldwide had opened.[40] In other words, if a particular movie is slated for theatre release in December in the United States, with region coding it can be made available on DVD a few months later in the United States, even though that same film will not be released in theatre version in Australia until the following summer.[41] Thus, region coding allows consumers to get the DVD soon after release at theatres in their country.[42] Of course, if region coding were not in place, people in other countries could purchase DVDs before the theatre release, and thus negatively impact box office sales.

At the time of CSS's release in 1996, it was designed as a relatively weak DRM encryption scheme (using a forty-bit key), in large part due to U.S. export policies on the exportation of encrypted products.[43] It has been suggested that the weakness of CSS's algorithm led to its being broken by a sixteen-year-old Norwegian (otherwise known as "DVD Jon"),[44] along with two other individuals. These three individuals collaborated to create DeCSS, which decrypts CSS and allows for the playback of encrypted DVDs.[45]

B. DRM Into the Future

Just as the DVD was a significant advancement over CD capacity, so too the next generation of DVD optical disc, the Blu-ray

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[38] Legal ramifications such as the legal doctrine of Fair Use and the Copyright Clause are discussed in Part III, *infra*.

[39] DVD Copy Control Association, FAQ, *supra* note 34.

[40] *Id*.

[41] *Id.*

[42] *Id.*

[43] The Openlaw DVD/DeCSS Forum Section 1.1.3, http://cyber.law.harvard.edu/openlaw/DVD/dvd-discuss-faq.html#ss1.1.3 (last visited May 1, 2007).

[44] Faultine, *US Inspired Copyright Laws Set to Sweep the Globe – For Fun and Profit*, Jan. 6, 2004, http://www.theregister.co.uk/2004/01/06/us_inspired_copyright_laws_set.

[45] The Openlaw DVD/DeCSS Forum Section 1.1.1, http://cyber.law.harvard.edu/openlaw/DVD/dvd-discuss-faq.html#ss1.1.1 (last visited May 1, 2007).

Disc and its rival counterpart High Definition DVD ("HD-DVD"),[46] exemplify another leap in digital capacity well-suited to deliver high definition video content.[47] Although both standardizations incorporate advanced DRM schemes, Blu-ray's is stricter by way of its utilization of a unique encryption form known as Blu-ray Disc+, which is being implemented into this next generation of DVDs.

Blu-ray[48] DVD discs integrate the latest protective mechanisms via DRM. Essentially, the DRM scheme is three-tiered. One level comprises digital watermarking, another Blu-ray Disc+, and a third is comprised of an Advanced Access Content System ("AACS").[49] What is unique about this DRM scheme is its ability to avoid the problems CSS encountered.

In essence, Blu-ray Disc+ is a dynamic system which can continuously update its algorithms when a user is connected to the Internet. If a code related to a particular disc player is compromised, that player can be denied, via signal, to play any Blu-ray Discs.[50] Both HD-DVD and Blu-ray utilize the DRM scheme AACS; however, in order to get Fox Studios to sign on with the Blu-ray format, Fox required the even stricter layer of content protection via Blu-ray Disc+.[51] According to Mark Knox, a representative of HD-DVD, Fox Studios did not like the idea of consumers being able to watch movies where they pleased.[52] In other words, some would advocate that HD-DVD is more consumer friendly by allowing for more interoperability, whereas the Blu-ray format allows for no transferability of content whatsoever.

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[46] The Digital Rights Management Dictionary, http://www.info-mech.com/drm_dictionary.html#hddvd (last visited May 1, 2007). Like the Blu-ray DVD proposal, HD-DVD format utilizes the AACS encryption scheme, and is backed by Microsoft.

[47] Blu-ray disc format was introduced in February 2002 as an example of what the future holds. Some of the supporting companies and members of the Blu-ray Disc Association include: Sony, Philips, Pioneer, Sun, Hitachi, Walt Disney, and Lionsgate. http://www.blu-raydisc.com.

[48] The "Blu-ray" name refers to the blue-violet laser used to read/write. The name was also purposely misspelled for instant trademark recognition. Blu-ray Disc Association, http://www.blu-ray.com/faq/#bluray_name (last visited May 1, 2007).

[49] Home Theater Blog, Jul. 19, 2006, http://www.hometheaterblog.com/home theater/2006/07/disney_fox_divx.html. *See also* http://www.aacsla.com/press (last visited May 1, 2007).

[50] Home Theater Blog, *supra* note 49.

[51] Aaron Dobbins, *HD DVD: Blu-ray Has Problems*, BETANEWS, Jan. 7, 2006, http://www.betanews.com/article/HD_DVD_Bluray_Has_Problems/1136673259.

[52] *Id.*

The Blu-ray Disc Association has over 140 members including Sony, Walt Disney Pictures, 20th Century Fox, Dell, Hitachi, Panasonic, and Apple.[53] If one contemplates the vast list of backers for this latest development in DVD technology, it is easy to see the implications of such a far-reaching DRM platform, especially if it were to become the industry standard. Backed by the DMCA, digital rights management technologies seem to be in conflict with many of the basic tenets which underlie Congress' constitutional powers over intellectual property.

III. CASE LAW AND STATUTORY ANALYSIS OF FAIR USE AND DVD IMPLICATIONS

What exactly is "fair use" anyway? In large part it depends on whom you ask and where you look for authority. In certain sections of the entertainment industry there are those who believe fair use should not apply to DVDs at all.[54] Fortunately, for consumers of digital media fixed in DVDs, the inquiry does not end there. The Fair Use Doctrine has existed in various forms throughout common law history and is codified in Title 17 U.S.C. § 107, commonly known as the Copyright Act of 1976.[55]

Fair use is essentially an exception to the exclusive rights that copyright law affords to the author of works fixed in a tangible medium, or her employer in the case of a work for hire.[56] The doctrine lays out four non-exclusive factors, which carry varying degrees of weight depending on what is at issue.[57] In addition, § 107 provides a

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[53] Mark Hachman, *Update: Blu-Ray DRM Plans Released*, August 2005, EXTREMETECH, http://www.extremetech.com/article2/0,1697,1845993,00.asp.

[54] Pamela Samuelson, Towards More Sensible Anti-Circumvention Regulations, http://www.ischool.berkeley.edu/~pam/papers/fincrypt2.pdf (last visited May 1, 2007).

[55] Princeton Univ. Press v. Mich. Document Serv., Inc., 99 F.3d 1381 (6th Cir. 1996).

[56] 17 U.S.C. §107 (2006) ("Notwithstanding the provisions of sections 106 and 106A the fair use of a copyrighted work…is not an infringement of copyright.") *See also* 17 U.S.C. §106 (2006) (listing those enumerated exclusive rights as the right to reproduce, to prepare derivative works, to publicly distribute, to publicly display, to publicly perform and in the case of sound recordings, to publicly perform by means of digital audio transmission).

[57] 17 U.S.C. §107 (2006) ("(i) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (ii) the nature of the copyrighted work; (iii) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (iv) the effect of the use upon the potential market for or value of the copyrighted work"). *See also*

non-exhaustive list of acts that may be deemed a fair use in light of those four factors. To illustrate, such acts may include: criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, and research.

An examination of the House Report for codification of the Fair Use Doctrine in the 1976 Copyright Act specifically recognized that the doctrine should not be frozen in time, "especially in a period of rapid technological change," thus emphasizing its expansive reach.[58] Perhaps now it becomes slightly clearer how DRM can negatively impact the Fair Use Doctrine's worth with respect to DVDs. By essentially locking up copyrighted works in DVDs behind the cloak of encryption, an individual seeking to exercise his or her rights as defined in the doctrine under § 107 of the Copyright Act is blocked from doing so.

As will become more evident, while the crux of the tension between the public's fair usage rights pertaining to accessing DVD content blocked by DRMs is rooted in complexities of the DMCA, a proper starting point nonetheless must spring from foundational decisions that will aid in framing the issues and provide contextual support.

A. Essentials in Fair Use and Access to Building Blocks Fixed Onto DVDs

"The Congress shall have power . . . To 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."[59] It is this clause of the U.S. Constitution which broadly empowers Congress to grant or deny copyrights and patents. As Professor Melville Nimmer stated in his treatise, "[t]he primary purpose of copyright is not to reward the author, but is rather to secure the general benefits derived by the public from the labors of authors."[60] From the first Copyright Act of 1790 to the present day, this was the common theme to copyright.[61] This theme now appears to be in jeopardy by the threat of digital piracy, DRM, and its DMCA countermeasures.

Harper & Row Publishers Inc. v. Nation Enters., 471 U.S. 539 (1985) (suggesting the fourth factor to be the most important one).

[58] H.R. REP. NO. 94-1476, at 65-66 (1976).

[59] U.S. CONST. art. I, § 8, cl. 8.

[60] N.Y. Times Co. Inc. v. Tasini, 533 U.S. 483, 519 (2001).

[61] Eldred v. Ashcroft, 537 U.S. 186, 227-28 (2003) (Stevens, J., dissenting).

If, as this author suggests and will expound upon in Part III.C *infra*, DMCA infringement cases must take into account fair use at least on a case-by-case basis, then it shall follow that a proper examination requires, at a bare minimum, a succinct examination of seminal decisions respecting access to ideas, facts, theories, and those specific exemptions under § 107.[62]

1. Non-Copyrightable Elements

Copyright protects expression, yet this protection has its limits.[63] *Feist Publications, Inc.*, held that although a work as a whole may be protected by copyright, such protection does not extend to underlying elements that do not originate with the author.[64] As emphasized by one commentator in 1990: "[N]o matter how much original authorship the work displays, the facts and ideas it exposes are *free for the taking . . .*" (*emphasis added*).[65] Although the demarcation between an idea and its expression has always been difficult to draw, as Judge Learned Hand stated in *Nichols v. Universal Pictures*, "that is no excuse for not drawing it."[66] This illustrates that the concept of distinguishing between the two has played a vital role in balancing the *quid pro quo* of copyright.

From *Baker v. Selden*'s seminal decision in 1879, refusing to extend copyright to blank forms,[67] to codification of that principle in 1976 in Title 17 U.S.C. § 102(b), that "in no case does copyright protection extend . . . to any idea/principle regardless of the form in which it is embodied," the underlying theme has been unwavering. This bedrock principle should play a central role in analysis respecting access to underlying factual theories buried in a DVD's outtakes. Because the DMCA only protects copyrighted works, should not a proper starting point be whether the material extracted from the DVD had a right to copy protection in the first place? This author would suggest such a route; if the material is not subject to copyright, the

[62] 17 U.S.C. §107 (2006). Such examples include, but are not limited to, criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, and research.

[63] Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 348 (1991).

[64] *Id.*

[65] *Id.* at 349 (quoting Jane C. Ginsburg, *Creation and Commercial Value: Copyright Protection of Works of Information*, 90 COLUM. L. REV. 1865, 1868 (1990)).

[66] Nichols v. Universal Pictures Corp., 45 F.2d 119, 122 (2d Cir. 1930).

[67] Baker v. Selden, 101 U.S. 99, 107 (1879).

DMCA should give way to the underlying non-copyrightable elements.

2. Parodies

Parody of a copyrighted work has not only been long regarded as falling within the ambit of the Fair Use Doctrine, but also as an important aspect of social commentary. Thus, if a film critic wishes to excise portions of a DVD to parody the work, it would appear his ability to do so would be frustrated by DRM countermeasures as well as the threat of civil and criminal liability under the DMCA. As stated by Justice Kennedy, "[t]he parody must target the original, and not just its general style . . ."[68] Further, in *Dr. Seuss Enterprises v. Penguin Books*, the Ninth Circuit Court of Appeals opined that parody is "a form of social and literary criticism, having a socially significant value as free speech under the First Amendment."[69] This author posits that in making such sweeping legislation as the DMCA, and further permitting elements which should be free for the taking to hide behind the cloak of copyright, is to lose sight of the underlying purposes of copyright.

As stated earlier, application of the four factors of fair use is very fact specific; however, in the context of parodies, a few generalizations can be made. For instance, in *Campbell v. Acuff-Rose Music*,[70] the Supreme Court shed light on two of the § 107 factors of particular relevance to parodies. Since a parody by nature draws upon the original, yet adds to it in order to poke fun at the work, it is these additions that, although unnecessary for a finding of fair use, are highly regarded as underlying the purpose of the Fair Use Doctrine, especially as it pertains to the first factor of § 107, the purpose and character of the use.[71]

Additions to the original work in the context of commentary or criticism are said to be transformative.[72] These transformations, in a constitutional sense, promote the progress of science.[73] Likewise, the fourth factor, relating to market harm, in most cases is not invoked in

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[68] Dr. Seuss Enters., L.P. v. Penguin Books U.S.A., Inc., 109 F.3d 1394, 1400 (9th Cir. 1997) (quoting Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 597 (1994) (Kennedy, J., concurring)).

[69] *Id.*

[70] Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569 (1994).

[71] *Id.* at 578.

[72] *Id*. at 579.

[73] *Id.*

parodies against one who utilized the copyrighted work, primarily because the kind of economic harm caused by a parody is not the type of harm the statute recognizes.[74] Rather, the economic harm must stem from the alleged infringing work replacing demand for the original in the market; however, any reduction in demand caused by the negative impact of the parody is not cognizable.[75]

3. Time and Space Shifting

The ability to record a television show for later viewing and to fast-forward through commercials in VCR tapes and DVDs, otherwise known as "time-shifting," is something that consumers have become accustomed to due in large part to the decision in *Sony Corp. v. Universal City Studios.*[76] There, the Supreme Court held such acts to fall within fair use.[77] However, various DRM initiatives built into DVDs as well as digital signals, or broadcast flags, will block the ability not only to fast forward through commercials, but also will not allow a recorder to save television shows for later viewing.[78]

Currently, under the Copyright Office's triennial review (a review to uphold Congress' commitment to fair use),[79] the Office has placed the onus on users of digital works to show a substantial harm for an exception to be carved out of the DMCA. However, of particular interest is what appears to be a shift in which party has the burden. As stated by the Court in *Sony*, the copyright holder bears the burden of bringing forth evidence of harm "before he may condemn a private act of time-shifting as a violation of federal law."[80] In analyzing the four fair use factors, time-shifting was found to be a noncommercial and nonprofit activity with no demonstrable effect upon the copyright holder's market.[81] The testimony of one individual in *Sony*, Fred Rogers from *Mr. Rogers' Neighborhood*, best sums up

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[74] *Id.* at 590.

[75] Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 591 (1994).

[76] Sony Corp. v. Universal Studios, 464 U.S. 417 (1984).

[77] *Id.* at 423.

[78] Electronic Frontier Foundation, Digital Video Restrictions, http://www.eff.org/IP/digitalvideo (last visited May 1, 2007).

[79] Copyright Office, Rulemaking on Exemptions from Prohibition on Circumvention of Technological Measures that Control Access to Copyrighted Works (2006), *available at* http://www.copyright.gov/1201/docs/1201_recommendation.pdf.

[80] *Sony Corp.*, 464 U.S. at 454.

[81] *Id.* at 449.

what then, and probably today, would be the consumer consensus on time-shifting:

> Very frankly, I am opposed to people being programmed by others. My whole approach in broadcasting has always been 'You are an important person just the way you are. You can make healthy decisions.' Maybe I'm going on too long, but I just feel that anything that allows a person to be more active in the control of his or her life, in a healthy way, is important.[82]

Similar to time-shifting is "space shifting," which is a method of transferring digital media files already stored on one's computer hard drive to a portable device, in other words, to shift its location.[83] *Recording Industry Association of America v. Diamond Multimedia Systems* found such shifting of digital audio files (e.g., music) to be a fair use.[84] There are several advantages of space shifting, such as avoiding the hassle of carrying bulky discs while traveling, reducing the chance of theft (it is easier to conceal one small portable player than many DVDs), or making a backup copy in the event the original disc becomes corrupt.

In support of the notion that personal transferring of audio content should also apply to audiovisual works fixed onto DVDs, consider that in *A & M Records v. Napster* (the music file-sharing case), the court refused to apply time and space shifting fair use methods, primarily because the music was being distributed to the general public.[85] Conversely, *A & M Records* specifically noted that in both *Sony*[86] and *Recording Industry Association of America*, the shifting was limited to the original owner.[87] As mentioned earlier, DRM platforms will prevent this transferability; thus, following the rationale of *Sony*, *A & M Records*, and *Recording Industry Association of America*, consumers of legally purchased DVDs should be able to shift the audiovisual content from optical discs to a portable player for personal, not public, use.

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[82] Sony Corp. v. Universal Studios, 464 U.S. 417, 445 n.27 (1984).

[83] Recording Indus. Ass'n of Am. v. Diamond Multimedia Systems Inc., 180 F.3d 1072, 1072 (9th Cir. 1999).

[84] *Id.* at 1079.

[85] A & M Records, Inc. v. Napster, Inc. 239 F.3d 1004, 1019 (9th Cir. 2001).

[86] *Sony Corp.*, 464 U.S. at 417.

[87] *A & M Records, Inc.*, 239 F.3d at 1019.

Having explored a contextual snapshot of fair use, access to facts and ideas, and the origins of the Copyright Act, this article will now ascertain the interrelation of the DMCA and the near consumption of consumers' fair use rights of DVD content by DRMs.

B. The DMCA's Statutory Effect upon DVD Fair Use Analysis

The enactment of the Digital Millennium Copyright Act in 1998 made matters even more convoluted in terms of fair use access to copyrighted works which were hiding in plain sight behind DRM encryption schemes.[88] While it has been suggested that the DMCA was enacted to provide an incentive for authors to digitalize their works for placement on the Internet[89] by providing a legal mechanism for targeting pirates, arguably the Act has exceeded its constitutional scope.[90]

The DMCA's origin in large part can be traced to two sources, one being a 1995 White Paper, *Intellectual Property and the National Information Infrastructure,* which was an extensive study on the state of intellectual property rights (patent, copyright, and trademark) in the new global, Internet-connected world.[91] The other prod leading to the DMCA was pressure on the United States from the 1996 enactment of the WIPO[92] Treaty, which imposed on all signatories a duty to enact adequate legal measures and effective remedies to combat digital piracy.[93]

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[88] 17 U.S.C. § 1201 (2006) (Circumvention of Copyright Protection Systems).

[89] Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks Chair, White Paper, *Intellectual Property and the National Information Infrastructure, The Report of the Working Group on Intellectual Property Rights* (1995), *available at* http://www.uspto.gov/web/offices/com/doc/ipnii/execsum.html.

[90] Samuelson, *supra* note 54, at 2.

[91] Lehman, *supra* note 89.

[92] World Intellectual Property Organization, http://www.wipo.int (last visited May 1, 2007). The WIPO is a division of the United Nations and was established in 1967. WIPO currently has 183 member states. WIPO seeks to provide a globally balanced intellectual property system; one of its goals is promotion of the economic development of intellectual property while concurrently protecting the public interest. *Id.*

[93] *Unintended Consequences: Seven Years Under The DMCA*, ELECTRONIC FRONTIER FOUNDATION, Apr. 2006, http://www.eff.org/IP/DMCA/?f=unintended_consequences.html#Section4; *see also* World Intellectual Property Organization Treaty, art. 11, Apr. 12, 1997, S. TREATY DOC. NO. 105-17 (1997).

1. Anti-Access and Anti-Copy Measures

Two particular sections of the DMCA are highly germane to DVD-DRM fair use analysis, namely § 1201(a)(1)(A) and § 1201(b). Section 1201(a)(1)(A) makes it a crime, punishable by both fines and/or imprisonment, to circumvent anti-access measures.[94] Section 1201(b) makes it illegal to traffic, make, or offer any tool which has a primary purpose of circumventing *either* anti-access or anti-copying technology (emphasis added). Thus, while one may circumvent anti-copying technology to make a copy, one may not circumvent[95] anti-access technology. Moreover, in neither case may one make or sell tools allowing the utilization of articles protected by anti-access or anti-copying technology.

It has been suggested that Congress' intent in making it lawful to circumvent anti-copying technology in order to make a copy but not to gain access, was to preserve the Fair Use Doctrine.[96] Further, such allowance was intended to strike a balance between the competing interests of lawful access and the strong opposition to deny such access by those desiring legal tools to strengthen encryption methods.[97] However, to allow one to make a copy of a DVD, but not be able to watch it since circumventing anti-access measures is illegal, is pointless. Rather than striking a balance, it appears a heavy thumb was placed on one side of the scale.

2. A Legislative Perspective

The legislative history of the DMCA devotes a substantial portion to concerns over fair use implications. Of particular interest are the Committee on the Judiciary's comments in House Report 2281.[98] Therein, the Committee continuously emphasized the necessity of balancing the competing interests of authors of

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[94] 17 U.S.C. § 1204(a)(1)(2) (2006). The Copyright Act provides for fines of up to $500,000 and/or up to five years imprisonment for first offense and for subsequent offenses up to $1 million and/or ten years imprisonment. *Id.*

[95] 17 U.S.C. § 1201(a)(2)(A) (2006) ("To circumvent a technological measure means to descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner").

[96] *See* Universal City Studios, Inc. v. Reimerdes, 111 F. Supp. 2d 294, 323 (S.D.N.Y. 2000).

[97] *Id.* at 322.

[98] H.R. REP. NO. 105-551(II), at 1 (1998).

copyrighted works against the interests of the public wishing to exercise fair use rights. [99]

Fearful of creating a "pay-per-use" society, the Committee on Commerce claimed in its report that H.R. 2281 "fully respects and extends into the digital environment the bedrock principle of 'balance' in American intellectual property law for the benefit of both copyright owners and users."[100] Yet, immediately following such statements of concern, the Committee seemed to brush this aside, at least implicitly, and affirmed the United States' commitment to abiding by the WIPO Treaties. Thus, one inference that can be drawn from the legislative history behind the DMCA is that while trying to provide "adequate protection and effective remedies" under WIPO, the DMCA swallowed up that "bedrock" of American copyright law. Furthermore, the capability of DRM technologies on DVDs exemplifies this quandary.

While the DMCA, operating upon a DRM/DVD platform, may have certainly narrowed (or eliminated) fair use, it would be without merit to suggest that the House Committee on Commerce, which was assigned the task of amending Title 17 of the U.S. Code, was not cognizant of the immense magnitude of its amendment modifications.[101] The Committee saw H.R. 2281 as something greater than just a bill about intellectual property; rather, the Committee recognized that H.R. 2281 would have substantial effects on how electronic commerce was recognized generally.[102] The Report repeatedly cited to a Department of Commerce Report, *The Emerging Digital Economy*, which contained staggering estimates of electronic economic activity that were no doubt an impetus to the adoption of the bill.[103]

The Emerging Digital Economy estimated that over 7.4 million Americans were employed in the information technology sector at the end of 1997.[104] It is estimated that there was approximately $500 billion in online economic activity in 2002, and that in 1998 approximately 8.2% of the gross domestic product stemmed from information technology.[105] These numbers may aid in illuminating

[99] *Id.* at 25.
[100] *Id*. at 26.
[101] *Id.* at 1.
[102] *Id.* at 22.
[103] *Id.*
[104] *Id.*
[105] *Id.*

some of the theory behind enactment of the DMCA.[106] Yet, as alluded to earlier, perhaps the real impact of this data was to mask some of the underlying tribulations that stemmed from the erosion of fair use.

Due to the global nature of the DMCA with respect to WIPO commitment, it is necessary to consider a recent decision by a French Court of Appeals in Paris. An individual who owned a DVD, but who was unable to watch DVDs and wanted to copy the DVD onto VHS, brought suit against the makers of the DVD who had installed copy protection mechanisms on the DVD.[107] The French Appeals Court held that DVD content providers must remove copy protection mechanisms from all movies because the mechanisms violate the fair usage rights of consumers.[108] While many heralded the decision as a great advance for the public interest, the celebration was short-lived. France's highest court, Cour de cassation, felt otherwise and found in favor of the DVD content providers in order to come more in compliance with WIPO commitments.[109]

Unfortunately, as international treaties and organizations lobby to provide global protection and remedies for infringement of copyrighted works, the decision by the French court may have a ripple effect resulting in a further bolstering of U.S. restrictive enforcement policies in relation to fair use rights pertaining to DVDs. It is from this point that this article will now address case law decisions in the United States in order to better grasp the contours of the legal landscape.

C. The DMCA's Case Law Effect upon DVD Fair Use Analysis

If a film review critic wishes to compile excerpts from various documentaries in a series of DVDs in order to make a point to the public about misleading arguments, and yet a DRM blocks him from

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[106] *Id.*

[107] Andrew Orlowski, *French Court Bans DVD DRM, Keep It In the Family*, THE REGISTER, Apr. 26, 2005, http://www.theregister.co.uk/2005/04/26/french_drm_non; *see also* Eric Bangeman, *French Court Rules Against Copy-Protected DVDs*, ARS TECHNICA, Apr. 25, 2005, http://arstechnica.com/news.ars/post/20050425-4846.html.

[108] Orlowski, *supra* note 107; *see also* Bangeman *supra* note 107.

[109] PC PRO, *French Court Rules Against Fair Use for DVD Copies*, Mar. 3, 2006, http://www.pcpro.co.uk/news/84406/french-court-rules-against-fair-use-for-dvd-copies.html.; *see also* Gabriele Parussini, *France's Highest Court Boosts Copyright Protection on Film DVDs*, BLOOMBERG.COM, Mar. 1, 2006, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a8Dz7xQuZ_l4.

making a single disc compilation, such use is admittedly within the purview of fair use. Thus it is not difficult to envision how the Fair Use Doctrine, and through it the public's right of access, is frustrated by DRMs. This was the conclusion of the district court in *Universal City Studios, Inc. v. Reimerdes*.[110] However, the court, while sympathetic to the apparent erosion of fair use, interpreted the DMCA with an eye toward the legislative history of the Act. As the court saw it, Congress was well aware of fair use at the time of enactment of the DMCA and held, in essence, that it was not for the court to disturb the findings of Congress.[111]

According to *Reimerdes*, if Congress wanted fair use to apply to the DMCA, Congress would have so stated. *Reimerdes* involved an infringement action brought against website owners who were posting DeCSS on their websites, as well as links to other sites posting similar decryption data.[112] The motion picture studios sought an injunction under the DMCA as such postings would allow consumers to decrypt the DVD-DRM scheme.[113] Interestingly, *Reimerdes* seems to draw a distinction between being sued for copyright infringement and being sued under the DMCA;[114] yet, the proper analysis cannot be so neatly divided.

1. Where to Draw the Line

To bolster the position that the demarcation between the DMCA and supplemental portions of the Copyright Act is not so bright, one need only consider the comments of the Copyright Office in its triennial review respecting the proposed class of public domain works. In rejecting arguments for another DMCA exemption, the Copyright Office sets forth that no such exception is necessary, as the DMCA is not applicable to works which are in the public domain.[115] Hence, the tie-in between the DMCA and copyright law seems not as

[110] Universal City Studios, Inc. v. Reimerdes, 111 F. Supp. 2d 294, 322-324 (S.D.N.Y. 2000).

[111] *Id.*

[112] *Id.* at 303.

[113] *Id.*; *see also In re* Implementation of Section 304 of Telecommunications Act of 1996, 15 F.C.C.R. 18199, 18203-05 (F.C.C. Sept. 18, 2000).

[114] *Reimerdes*, 111 F. Supp. 2d at 294.

[115] United States Copyright Office, Rulemaking on Exemptions from Prohibition on Circumvention of Technological Measures that Control Access to Copyrighted Works 13 (2006), *available at* http://www.copyright.gov/1201/docs/1201_recommendation.pdf.

attenuated as the *Reimerdes* court might suggest. By stating that the DMCA is inapplicable if a work is not copyrightable, the Copyright Office appears to suggest a relationship, which one would normally assume, between various subsections within the same statute.

Comparing various sections of the Copyright Act seems to further draw a more narrow view of the DMCA than *Reimerdes* puts forth. The Copyright Act itself, and more specifically § 1201(c)(4), states "nothing in this section shall diminish or enlarge any rights of free speech . . . for activities using computing products." Likewise, the parallel section of the DMCA, read in light of § 102(b) states that "in no case does copyright protection extend . . . to any idea, concept, or principle . . . *regardless* of the form in which it is embodied" (*emphasis added*).[116] Based on this comparison, it is difficult to reach the same conclusion as *Reimerdes*.

While the DMCA adds some real teeth to DRM technologies, it is important to note that for the copyright owner to have the legal backing of the Act, her other anti-access control measure must be effective.[117] Thus, if a DRM encryption scheme blocks one route of access but freely allows another, the DMCA cannot be enforced by the copyright holder.[118] As the Ninth Circuit stated in *Lexmark International*: "[A]s one would not say that a lock on the back door of a house 'controls access' to a house whose front door does not contain a lock . . . it does not make sense to say that this provision of the DMCA applies to otherwise-readily-accessible copyrighted works."[119]

Lexmark International involved a printer manufacturer that brought a copyright infringement and DMCA action against a vendor whose computer chip mirrored their own, and which allowed a third party's toner cartridges to be operable in Lexmark's printers.[120] Although *Lexmark International*'s emphasis is on matters tangential to DVD fair use implications, the opinion nonetheless provides helpful guidance, with respect to modern fair use interpretation, and therefore may provide guideposts of suggestion.

Lexmark International provides an excellent review of the first factor of § 107 of the Copyright Act, namely the purpose and character of the use, including whether the use is of a commercial or not-for-

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[116] 17 U.S.C. §§ 1201(c)(4); 102(b) (2006).

[117] Lexmark Int'l, Inc. v. Static Control Components, Inc., 387 F.3d 522 (6th Cir. 2004).

[118] *Id.* at 547.

[119] *Id.*

[120] *Id.* at 529.

profit nature.[121] The Court of Appeals in *Lexmark International*, citing *Harper & Row Publishers*, stated that the question is not whether commercial gain is realized, but rather, whether "the user stands to profit from exploitation of the copyrighted material without paying the customary price."[122]

Taking factor one for comparison, it would be a difficult task indeed for a copyright holder to suggest a cognizable loss of profit against a parodist who samples the holder's DVD for behind-the-scenes commentary and criticizes the work. Certainly, such transformative use is favored under fair use, both statutorily and through years of case law. Likewise, the fourth, and arguably most important factor, respecting the effect upon the potential market for the value of the copyrighted work, seems also to weigh heavily in favor of the parodist desiring to sample various DVDs to make a compilation of commentaries.

Perhaps Nimmer best framed the issue as "whether unrestricted and widespread conduct of the sort engaged in by the defendant . . . would result in a substantially adverse impact on the potential market for" the original.[123] Again, assuming the DMCA is overbroad, a copyright holder would have a difficult time convincing a court that a movie critic merely sampling behind-the-scenes footage for commentary or criticism would have any *cognizable* impact upon sales. However, due to the fact that the DMCA created a new cause of action[124] against an encryption infringer, which is separate from the issue of copyright infringement, such penalties might dissuade individuals from exercising their fair use rights out of fear of a DMCA suit.

These new causes of action were without question in the minds of commentators at the time leading up to enactment of the DMCA. This new zone of rights to bolster copyright law, termed "paracopyright," was discussed by sixty-two professors of copyright law in a letter to Congress in September 1997. The letter expressed concern over these new supplemental copyright enforcement mechanisms.[125] Nonetheless, the Committee on Commerce felt compelled to tackle this new digital threat to copyright. Emphasizing

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[121] *Id.* at 544.

[122] *Id.* (citing Harper & Row Publishers, Inc. v. Nation Enters., 471 U.S. 539, 562 (1985)).

[123] NIMMER ON COPYRIGHT § 13.05[A][4] (2007).

[124] Chamberlain Group, Inc. v. Skylink Techs., Inc., 381 F.3d 1178, 1192 (Fed. Cir. 2004).

[125] H.R. REP. NO. 105-551, pt. 2, at 24 (1998).

the dangers facilitated by the ease of making near-perfect copies and mass distribution thereof in comparison to the earlier analog model, the Committee stated "[a]s technology advances, so must our laws."[126]

2. Stymieing Fair Use

If indeed the DMCA has hindered the Fair Use Doctrine in the DVD medium, the implications are not patently obvious. In the Copyright Registrar's triennial recommendation memorandum to the Librarian of Congress,[127] it is suggested that to invocate the four factors of § 107, proper analysis requires a case-by-case determination.[128] While this is true, as the four factors are non-exclusive and receive varying degrees of weight depending on the facts before the court, one might argue that since the DMCA creates this new cause of action, fewer fair use cases are litigated. Thus, with fewer cases making it to court (assuming settlement and/or parties not wishing to exercise fair use rights), a body of law is left undeveloped in the face of these new emerging technologies. This situation is exacerbated by the unique case-by-case analysis the Fair Use Doctrine demands for its proper implementation.

Of particular relevance to this article is the rejection in the Copyright Office's triennial review of the proposed class relating to "ancillary audiovisual works distributed on DVDs encrypted by CSS."[129] While the Registrar states that such matters (e.g, outtakes, interviews with actors and directors, and similar features) would fall within the fair use purview, the class is dismissed with the principal rejection based upon two premises.[130] The first premise is the

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[126] *Id.* at 25.

[127] Under 17 U.S.C. §§ 1201(a)(1)(C)-(D) (2006), the Librarian of Congress is empowered to create exemptions to DMCA § 1201 for a three-year period.

[128] United States Copyright Office, Recommendation of the Register of Copyrights in RM 2002-4, Rulemaking on Exemptions from Prohibition on Circumvention of Technological Measures that Control Access to Copyrighted Works 29 (2006), *available at* http://www.copyright.gov/1201/docs/1201_recommendation.pdf.

[129] United States Copyright Office, Recommendation of the Register of Copyrights in RM 2002-4, Rulemaking on Exemptions from Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies 116 (2003), *available at* http://www.copyright.gov/1201/2003/index.html. Interestingly, this particular class was not addressed in the Nov. 27, 2006 triennial review; thus, one may surmise that the positions underlying the 2003 review on this point have not faltered. *Id.*

[130] *Id.*

capability of users to circumvent copy control methods to record the analog output of DVD players; the second is the capacity to take a digital camcorder and place it in front of a television to record while a DVD is playing.[131]

This author suggests that both of these alternative fair use methods are without substance. As for the analog output option suggested, there are already DRM schemes in the works to plug the "analog hole."[132] Both the Blu-ray disc and HD-DVD format, discussed previously as the next generation of DVDs to set the new standard, are said to cripple the analog capabilities.[133] As for taking a camcorder and placing it in front of a television screen, at first glance it seems a bit absurd that one must go to such lengths to exercise fair use rights. Moreover, even if one were to go through the trouble of obtaining a camcorder, this avenue will also soon be plugged. If the next generation of DVDs (Blu-ray and/or HD-DVD) becomes the standard, the technology will prevent those camcorder recordings from playing on Blu-ray players, according to Andrew Setos, President of Engineering for the Fox Entertainment Group.[134]

The rivalry between the Blu-ray format and HD-DVD is similar to the old fight between the VHS and Betamax formats. As both of these rival standardizations for DVDs have strong supporters, one might suggest that consumer rights respecting access, use, and transferability of purchased DVD content might be no more than an afterthought, thus maintaining a "copyright-centric" position.[135] Moreover, legislation has previously been introduced in Congress, namely the Digital Transition Content Security Act of 2005, which would wipe out the capacity to record digital works via the analog output option on DVD players.[136]

As for the alternative to making direct digital-digital copies for ancillary commentary via placing a digital recorder in front of a

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[131] *Id.*

[132] Eric Bangeman, *"Analog Hole" Legislation Introduced*, ARS TECHNICA, Dec. 18, 2005, http://arstechnica.com/news.ars/post/20051218-5797.html%20 discussing.

[133] David Katzmaier, *Blu-ray and HD-DVD: Crippled HD Analog Output Option*, ALPHA THE CNET BLOG, Jan. 20, 2006, http://reviews.cnet.com/4531-10921_7-6423704.html.

[134] Mark Hachman, *Update: Blu-Ray DRM Plans Released*, Aug. 2005, EXTREMETECH, http://www.extremetech.com/article2/0,1697,1846092,00.asp.

[135] Samuelson, *supra* note 54. This article discusses the idea of "copyright-centricity" in greater detail.

[136] Digital Transition Content Security Act of 2005, H.R. 4569, 109th Cong. (2005).

television, having to resort to such less than optimal means is not required. The triennial review cites to *Universal City Studios v. Corley* for support of the notion that placing a camcorder in front of a television is sufficient.[137] However, the later case of *Eldred v. Ashcroft*, with its discussion of fair use that was lacking in *Corley*, might not have relegated fair use to camcorder taping only.[138] Since *Eldred* was decided in January 2003, and the triennial report was released in October of 2003, one might infer that the fair use the Supreme Court read as being mandated by the Constitution in *Eldred*, prevents such a narrow reading of fair use as the Second Circuit suggested in *Corley*. Furthermore, it suggests that the Second Circuit erred in not applying *Eldred*.

Circumventing an anti-access DRM measure is not copyright infringement.[139] Rather, such unauthorized access to an anti-circumvention technology is a new cause of action upon which a copyright holder may enforce his copyright.[140] According to *Chamberlain Group, Inc. v. Skylink Technologies, Inc*., this distinction is critical to a proper DMCA fair use analysis.[141] The copyright holder in *Chamberlain Group* argued that creation of the DMCA effectively reshaped the legal landscape so that any and all uses of copyrighted works protected by anti-access measures without the copyright holder's permission became a violation of the DMCA.[142] The *Chamberlain Group* court pointed out, however, that such broad coverage would be a violation of both antitrust laws and the doctrine of copyright misuse.[143]

While *Chamberlain Group* involved a DMCA patent action on a garage door opener allegedly infringed by a universal remote control, the court's analysis of fair use and technologies is directly relevant to DVD/DRM fair use analysis. For example, while *Reimerdes* seemed to draw a distinct line between copyright and the DMCA, *Chamberlain Group* is more applicable to fair use concerns in

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[137] Universal City Studios, Inc., v. Corley, 273 F.3d 429 (2d Cir. 2001).

[138] Eldred v. Ashcroft, 537 U.S. 186 (2003).

[139] *Id.*

[140] Chamberlain Group, Inc. v. Skylink Techs., Inc., 381 F.3d 1178, 1192 (Fed. Cir. 2004).

[141] *Id.*

[142] *Id.* at 1193.

[143] *Id.* at 1194. *See also* Altera Corp. v. Clear Logic, Inc., 424 F.3d 1079, 1090 (9th Cir. 2005) (citing Alcatel USA, Inc. v. DGI Techs., Inc., 166 F.3d 772, 792 (5th Cir. 1999) (discussing copyright misuse as an affirmative defense that "forbids the use of the [copyright] to secure an exclusive right or limited monopoly not granted by the [Copyright] Office and which is contrary to public policy to grant")).

the DVD/DRM medium. Instead of reading the DMCA and other sections of the Copyright Act independently, *Chamberlain Group* provides an excellent marriage of the various statutory sections. The *Chamberlain Group* court suggested that any interpretation of § 1201(a) must be read in conjunction with § 1201(c)(1), which addresses fair use.[144] *Chamberlain Group* thereby rejects the copyright holder's assertion that fair use is inapplicable in a proper DMCA analysis.

Consider the application of the *Chamberlain Group* analysis to DMCA causes of action against a WebBlog movie critic who wishes to sample DVD outtakes from various movies. *Chamberlain Group* analysis should control because DVD outtakes are not available in VHS format (an alternative the triennial review suggested),[145] and § 1201 should be interpreted in light of the fair use exemption to the § 106 exclusive rights. Otherwise, fair use will no longer exist under the DMCA in the context of DRM/DVD platforms. In support thereof, the *Chamberlain Group* court quoted Justice Souter's dissent in *Reno v. American-Arab Anti-Discrimination Committee*: "[n]o canon of statutory construction familiar to me specifically addresses the situation in which two simultaneously enacted provisions of the same statute flatly contradict each other."[146] Applying this reasoning, it is difficult to see how commentators or critics desiring to breach anti-access DRM measures to sample DVD outtakes would be liable under the DMCA.

In contrast to the Court of Appeals for the Federal Circuit's approach in *Chamberlain Group*, an earlier decision by the Second Circuit in *Universal City Studios, Inc. v. Corley*, declined to read fair use into DMCA infringement analysis; rather, *Corley* interpreted the DMCA as targeting "the circumvention of digital walls guarding copyrighted material . . . but . . . not concern[ing] itself with the use of those materials after circumvention has occurred."[147] *Corley* involved a DMCA action brought by motion picture studios to enjoin the defendant from posting DeCSS, a decryption algorithm allowing users

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[144] *Chamberlain Group*, 381 F.3d at 1200.

[145] Copyright Office, Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies 13, Oct. 31, 2003, http://copyright.gov/fedreg/2003/68fr2011.html.

[146] *Id.* (quoting Reno v. Am.-Arab Anti-Discrimination Comm., 525 U.S. 471, 509 (1999) (Souter, J., dissenting)).

[147] Universal City Studios, Inc., v. Corley, 273 F.3d 429, 443 (2d Cir. 2001).

who downloaded it to play a DVD encrypted with Content Scramble System, on his website.[148]

Unlike *Chamberlain Group, Corley* relies on the legislative history of the DMCA by placing emphasis on the "fail-safe" triennial review by the Librarian of Congress as recommended by the Registrar of the Copyright Office.[149] In essence, the *Corley* court rejected the defendant's argument for a fair use defense, concluding that Congress is in the best position to decide how to best effectuate fair use. Additionally, by mandating a triennial review, Congress already provided for the protection of the Fair Use Doctrine. When the defendant in *Corley* asserted the affirmative defense of fair use as an alternative to no liability, the court used the example of a child desiring to sample portions of a DVD for a school project.[150] *Corley* suggests that fair use does not mandate the optimum method of exercising rights under the doctrine; instead, other means, such as using a camcorder to tape a DVD playing on a television, would satisfy fair use.[151]

The key to understanding *Corley* is its place in time. The Second Circuit decided the case in 2001, at which time *Eldred v. Ashcroft*[152] (holding that fair use is constitutionally required) had yet to come before the Supreme Court. *Corley* cited several Supreme Court decisions[153] which made isolated comments respecting the connection between the Fair Use Doctrine and the Constitution. However, these cases offered no clear guidance. As such, *Corley* dismissed the defendant's arguments.[154] Using the Court's reasoning in *Eldred*, *Corley* would likely have come out the same, as the primary issue was not related to sampling DVDs per se. If, however, the issue before the court had been DVD commentary sampling, using the *Eldred* Court's reasoning, it is possible *Corley* would have swayed in favor of DVD digital-to-digital sampling. This assertion is based on the fact that much of *Corley's* analysis is framed around the absence of

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[148] *Id.* at 435-437.
[149] *Id.* at 443, n.13.
[150] *Id.* at 459.
[151] *Id.*
[152] *Eldred*, 537 U.S. at 186.
[153] Universal City Studios, Inc., v. Corley, 273 F.3d 429, 458 (2d Cir. 2001) (citing Stewart v. Abend, 495 U.S. 207 (1990) ("fair use permits courts to avoid rigid application of the copyright statute when, on occasion, it would stifle the very creativity which the law is designed to foster")); Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569 (1994).
[154] *Corley*, 273 F.3d at 459.

a controlling decision mandating that fair use be read into the Constitution.

In recognition of decisions post-*Corley*, such as *Chamberlain Group*, as well as this author's agreement that proper statutory interpretation of § 1201 (DMCA) be read in light of § 107 (fair use) and § 106 (copyright's exclusive rights), the direction of this article will now shift to expounding upon the notion that free speech, as guaranteed by the First Amendment, and Fair Use are inextricably intertwined. In making any judgments respecting DRM's negative effects upon DVDs, in light of the DMCA, the factors elaborated below should be given due consideration.

3. A First Amendment Perspective

In 2003, the Supreme Court in *Eldred v. Ashcroft* made it clear that fair use is to be read into the Constitution.[155] *Eldred* concerned a challenge to a twenty year extension to existing and future copyright terms. While the Court upheld the term extension, the Court's First Amendment/Fair Use Doctrine discussion is highly relevant to issues surrounding DVDs, fair use, and the DMCA.

Where Congress has not altered the traditional contours of copyright protection, First Amendment heightened scrutiny is unnecessary.[156] The Supreme Court premised this upon copyright law's two built-in First Amendment safeguards. The first safeguard draws a distinction between copyrightable expression and the underlying ideas and facts via the Idea/Expression Dichotomy. The second safeguard, under the Fair Use Doctrine, allows access to the copyrighted expression itself in certain circumstances for commentary, criticism, and the like.[157]

In light of DRM's capability to block a DVD owner from excising outtakes or expression snippets for commentary while having the legal backing of the DMCA to enforce the technology measures, it is difficult to suggest that the traditional contours of copyright have not changed dramatically. This author suggests that the landscape has indeed changed. While the legislative history leading up to the DMCA, as discussed in Part III.B *supra*, provides some rationale for the shift, the DMCA should be examined under heightened scrutiny for proper First Amendment analysis, irrespective of that rationale.

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[155] Eldred v. Ashcroft, 537 U.S. 219 (2003).
[156] *Id.* at 221.
[157] *Id.* at 219.

While the Supreme Court rejected the imposition of heightened scrutiny in *Eldred*, it premised this upon the adoption of the Copyright Clause and First Amendment in close proximity, in addition to the aforementioned built-in safeguards.[158] The Court emphasized that the framers of the Constitution must have viewed "copyright's limited monopolies compatible with free speech principles."[159] This author suggests that the key to the Framers' intent was the limited nature of the monopoly; however, DRM effectively creates a perpetual monopoly, one that appears contrary to copyright's purpose of promoting the sciences for limited times.

Protecting free speech is a central tenet of the First Amendment. It bears repeating that *Eldred* further emphasized that any impediments to free speech are addressed by those built-in safeguards[160] in the Copyright Clause and not by heightened scrutiny. However, with DRM and the DMCA blocking such protections to gain access to DVD content altogether, heightened scrutiny should apply. If a film commentator cannot excise portions of various DVDs to make a point to viewers on her WebBlog, or a movie critic cannot remove what he deems inaccurate in a DVD for criticism, or a news reporter cannot take small portions of DVDs in a certain genre to illustrate a point, how can it be said that there has not been prior restraint and a chilling of free speech rights?

If a controversial documentary were to be released in DVD format exclusively, having DRM control measures, it could be suggested that this is a form of government control of information by way of DMCA backing. In the words of the Supreme Court in *Bartnicki v. Vopper*,[161] such "prior restraints on speech bear a heavy presumption against . . . constitutionality."[162] The rationale of Congress' term extension was one point the Supreme Court in *Eldred* kept referring to with respect to the built-in safeguards. However, as explained above, with such protections being non-existent in a DVD format, where a law is generally applicable without regard to content, it may still be subject to heightened review under the First Amendment. As was stated in *Turner Broadcasting System, Inc. v. F.C.C.*,[163] "[w]here a law is subjected to a colorable First Amendment

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[158] *Id.*

[159] *Id.*

[160] *Id.* at 221.

[161] Bartnicki v. Vopper, 532 U.S. 514 (2001).

[162] *Id.* at 555 (Rehnquist, J., dissenting) (citing N.Y. Times Co. v. United States, 403 U.S. 713, 714 (1971) (per curiam)).

[163] Turner Broad. Sys., Inc. v. F.C.C., 512 U.S. 622 (1994).

challenge, the rule of rationality which will sustain legislation against other constitutional challenges typically does not have the same controlling force."[164]

Some may argue that free speech is not impinged by the DMCA providing legal teeth to DRMs locking up DVD content because critics can still quote from such movies and post commentary. However, as the clichéd phrase goes, a picture is worth a thousand words. For a speaker to get her point across in a digital environment, a more meaningful message and a more even playing field can be created when the audience is able to visualize what the speaker is criticizing.

Whether the Court will see the DMCA's effect upon DVD fair use access as an impediment to the exercise of free speech, from the perspective outlined above, remains to be seen. While the above statutory and case law analysis provides a legislative and judicial perspective, this article will now examine comments by those in the industry for comparison. The DRM/DVD controversy has a vast array of opponents and supporters too numerous to give full exposition herein, but a flavor of what is out there can be illuminating.

D. Comments and Perspectives by Industry Stakeholders

The Electronic Frontier Foundation ("EFF"),[165] a not-for-profit organization that seeks to inform and defend consumer rights in the digital world, presents the interesting position that DRM and the DMCA stifle innovation in new technologies due in large part to the nonexistence of fair use.[166] To illustrate, the EFF cites to the *Sony* time-shifting decision and suggests that if fair use had not been found, many of the technologies that surrounded and developed work from the VCR would not have been created.[167] Thus, on a broader scale the EFF suggests that where fair use is found, companies will develop products and services to aid consumers in getting the most out of those

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[164] *Id.* at 641 (citing Los Angeles v. Preferred Commc'ns, Inc., 476 U.S. 488, 496 (1986) (Blackmun, J., concurring)).

[165] *See* Electronic Frontier Foundation Home Page, http://www.eff.org (last visited May 1, 2007).

[166] Fred von Lohmann, *Fair Use and Digital Rights Management: Preliminary Thoughts on the (Irreconcilable?) Tension between Them*, ELECTRONIC FRONTIER FOUNDATION 1, Apr. 16, 2002, http://www.eff.org/IP/DRM/cfp_fair_use_and_drm.pdf.

[167] *Id.* at 3-4.

copyrighted works. Illustrative of this proposition are such products as the audio cassette deck, the photocopier, and the CD-RW drive.[168]

The United States Association for Computational Mechanics ("USACM") likewise has some interesting thoughts on DRM and technology, which are directly on point with DVD works.[169] The USACM views the marketplace, rather than the courthouse or Congress, as the proper venue to determine whether DRM will thrive or die.[170] The USACM suggests that competition among various DRM schemes is essential, and that there should be no standardization, which in turn will foster innovation.[171] Consumer protection is paramount and thus any DRM scheme should not alter those rights consumers already have.[172] Finally, the USACM suggests that DRM should be limited in scope to target only piracy-related activities of copyrighted works and to give consumers full disclosure of the restrictions that are embedded in the products they buy.[173]

From the other side of the aisle, DRM is viewed as something that can benefit the consumer. For instance, a spokesperson of the Motion Picture Association of America stated:

> Content owners use DRMs because it provides casual, honest users with guidelines for using and consuming content based on the usage rights that were acquired. Without the use of DRMs, honest consumers would have no guidelines and might eventually come to totally disregard copyright and therefore become a pirate, resulting in great harm to content creators.[174]

Suffice it to say, not all parties see DRM through such rosy glasses. For instance, in June 2006, supporters frustrated with DRM called upon the Recording Industry Association of America to voice their concerns in the Defective By Design Anti-Digital Rights Campaign.[175]

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[168] *Id.* at 5.

[169] *See* USACM Home Page, http://www.usacm.org (last visited May 1, 2007).

[170] U.S. Public Policy Committee of the Association for Computing Machinery, USACM Policy Brief, USACM Policy Recommendations on Digital Rights Management (2006), http://www.acm.org/usacm/Issues/DRM.htm.

[171] *Id.*

[172] *Id.*

[173] *Id.*

[174] Ken Fisher, *MPAA: DRM "helps honest users*," ARS TECHNICA, Feb. 10, 2006, http://www.arstechnica.com/news.ars/post/20060210-6153.html.

[175] Anti-DRM Campaign Targets the RIAA, DRM NEWS, June 22, 2006, http://www.drmblog.org/index.php?/archives/422-Anti-DRM-campaign-targets-the-

As was discussed earlier respecting Blu-ray, HD-DVD, and their advanced DRM schemes, it is noteworthy to mention what Bill Gates, Chairman of Microsoft, had to say about the effects upon consumers of the Blu-ray format. Gates was quoted in an interview stating that Blu-ray's copyright protection is "anti-consumer," and that "[t]he inconvenience is that the [movie] studios got too much protection at the expense of consumers . . ."[176] Conversely, Maureen Weber, general manager of optical storage at Hewlett-Packard, touted the advantages and her company's endorsement of the Blu-ray standard, in large part due to the "capacity advantage (over HD-DVD) as well as the interactive features being built into the specification."[177]

In addition to the two aforementioned DVD DRM standardizations going head-to-head, there are also a myriad of other DRM platforms relating to computer-based schemes, most of which are incompatible with one another. Thus, buying digital media from one online service will not work with another service provider's devices. To illustrate the morass of DRM varieties, consider the following: Sony uses OpenMG; RealNetworks uses Helix; Microsoft uses Windows DRM; and Apple uses FairPlay.[178] According to Peter Lee, an executive at Disney, "if consumers even know there's a DRM, what it is, and how it works, we've already failed."[179]

As with all things, time will tell which format, and hence which DRM scheme, the market brings forth. However, one thing that can be assured is that the debate over DRM schemes, content owners, and consumer rights will continue. Irrespective, it is this author's view that as technology manipulates the balance between authors and the public, it is the duty of the Supreme Court and Congress to maintain the inherent stability that the copyright laws were intended to facilitate. Consider the comment of the Supreme Court in *Twentieth Century Music Corp. v. Aiken*, which nicely captures the essence of this balance, stating "[t]he immediate effect of our copyright law is to

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RIAA.html.

[176] Nate Mook, *Gates: Blu-Ray DRM is "Anti-Consumer,"* BETANEWS, Oct. 17, 2005, http://www.betanews.com/article/Gates_Bluray_DRM_is_AntiConsumer/1129572265.

[177] Richard Shim, *HP Strikes Blu Note for DVDs, Talks of Fat Storage*, Nov. 16, 2004, http://news.com.com/2102-1041_3-5455018.html?tag=st.util.print. HP is actually endorsing both HD-DVD and Blu-ray to give consumers the best of both formats. *See* Hewlett Packard News Release, HP to Support HD-DVD High Definition DVD Format and Join HD-DVD Promotions Group, Dec. 16, 2005, http://www.hp.com/hpinfo/newsroom/press/2005/051216a.html.

[178] *Science Fiction?*, THE ECONOMIST, Sept. 3, 2005, at 59-62.

[179] *Id.*

secure a fair return for an 'author's' creative labor but the ultimate aim is . . . to stimulate artistic creativity for the general public good . . . [but] *when technological change has rendered its literal terms ambiguous*, the Copyright Act must be construed in light of this basic purpose" (emphasis added). [180]

IV. CONCLUSION

If Congress and the Supreme Court were to take a more balanced or holistic approach to copyright instead of what appears to be, according to University of California at Berkeley Professor Pamela Samuelson,[181] one that favors the entertainment industry without equally factoring in broader implications, then perhaps companies would be inspired to devise technologies and services that would allow for fair use access while protecting authors from unlimited copying. For instance, the Copyright Office seemed open to the idea of permitting the forwarding on of digital content provided the original file could be automatically destroyed.[182]

Under what is termed the "first sale" doctrine, the Copyright Office declined to extend the doctrine to digital media since current computer technology is not able to recognize that if one user sells his copy to another, the original should be deleted.[183] However, if technology companies were put on notice that such functions (a forward and delete function) were legal, these companies could invest in developing such software, which in turn would allow consumers to regain the rights to which they have become accustomed.

As suggested above by the Center for Democracy and Technology and by comments of industry spokespeople, consumer awareness, or lack thereof, relating to DRM restrictions upon content usage should be brought to the forefront. In 2003, Representative Rick Boucher introduced the Digital Media Consumers' Rights Act, which would prohibit the advertising of CDs unless the package wrap gives full disclosure relating to DRM restrictions.[184] Likewise,

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[180] Twentieth Century Music Corp. v. Aiken, 422 U.S. 151, 156 (1975).

[181] Pamela Samuelson, Towards More Sensible Anti-Circumvention Regulations, http://www.ischool.berkeley.edu/~pam/papers.html (last visited May 1, 2007).

[182] United States Copyright Office, *A Report of the Register of Copyrights Pursuant to §140 of the Digital Millennium Copyright Act* 136 (2001) http://www.copyright.gov/reports/studies/dmca/sec-104-report-vol-1.pdf.

[183] *Id.* at 150.

[184] Declan McCullagh & Milana Homsi, *Leave DRM Alone: A Survey of*

proposed legislation from Senator Sam Brownback, called the Consumers, Schools, and Libraries Digital Rights Management Awareness Act, is similarly situated to monitor DRM schemes through government regulation banning media products that do not comply with consumer friendly mandates.[185] While these bills do not address all of the issues this author presents, they certainly do take a step in the right direction. Moreover, as emphasized earlier, with powerful groups lobbying to maintain the *status quo* of a digital media environment favoring content providers, one cannot expect giant leaps forward. Perhaps, like evolution, more bills will pass and the courts will give wider interpretation thereafter, and thus provide a more balanced approach to fair use.

The tensions between protecting an author's exclusive rights in the digital age on the one hand, and the right of the public to fully utilize and build upon prior works on the other, is one of the most challenging balancing acts in copyright law today. By examining the DMCA, its legislative history, case law, and commentary from industry players, this article hopefully illuminated the contours of how the Fair Use Doctrine has changed in the face of new DRM technologies while simultaneously suggesting alternative interpretations, which would provide for a more balanced approach.

Legislative Proposals Relating to Digital Rights Management Technology and Their Problems, 2005 MICH. ST. L. REV. 1, 4.

[185] *Id.* at 3; *see also* Brian Fitzgerald, *Digital Rights Management (DRM) Australian Anti-Circumvention Law Sony PS2 Mod Chip Case*, QUT Law School, http://iacits2005.iitm.ernet.in/presentations/DRM_DrBrianFitzgerald.pdf (analyzing the Kabushiki Kaisha Sony Computer Entm't v. Stevens case in Australia where the court held that reproducing a copy in RAM does not infringe copyright, and thereby playing a game is not an infringement either) (last visited May 1, 2007).

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THE HIGH COST OF GLOBAL INTELLECTUAL PROPERTY THEFT: AN ANALYSIS OF CURRENT TRENDS, THE TRIPS AGREEMENT, AND FUTURE APPROACHES TO COMBAT THE PROBLEM

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In 2002, the United States Department of Justice reported that a sixteen-year-old liver transplant patient in New York began receiving regular injections to treat his post-transplant related anemia shortly after surgery.[1] Anemia robs the body's red blood cells of oxygen and, in turn, adds extreme pressure on the heart.[2] It is a potentially deadly disease if left untreated.[3] Despite receiving weekly injections of the anemia medication, the name of which was not disclosed by the Department of Justice for privacy reasons, the boy's anemic condition did not improve and he began to develop atypical complications following his treatments.[4] The boy experienced excruciatingly painful muscle spasms after each injection, despite an otherwise successful transplant.[5] Eight weeks later, after extensive testing, doctors discovered that the injectable medication used to treat the boy's anemia was counterfeit and lacked the sufficient dosage necessary for his treatment.[6]

Counterfeit versions of medications used to treat Parkinson's disease, HIV-AIDS, heart-related conditions, and various infections have also been discovered throughout the United States.[7] For example, reports to the Department of Justice include counterfeit prescription tablets made with lead-based paint (the type normally used to paint road lines) and floor wax,[8] oral contraceptives made of wheat flour, and antibiotic eye drops composed of tap water.[9] In September 2004, a young teenager from Connecticut awoke to an explosion in his bedroom.[10] Investigators determined a counterfeit cellular phone battery that was charging in the boy's bedroom caused the explosion.[11]

The economic cost of such counterfeit goods and intellectual property theft to United States businesses and workers is even more

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[1] UNITED STATES DEPARTMENT OF JUSTICE, OFFICE OF THE ATTORNEY GENERAL, REPORT OF THE DEPARTMENT OF JUSTICE'S TASK FORCE ON INTELLECTUAL PROPERTY, iii (2004), *available at* http://www.usdoj.gov/criminal/cybercrime/IPTaskForceReport.pdf.

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.* at 8.

[8] *Id.* The name of this medication was not disclosed.

[9] *Id.*

[10] *Id.*

[11] *Id.*

staggering. The Department of Homeland Security's U.S. Customs and Border Protection reported seizing over $155 million in counterfeit goods at United States borders in 2006 alone.[12] It is estimated that global intellectual property theft costs over $500 billion each year worldwide.[13] The U.S. Department of Commerce recently released a statement that in the United States alone, intellectual property theft costs at least $250 billion and over 750,000 jobs each year.[14] The vast majority of this theft is in the form of counterfeit goods produced in China and sold in the mainstream United States marketplace; China was responsible for 81 percent of counterfeit goods seized by U.S. Customs and Border Protection in 2006.[15]

This article examines the burgeoning issue of international intellectual property theft, its costs and effects, and the future prospects of the efforts of the United States to curtail the problem. This article first defines intellectual property rights and current domestic protections of intellectual property rights. The cost of global intellectual property theft is then analyzed in several discrete categories. First, the economic cost on businesses and the American economy is analyzed. Second, this article addresses the specific problems associated with pharmaceutical patent theft. Next, the article examines current methods and techniques employed by counterfeiters to manufacture and distribute their fraudulent goods. Intellectual property theft by China and Russia is specifically discussed, as these two countries currently top the United States' priority list of problem countries.

The next part of this article analyzes the collective international response to intellectual property theft. Beginning with the Uruguay Round Agreements, this article addresses the establishment of the World Trade Organization ("WTO"), including

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[12] Department of Homeland Security, U.S. Customs and Border Protection, L.A. Strategic Trade Center, FY 2006 Top IPR Commodities Seized (Nov. 7, 2006), http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/trading/fy06_ipr_stat.ctt/fy06_ipr_stat.pdf.

[13] Frederik Balfour, *Fakes!*, BUSINESSWEEK, Feb. 7, 2005, at 56.

[14] Press Release, Hon. Carlos Gutierrez, Secretary, United States Department of Commerce, Commerce Secretary Carlos Gutierrez Unveils Initiatives to Fight Intellectual Property Theft (Sept. 21, 2005), http://www.commerce.gov (follow "Newsroom" hyperlink; then follow "September 2005 Press Releases" hyperlink; then follow "9/21/2005" hyperlink).

[15] Department of Homeland Security, U.S. Customs and Border Protection, L.A. Strategic Trade Center, FY 2004 Top Trading Partners for IPR Seizures (Nov. 7, 2006), http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/trading/fy06_ipr_stat.ctt/fy06_ipr_stat.pdf.

the functions and responsibilities of this organization as the primary dispute resolution mechanism for intellectual property theft complaints. The focus of this analysis is the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") and its provisions for intellectual property protection and dispute settlement. The later-in-time doctrine is analyzed for its potential effects on obligations of the United States under the TRIPS Agreement. The article next discusses in detail WTO dispute cases which have been brought by the United States under the TRIPS Agreement and analyzes the effects of those cases. The 2006 Special 301 Report of the United States Trade Representative ("USTR") is also discussed, with a focus on the status of China and Russia and the implications of those countries' status on future intellectual property rights international measures. Finally, the Dominican Republic-Central America-United States Free Trade Agreement ("CAFTA-DR"), which came into force on January 1, 2006, is analyzed in light of the intellectual property protections provided in the agreement; the article comments on the potential effectiveness of those provisions in light of the 2006 Special 301 Report.

The final part of this article looks to the future prospects of intellectual property protection and theft. It evaluates congressional legislation and considers various new government initiatives in light of Congress' efforts to increase intellectual property rights protections globally.

Although significant strides have been made recently, both in the United States and internationally, there remains a great deal of work to be done to ensure the greatest possible intellectual property protections to rights holders under current international agreements. The key to increased protection is enforcement by those countries that continue to have a significant problem with theft of intellectual property rights.

I. DEFINING INTELLECTUAL PROPERTY RIGHTS

The term intellectual property governs intangibles which are a creation of the mind.[16] Traditionally, intellectual property rights ("IPRs") protected trademarks, copyrights and patents. Since the

[16] KARLA C. SHIPPEY, A SHORT COURSE IN INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS: PROTECTING YOUR BRANDS, MARKS, COPYRIGHTS, PATENTS, DESIGNS, AND RELATED RIGHTS WORLDWIDE 1 (World Trade Press 2002).

Eighteenth Century's Era of Enlightenment, developed countries have recognized and legally protected the value of intellectual property.[17]

Trademarks distinguish and identify goods and now provide protection for such sub-categories as trade secrets, designs, brand names and domain names among others.[18] Trademarks include:

> any word, name, symbol, or device, or any combination thereof (1) used by a person, or (2) which a person has a bona fide intention to use in commerce…to identify and distinguish his or her goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods.[19]

Trademarks serve a "quality" function by acting as a warranty of the goods and their composition.[20] Many countries, including the United States, require proof of use of the trademark in commerce before the trademark will be issued.[21] A federally registered trademark is valid for ten years, but may be renewed, so long as it is not cancelled or abandoned.[22] Trademarks that do not continue to be used may be cancelled.[23]

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[17] *Id.*

[18] *Id.* at 2, 14-15.

[19] Trademark Act of 1946, 15 U.S.C. § 1127 (2006).

[20] ANNE GILSON LALONDE, GILSON ON TRADEMARK PROTECTION & PRACTICE § 1.03[3](a). Although owners may alter the composition of their trademarked goods, the goods should stay within the range of quality to which the public has become accustomed. *Id*. The quality function becomes particularly significant in the context of counterfeit goods where consumers lose the quality and protective function of trademarks. *Id*. § 1.03[8](a). As a result, trademarks often symbolize the goodwill earned by a particular business. *Id.* § 1.03[6].

[21] SHIPPEY, *supra* note 16, at 8.

[22] LALONDE, *supra* note 20, § 4.09. *See also* 15 U.S.C. § 1058(a) (2006) (providing trademark registrations effective for ten years). Under the Trademark Act, "a mark shall be deemed to be 'abandoned' if either of the following occurs:

(1) When its use has been discontinued with intent not to resume such use. Intent not to resume may be inferred from circumstances. Nonuse for 3 consecutive years shall be prima facie evidence of abandonment. "Use" of a mark means the bona fide use of such mark made in the ordinary course of trade, and not made merely to reserve a right in a mark.

(2) When any course of conduct of the owner, including acts of omission as well as commission, causes the mark to become the generic name for the goods or services on or in connection with which it is used or otherwise to lose its significance as a mark. Purchaser motivation shall not be a test for determining abandonment under this paragraph." 15 U.S.C. § 1127 (2006).

[23] *Id.*

A copyright is a protection given to the exclusive author of an original creative work such as a musical, literary, or otherwise graphic or artistic performance or work.[24] Copyrights have a limited duration of protection; under the Copyright Act of 1976, copyrights issued after January 1, 1978 are afforded protection for the life of the author plus seventy years.[25]

A patent, which is a statutory right granted to the inventor who discovers or formulates a new and non-obvious invention, protects the inventor's exclusive right to manufacture, use, sell, and develop the invention.[26] Patent rights, which cover useful, novel, and non-obvious inventions, are granted for limited terms, generally from fourteen to twenty years, and cannot normally be extended. Patent rights include protecting design inventions such as clothing and textiles, novel plant hybrids and utility inventions encompassing machines, chemical formulas, electronic circuits, and pharmaceuticals.[27]

It is estimated that the value of intellectual property protected by trademarks, copyrights, and patents in the United States is between $5 trillion and $5.5 trillion, or roughly 45 percent of the United States Gross Domestic Product.[28] Clearly, the value of intellectual property to the United States economy is tremendous. As the growth rate of a country directly correlates to that nation's development of and commitment to the adoption of economic innovation,[29] developing nations with poor intellectual property investments and protection remain far behind countries with such protections in economic growth.[30] Economic growth is no longer measured by a country's natural resources, but instead by the technological innovations created in or imported into that country.[31]

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[24] Copyright Act of 1976, 17 U.S.C. § 102(a) (2006).

[25] *Id.* § 302(a).

[26] SHIPPEY, *supra* note 16, at 4.

[27] SHIPPEY, *supra* note 16, at 8, 13.

[28] Robert J. Shapiro & Kevin A. Hassett, The Economic Value of Intellectual Property 3 (Oct. 2005) (unpublished manuscript, on file with U.S.A. for Innovation).

[29] *Id.* at 6.

[30] *Id.* at 5.

[31] *Id.* Shapiro and Hassett compare the growth of South Korea and Brazil between the years 1960 to 2000 based on World Bank Development Indicators. *Id.* The authors note that the *per capita* income economic output of South Korea, a country with few natural resources, grew over three times as fast as the economic output of Brazil, a country with plentiful natural resources (emphasis in original). *Id.*

II. THE PROBLEM OF GLOBAL INTELLECTUAL PROPERTY THEFT

Considering the value of intellectual property, it is understandable that theft of this commodity can have a devastating impact on the businesses and economy of the affected country. Theft of intellectual property most notably comes in the form of counterfeit or pirated goods produced and distributed without proper authorization. The TRIPS Agreement defines counterfeit and pirated goods as follows:

> a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;
>
> b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.[32]

Thus, counterfeit goods so closely mirror the appearance of legitimate goods that it is often extremely difficult or impossible to distinguish a true product from a counterfeit copy.

Each year, intellectual property theft costs businesses in the United States at least 750,000 jobs and at least $250 billion.[33] The World Customs Organization estimates that five to seven percent of global goods traded are counterfeit.[34] The counterfeit market led to a

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[32] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 51, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS or the TRIPS Agreement].

[33] Press Release, Hon. Carlos Gutierrez, *supra* note 14. Experts agree these estimates are likely conservative. *Id*.

[34] Balfour, *supra* note 13, at 56. The World Customs Organization ("WCO")

worldwide loss of sales as great as $512 billion in 2004.[35] The sale of counterfeit goods spans nearly every trade and industry.

Counterfeit products seized by U.S. Customs and Border Protection each year include clothing, footwear, computer hardware and software, digital media such as compact discs and digital versatile discs, toys, cigarettes, electronics, and batteries.[36] In Fiscal Year 2002, U.S. Customs and Border Protection officials seized 5,793 counterfeit goods at the border, yet by 2006, the number of seizures had more than doubled to 14,675.[37] The domestic value of these seizures also rose exponentially during this brief time period. U.S. Customs and Border Protection seized over $98 million in counterfeit goods in 2002.[38] By 2006, that figure had risen to $155,369,236, an increase of nearly 159 percent in just four years.[39] Perhaps even more alarming is that the value of goods seized jumped nearly 165 percent between 2005 and 2006 alone, despite measures to provide greater protections for intellectual property rights.[40] It is clear, based on these figures, that the problem of intellectual property theft and counterfeiting is rapidly increasing in the United States.

Individuals counterfeiting goods are reaping the financial rewards of getting illegal products into the mainstream market and selling them at huge profit margins. Counterfeit goods are made more cheaply than legitimate goods because they can be made using inferior raw materials and processes. Another important factor in this analysis is that counterfeiters do not expend money for research and development—they simply copy a legitimate product and are unconcerned with whether the product functions properly.[41] As Frederik Balfour reported in a *BusinessWeek* article in 2005:

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was established in 1952 to support customs administration and protect its member countries by promoting legitimate international trade. The World Customs Organization Fact Sheet 1 (2005-2006), http://www.wcoomd.org/ie/en/AboutUs/fiche1%20Ang.pdf. Currently, there are 170 member countries in the WCO. About the World Customs Organization (2005-2006), http://www.wcoomd.org/ie/tableau%20171%20membres.pdf.

[35] Balfour, *supra* note 13, at 56.

[36] REPORT OF THE DEPARTMENT OF JUSTICE, *supra* note 1, at 8.

[37] Department of Homeland Security, U.S. Customs and Border Protection, L.A. Strategic Trade Center, Comparison of Yearly Seizure Totals (Nov. 7, 2006), http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/trading/fy06_ipr_stat.ctt/fy06_ipr_stat.pdf.

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] Balfour, *supra* note 13, at 60.

"Counterfeiters, after all, don't have to cover research and development, marketing and advertising costs, and most of the expense goes into making goods look convincing, not perform[ing] well."[42] Thus, counterfeit goods are less reliable than the legitimate goods they imitate. Counterfeit batteries do not last as long, fake "designer" clothes, purses, and accessories wear out more quickly, and counterfeit automobile parts do not meet the same safety standards as authentic goods.[43]

A. The Social and Labor Related Costs of Intellectual Property Theft

The cost of counterfeit goods extends far beyond the economic lost profits of legitimate companies and consumers. Because counterfeit products are made with lower quality components and are not subject to the standards and regulations governing safety and quality, many counterfeit goods are dangerous to the health and safety of consumers. For example, United States law enforcement agents discovered hundreds of thousands of counterfeit general-use batteries made with unsafe levels of mercury that could explode if exposed to sunlight.[44] These batteries were set for sale in bargain stores and were branded with a trusted household name. The Department of Justice reports that, once the batteries were discovered, it took federal authorities several months to destroy them.[45] Counterfeit food products, insecticides, brake pads, headlights, car batteries, and other parts have been found throughout retail stores in the United States.[46] The estimated cost of counterfeit parts to automobile companies worldwide is $12 billion.[47] Hanns Glatz, an intellectual property expert for DaimlerChrysler, characterizes counterfeiting as a trade that "has gone from a local nuisance to a global threat."[48] The U.S. Department of Justice reports that counterfeit brake pads composed of compressed sawdust were discovered in Asia after seven children were killed when the pads failed.[49] Such counterfeit parts are particularly dangerous to everyday consumers who rely on the assumption that

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[42] *Id.*
[43] *Id.*
[44] REPORT OF THE DEPARTMENT OF JUSTICE, *supra* note 1, at 8.
[45] *Id.*
[46] *Id.*
[47] Balfour, *supra* note 13, at 56.
[48] *Id.*
[49] REPORT OF THE DEPARTMENT OF JUSTICE, *supra* note 1, at 8.

purchasing brand name products generally guarantees better quality and an ultimately safer product. The U.S. Department of Justice Task Force on Intellectual Property reported in October 2004 that hundreds of medical students and doctors used stolen textbooks with incorrect prescription dosage data which may have proved fatal if prescribed improperly.[50]

Theft of digital media and the production of counterfeit compact discs, digital versatile discs, movies, music and software is a rapidly expanding industry worldwide. The U.S. Department of Commerce reported in July 2005 that 90 percent of all movies and music sold in China are pirated.[51] By 1999, domestic sales of music recordings had sky rocketed to $15 billion from only $4 billion in 1980. [52] However, since that time, the music recording industry has seen a 20 percent decline due to piracy.[53] There had also been over 4,000 domestic jobs lost in the music industry as a result of intellectual property piracy as of the April 2004 hearing.[54]

The Entertainment Software Association reports the entertainment software industry fears it will soon experience similar losses.[55] Douglas Lowenstein, President of the Entertainment Software Association, reported at the same Senate hearing that video games cost on average $5 to $10 million to create over a period of two to three years.[56] However, the ability to recover this investment through sales overseas has become nearly impossible, as some regions have piracy rates of 80 to 90 percent.[57] Lowenstein testified that the industry will not be able to sustain growth unless the problem of

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[50] *Id.*

[51] Press Release, Hon. Carlos Gutierrez, Secretary, United States Department of Commerce, Gutierrez Hails Announcement of International IPR Enforcement Coordinator: New Position to Focus on Combating International Intellectual Property Theft (July 22, 2005), http://www.commerce.gov/opa/press/Secretary_Gutierrez/2005_Releases/July/22_IPR_Coordinator.htm.

[52] *International and Domestic Intellectual Property Enforcement: Hearing Before the Subcomm. on Commerce, Justice, State, and the Judiciary of the Senate Comm. on Appropriations*, 108th Cong. 9 (2004) (statement of Mitch Bainwol, Chairman and Chief Executive Officer, Recording Industry Association of America regarding music sales). Bainwol reported a similar increase in worldwide music recording sales of $39 billion in 1999, up from $11 billion in 1980. *Id.*

[53] *Id.* at 10. Bainwol stated this decrease was due to a combination of Internet piracy, physical global piracy, and illegal burning of compact discs. *Id.*

[54] *Id.*

[55] *Id.* at 17 (statement of Douglas Lowenstein, President, Entertainment Software Association).

[56] *Id.*

[57] *Id.*

global piracy is better controlled.[58] Robert W. Holleyman, II, President and Chief Executive Officer of the Business Software Alliance, characterizes the struggle against intellectual property theft as a daily fight.[59] He estimates that piracy has cost the worldwide software industry $12 billion per year for each of the last three years, with average losses of $2 billion in the United States, the country with the greatest losses.[60]

B. Impact of Counterfeit Pharmaceutical Products

Fake pharmaceutical products present a particularly grave threat to consumers. The World Health Organization ("WHO") defines a counterfeit drug as:

> a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.[61]

The WHO estimates that five to seven percent of pharmaceuticals worldwide are counterfeit.[62] Pfizer, Inc., is one of many pharmaceutical companies teaming up with law enforcement officials to enforce criminal counterfeiting sanctions. Pfizer reported seizures of over 11.5 million counterfeit Pfizer products in 2004 in the United States, which led to 364 arrests by law enforcement authorities.[63] The United States Food and Drug Administration Office of Criminal Investigations initiated fifty-eight cases against pharmaceutical

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[58] *Id.*

[59] *Id.* at 25 (statement of Robert W. Holleyman, II, President and Chief Executive Officer, Business Software Alliance).

[60] *Id.*

[61] Michele Forzley, Combating Counterfeit Drugs: A Concept Paper for Effective International Collaboration 11 (Sept. 2005) (unpublished draft paper, on file with the World Health Organization Health Technology and Pharmaceuticals), *available at* http://www.who.int/medicines/services/counterfeit/CombatingCounterfeitDrugs_Conceptpaper.pdf.

[62] *Id.* at 8.

[63] Pfizer, Inc., Keeping Medicines Safe: Combating Counterfeit Medicines (2005), http://www.pfizer.com/Pfizer/subsites/corporate_citizenship/report/combating.jsp.

counterfeiters in 2004, as compared to only thirty cases of the same type in 2003.[64] This increase in cases suggests an increase in the prevalence of fake products in the United States. Fortunately, most counterfeit pharmaceuticals have been intercepted before distribution to consumers in the United States.[65] Yet, although actual numbers remain relatively low in the United States, incidences are rising, and this pattern concerns the U.S. Food and Drug Administration, pharmaceutical companies, law enforcement officials, and lawmakers alike.

Counterfeit pharmaceuticals worldwide cost pharmaceutical companies up to $46 billion each year.[66] As reported by Pfizer, the Center for Medicine in the Public Interest estimates that by the year 2010, worldwide sales in counterfeit pharmaceutical products will likely reach $75 billion.[67] Robert Shapiro and Kevin Hassett of USA for Innovation state: "Experts in pharmaceutical piracy have found that counterfeits account for up to 50 percent of certain drugs sold in China and Pakistan, and more than 10 percent of the entire markets in other Asian countries and Russia."[68] In China, fifteen infants died after consuming fake milk powder products in 2004.[69] Pfizer reports that for the period from January 1, 2005 to September 16, 2005, authorities confiscated nearly 4.8 million counterfeit tablets.[70] Pfizer also reports that in 2005, Chinese authorities seized one million counterfeit Lipitor hyperlipidemia (high cholesterol) tablets, 446,400 Viagra tablets, and 449,200 Norvasc hypertension tablets in one seizure alone.[71] These reports are particularly alarming because counterfeit versions of life-saving drugs, such as those used for high cholesterol and hypertension, present an increased threat to the safety and overall health of consumers.

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[64] U.S. Food and Drug Administration, *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update* (May 18, 2005), http://www.fda.gov/oc/initiatives/counterfeit/update2005.html.

[65] *Id.*

[66] Balfour, *supra* note 13, at 56.

[67] Pfizer, Inc., *supra* note 63.

[68] Shapiro & Hassett, *supra* note 28, at 4.

[69] Balfour, *supra* note 13, at 62.

[70] Pfizer, Inc., *2005 Corporate Citizenship Report*, 27 (2005) (unpublished manuscript), *available at* http://www.pfizer.com/pfizer/subsites/corporate_citizenship/report/cc_report_2005.pdf.

[71] *Id.*

C. Methods of Intellectual Property Theft and Counterfeit Distribution

The World Customs Organization has estimated that "counterfeiting accounts for 5% to 7% of global merchandise trade, equivalent to lost sales of as much as $512 billion [in 2004] – though experts say this is only a guess."[72] Counterfeiters employ many different methods to produce and distribute their goods in the mainstream market. Reports show that legitimate, licensed brand name producers often also run counterfeit operations. Because these producers have the designs, molds, and information concerning the products, the producers can easily manufacture counterfeit versions of the brand name goods using cheaper materials.[73] Generic manufacturers utilize this same process to produce counterfeit drugs and other goods. Financing for these operations can come "from a variety of sources, including Middle East middlemen, local entrepreneurs, and organized crime."[74] Thus, some of the proceeds from these operations are likely to be used in other criminal activities.[75] Additionally, "although the information is sketchy at best, there have been a series of rumored ties between [counterfeiting] operations and terrorist organizations."[76]

The physical dangers to those who consume these fake drugs are obvious. However, how are pharmaceutical companies and consumers to distinguish between real and fake drugs or between authentic brake pads and those made of compressed sawdust? Unfortunately, counterfeiters have become so sophisticated that they are able to mimic both products and packaging so closely that even a trained eye often cannot distinguish between them. As Frederik Balfour reports, as counterfeiters' technology increases, legitimate companies find they must turn to forensic science to aid them in distinguishing their product from a copy manufactured by a counterfeiter.[77] Alexander Theil, Director of Investigation for General

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[72] Balfour, *supra* note 13, at 56.

[73] *Id.* at 58.

[74] *Id.*

[75] *Piracy of Intellectual Property: Hearing Before the Subcomm. on Intellectual Property, Comm. on the Judiciary United States Senate*, 109th Congress 7 (May 25, 2005) (statement of Marybeth Peters, The Register of Copyrights, United States Copyright Office), *available at* http://judiciary.senate.gov/testimony.cfm?id=1514&wit_id=4303.

[76] *Id*.

[77] Balfour, *supra* note 13, at 57.

Motors Asia Pacific, stated when speaking of various brake pads, batteries, and air filters that General Motors had discovered being distributed to customers and retailers: "We had to cut them apart or do chemical analysis to tell" they were counterfeits.[78]

In an effort to stop the problem of counterfeiting at the point of manufacturing, many companies invest a great deal of capital to make their products counterfeit-proof. For example, when Anheuser-Busch Company began having problems with Chinese counterfeiters refilling used Budweiser beer bottles, the company started using expensive foil on its bottle labels that was not readily available in China.[79] The company also began using temperature-sensitive labels that changed color when cold.[80] Other companies such as Yamaha have decreased the costs of their own production so that they can lower their prices to compete with counterfeit products.[81] However, all too often counterfeiters drop their costs as well, further diminishing the quality and safety of their products. Some pharmaceutical companies, such as Pfizer, are creating radio-frequency identification tags that are placed on drugs sold in the United States to "enable [them] to track drugs all the way from the laboratory to the medicine cabinet."[82] Other companies frequently make slight alterations in the appearance of their products to try to stay one step ahead of counterfeiters.[83] Regardless of the method chosen by an individual company, one constant among all companies is the increased investment required to fight counterfeiters who are often on the other side of the globe. JT International, a cigarette producer, has increased its anti-counterfeiting budget to $15 million from just $200,000 in 1999.[84] These funds go toward hiring investigators, informants in suspected industries, and attorneys to find, prosecute, and eliminate counterfeit signatures with their name.[85]

Many counterfeiters are able to mix their fake goods with authentic products, thereby moving them into the mainstream market undetected.[86] In Shanghai, customs officials have discovered fake goods packaged with a non-brand name label during shipment;

[78] *Id*. at 58.
[79] *Id.* at 60.
[80] *Id.*
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.* at 58, 60.

however, once the goods are distributed, the fake name label is removed to reveal a brand name underneath.[87] Counterfeiters have found ways to deceive customs officials throughout the process of shipping and transporting goods to ensure they reach commerce undetected. Thus, even while companies continue to increase expenditures to fight counterfeit products and intellectual property theft, counterfeiters continue to lower their costs and make substantial profits on fake goods.

Besides the economic loss that intellectual property theft costs a country in direct loss of sales, companies also lose a great deal of funds in investments to fight counterfeiting of their products through both detection of counterfeit goods, marketing and replacement costs, prosecution of offenders, and future prevention and protection of their products.[88] However, as the Organization for Economic Co-Operation and Development reports, consumers purchasing counterfeit goods also lose feelings of goodwill toward the manufacturer and the industry that manufactures the legitimate goods, which has obvious repercussions for future sales and the reputation of the company and industry involved.[89] The future implications for legitimate businesses also include discouraging honest manufacturers from investing in the market when the legal system of that country clearly will not provide the necessary protection.[90]

Countries that are major producers of counterfeit products also suffer harm, despite the billions in profits a few individuals may make. First, those countries may develop a reputation for poor quality products and illegal trade practices, making the countries' own industries suffer job and revenue losses.[91] Second, those countries lose investments by other countries and the sharing of ideas and processes.[92] Likewise, counterfeiters will not pay taxes on the sale of counterfeit goods and the country itself will not gain from the illegal sale of these goods.[93]

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[87] *Id.* at 60.

[88] Hema Vithlani, Organization for Economic Co-Operation and Development, The Economic Impact of Counterfeiting 22 (1998) (unpublished paper on file with the ICC Counterfeiting Intelligence Bureau, for the Industry Division of the OECD's Directorate for Science, Technology and Industry).

[89] *Id.*

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.* at 23.

Socially, consumers suffer by being forced to pay increased costs for goods to help defer the cost companies absorb due to counterfeit goods and loss of sales.[94] As previously discussed, criminal organizations and terrorists often reap the financial rewards of intellectual property theft, while unwitting consumers bear the dangers and risks of poorly made products or fake medications.[95] Importantly, global intellectual property theft creates distrust and ill will between nations.[96] China and Russia have been major producers of counterfeit goods and have failed to provide strong protections for intellectual property rights holders—thus they remain on the United States' watch list of countries about which to be concerned.

D. China and Russia: Problem Countries

China is one of the United States' greatest trading partners. Trade in goods with China rose from $5 billion in 1980 to $231 billion in 2004.[97] William H. Cooper with the Foreign Affairs, Defense, and Trade Division of the Library of Congress Research Services reports that the United States' largest bilateral trade deficit is with China, which in 2004 was $162 billion.[98] This is more than twice the deficit with Japan, which is the second largest at $75.2 billion.[99] U.S. Customs and Border Protection reported that of the over $155 million in intellectual property rights seizures made in fiscal year 2006, 81 percent were of goods from China.[100]

In dealing with China's high rate of intellectual property theft and production of counterfeit goods, perhaps the biggest problem facing the United States is the apathy the Chinese government displays in recognizing and addressing the problem. Despite a long history of intellectual property rights protection agreements with China, theft in that country continues to grow.[101] Although China is a member of the

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[94] *Id.*

[95] *Id.*

[96] *Id.* at 22-23.

[97] William H. Cooper, Trade Issues in the 109th Congress: Policy Challenges and Opportunities 16 (Mar. 24, 2005) (unpublished Congressional Research Service Report for Congress, on file with The Library of Congress, Order Code RL32829).

[98] *Id.*

[99] *Id.*

[100] FY2006 Top Trading Partners for IPR Seizures, *supra* note 15.

[101] *Piracy of Intellectual Property: Hearing Before the Subcomm. on Intellectual Property, S. Comm. on the Judiciary*, 109th Cong. 5 (May 25, 2005) (statement of Stephen M. Pinkos, Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the U.S. Patent and Trademark Office), *available at* 2005

World Trade Organization ("WTO") and has created laws that provide intellectual property protection, experts say that China is falling dangerously short with its lack of enforcement.[102]

Besides being a WTO member, China must comply with TRIPS Agreement requirements for intellectual property protection.[103] However, even though tens of thousands of intellectual property rights enforcement actions are reportedly carried out each year in China, these actions are typically enforced by administrative-type agencies that impose penalties deemed "non-deterrent," which often do not include stiff fines or prison sentences.[104] For example, one Guangdong Province factory has been raided by authorities three times in two and one half years for producing counterfeit windshields with the Volvo, BMW, Audi, or DaimlerChrysler brand names.[105] This factory remains open and continues to produce these counterfeit windshields and sell them in the global market.[106] A recent interpretation of intellectual property criminal infringement by the Supreme People's Court and Supreme People's Procuratorate seemed to make progress towards punishing more offenders criminally by decreasing the value threshold required to substantiate an infringement.[107] However, in actuality, the interpretation lessened penalties for repeat offenders and now allows the value of goods to be determined based on their street rather than legitimate value.[108] Other problems plague increased intellectual property rights enforcement in China, such as the lack of coordinated efforts, the presence of extensive internal corruption, and the concept of local protectionism.[109] These social and cultural barriers present huge hurdles to those seeking increased intellectual property rights protection and enforcement in China.

Russia is also a major source of global intellectual property theft and a major counterfeit producer. Second only to China in fiscal

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WL 1248204 [hereinafter Statement of Stephen M. Pinkos]. The United States first entered into Intellectual Property Rights protection agreements with China through bilateral agreements as early as 1903. The history of these agreements continued with a number of commercial agreements focused on improving the IPR protections afforded by China, starting in the 1970s. *Id.*

[102] *Id.*

[103] *Id.*

[104] *Id.* at 7.

[105] *Id.* at 6.

[106] *Id.*

[107] *Id.*

[108] *Id.*

[109] *Id.*

year 2004, counterfeit goods seized by U.S. Customs and Border Protection from Russia accounted for some five percent of all seizures.[110] The copyright industry estimates losses to Russian piracy accounted for over $1.7 billion in 2004 alone.[111] As Deputy Under Secretary of Commerce for Intellectual Property Stephen M. Pinkos reported, "copyright piracy levels in the Russian Federation in 2004 were estimated by industry at 80 percent for motion pictures, 66 percent for records and music, 87 percent for business software, and 73 percent for entertainment software[;] [t]he production of optical media in Russia far exceeds legitimate demand."[112] Reports indicate that, despite action by law enforcement such as raids and seizures, the counterfeit plants in Russia continue to operate and do not seem to have been significantly impacted by those raids. This is likely because the penalties assessed were so minimal that they had little to no punitive or deterrent effect on the violators. The average penalty in 1300 raids conducted in 2004 targeting music pirates was only $50.[113] Like China, Russia has made efforts to recommit itself to intellectual property protection, such as reforming domestic laws to bring them into compliance with the 1992 United States-Russian bilateral trade agreement.[114] However, these steps are not enough, and Russian laws still fall short of providing sufficient intellectual property rights protections as required under the TRIPS Agreement.[115]

III. ADDRESSING INTELLECTUAL PROPERTY THEFT ON AN INTERNATIONAL LEVEL

A. The World Trade Organization

The WTO was created by the Uruguay Round Agreements Act of 1994, and officially came into force on January 1, 1995.[116] The Uruguay Round of Multilateral Trade Negotiations of the General

[110] Department of Homeland Security, U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement, FY 2004 Top Trading Partners for IPR Seizures (2004), http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/trading/top_seizures_04.ctt/top_seizures_04.pdf.

[111] Statement of Stephen M. Pinkos, *supra* note 101, at 14.

[112] *Id.*

[113] *Id.* at 15.

[114] *Id.*

[115] *Id.*

[116] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 (1994) [hereinafter Agreement Establishing the WTO] (entry into force Jan. 1, 1995).

Agreement on Tariffs and Trade ("GATT") and ensuing establishment of the WTO is the result of some seven years of trade negotiations lasting from September 1986 to December 1993, officially concluding in April 1994.[117] The WTO is a negotiating forum that seeks to help member countries' governments resolve trade-related disputes between each other while promoting freer trade through compromise and negotiations.[118] The WTO is the successor to the GATT.[119] Although the GATT still exists, the WTO is now the leading international trade organization.[120] One of the WTO's founding principles is that countries may not discriminate between trading partners, so that all receive the same status.[121] This trading principle, Most Favored Nation ("MFN") status, was adopted from the GATT era.[122] Thus, fair competition practices among member countries will be promoted and barriers to free trade will be removed. The WTO also promotes the principle known as "national treatment" whereby a country treats foreign goods in its market the same as if they were domestically produced.[123]

Currently, the WTO has 148 member countries, including the United States and China.[124] When the United States adopted the Uruguay Round Agreements Act in the 103d Congress, it maintained the right to end its membership in the WTO.[125] Under the Review of Participation in the WTO of the Uruguay Round Agreements Act section, Congress requires that:

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[117] JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 11 (2001).

[118] World Trade Organization, *Understanding the WTO* 9 (2007), http://www.wto.org/english/thewto_e/whatis_e/tif_e/utw_chap1_e.pdf.

[119] Agreement Establishing the WTO, *supra* note 116.

[120] *Understanding the WTO*, *supra* note 118, at 15-16, 19. The GATT provided most of the global trade rules for forty-seven years, beginning in 1948. During its reign, GATT held eight large trade rounds with many member countries, each addressing the necessary global trade issues of their time. These rounds have been deemed successful as the major conduits through which global liberalization of trade occurred. The largest and longest of these was the seven-year Uruguay Trade Rounds where 123 member countries participated and addressed issues such as dispute settlement, tariffs, rules, creation of the WTO and intellectual property rights. The GATT remained, "the only multilateral instrument governing international trade from 1948 until the WTO was established in 1995." *Id.*

[121] *Id.* at 10.

[122] *Id.*

[123] *Id.* at 11.

[124] *Id.* at 1.

[125] Uruguay Round Agreements Act, 19 U.S.C. § 3535(a) (2006).

> (1) after the end of the 5-year period beginning on the date on which the WTO Agreement enters into force with respect to the United States, and (2) after the end of every 5-year period thereafter, shall include an analysis of the effects of the WTO Agreement on the interest of the United States, the costs and benefits to the United States of its participation in the WTO, and the value of the continued participation of the United States in the WTO.[126]

If at that time Congress determines it does not approve of continued membership in the WTO, the United States can only declare the Agreement ineffective by a joint resolution of both Houses of Congress.[127] Although efforts have been made to withdraw the United States from the WTO, those attempts have been handily defeated.[128]

B. The TRIPS Agreement

The most significant result of the Uruguay Round Negotiations, besides establishment of the WTO, was the adoption of the TRIPS Agreement.[129] The TRIPS Agreement is the first international intellectual property protection agreement that protects the gamut of intellectual property rights.[130] Prior to the implementation of the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property of 1883 was the primary agreement protecting the rights of industrial intellectual property such as trademarks and patents.[131] The 1883 agreement was adopted by many countries under the belief that, "like medieval privileges, [patents] could convince foreign inventors to immigrate to the granting

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[126] *Id.*

[127] *See id.*; 19 U.S.C. §§ 3535(b)(1), (c)(2) (2005). The resolution may be introduced by either House.

[128] H.R.J. RES. 27, 109th Cong. (2005). On Mar. 2, 2005, House Joint Resolution 27 was offered by a limited number of Representatives. The House Ways and Means Committee reported out the resolution adversely and it was defeated by a wide margin on June 9, 2005, in the House of Representatives. The bill was defeated with 86 yea votes and 338 nay votes after two hours of general debate. *Id.*

[129] TRIPS Agreement, *supra* note 32.

[130] NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 28 (2d ed. 2005).

[131] *Id. See generally* Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 1, 25 Stat. 1372 [hereinafter the Paris Convention].

country."[132] The idea of granting the privilege of patent protection only to nationals reigned for many years throughout a host of countries, including the United States, which only entitled those foreigners residing in the United States to patent protection.[133] Even recently, some governments subjected non-national patent holders to cancellation or compulsory licensing requirements.[134]

The Berne Convention for the Protection of Literary and Artistic Works of 1866 was the major agreement protecting copyrighted literary and artistic works until the birth of the TRIPS Agreement.[135] The protection provided by this agreement included "every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression, such as books, pamphlets . . . lectures, addresses, sermons…dramatic or dramatico-musical works; . . . musical compositions with or without words; . . . cinematographic works . . . works of drawing, painting, architecture . . . photographic works . . ., [and] . . . illustrations."[136] Thus, although there were international agreements protecting many intellectual property rights prior to the TRIPS Agreement, there was no comprehensive agreement spanning all sources of intellectual property. Further, it had been many years since a comprehensive agreement taking into account the rapid developments and changes in the regime of intellectual property had been signed.

The TRIPS Agreement made a significant leap forward in the world of intellectual property rights protection by "raising and harmonizing the minimum standards of protection of some areas of intellectual property, by establishing mechanisms of enforcement, and by submitting intellectual property disputes to the WTO dispute settlement mechanism."[137] The TRIPS Agreement, although comprehensive, does not encompass all areas of intellectual property. The TRIPS Agreement regulates copyrights and six categories of industrial property: patents, trademarks, industrial designs, layout designs of integrated circuits, geographical indications, and undisclosed information.[138] The TRIPS Agreement does not regulate

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[132] DE CARVALHO, *supra* note 130, at 16.

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] Convention for the Creation of an International Union for the Protection of Literary and Artistic Works art. 2, Sept. 9, 1886, 168 Consol. T.S. 185, 12 Martens Nouveau Recueil (2d) 173 [hereinafter the Berne Convention].

[137] DE CARVALHO, *supra* note 130, at 16-17.

[138] *Id*. at 29. *See* TRIPS Agreement, *supra* note 32, art. 9-39. de Carvalho notes,

protection of trade names, collective marks, and utility models among others, which are industrial properties explicitly protected under the Paris Convention.[139]

C. Dispute Settlement under TRIPS

1. General Provisions

The TRIPS Agreement is composed of four main elements.[140] It first sets out the required minimum substantive standards for intellectual property protection, including the scope of the seven categories of intellectual property protection, the content of those protections, and their reach.[141] The TRIPS Agreement also provides for specific enforcement of intellectual property provisions.[142] Because one of the major purposes of the TRIPS Agreement is to foster free trade, the enforcement provisions are designed to be fair and equitable in the name of supporting free trade, while preventing abuse of the enforcement procedures.[143] Article 42 makes available civil procedures to protect against intellectual property theft under the TRIPS Agreement.[144] Article 51 requires protections against the importation of counterfeit goods at a country's borders.[145] Article 63 requires that member countries provide other member countries with laws, regulations, and case resolutions available under the transparency provision.[146] Importantly, Article 61 provides for criminal penalties and procedures in the case of willful counterfeiting or large scale commercial piracy.[147] The third element of the TRIPS

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however, that the protection of undisclosed information is limited to protection against unfair competition, much as it was protected under the Paris Convention. DE CARVALHO, *supra* note 130, at 29. In addition, use and loss rights and unfair competition are also "mentioned" by the Agreement but not detailed. *Id.*

[139] DE CARVALHO, *supra* note 130, at 30. *See also* Paris Convention, *supra* note 130.

[140] DE CARVALHO, *supra* note 130, at 30.

[141] *Id. See* TRIPS Agreement, *supra* note 32, Part II Standards Concerning the Availability, Scope and Use of Intellectual Property Rights.

[142] DE CARVALHO, *supra* note 130, at 30. *See* TRIPS Agreement, *supra* note 32, Part III, Enforcement of Intellectual Property Rights.

[143] DE CARVALHO, *supra* note 130, at 30.

[144] TRIPS Agreement, *supra* note 32, art. 42.

[145] *Id.* at art. 51.

[146] *Id.* at art. 63.

[147] *Id.* at art. 61.

Agreement is the dispute settlement provision under the WTO's dispute settlement procedures.[148]

2. Later-in-Time Doctrine Effect

The TRIPS Agreement is a non self-executing Agreement, meaning that member countries must adopt their own laws and regulations to make the provisions effective and are required to do so by virtue of their membership.[149] Like its predecessor agreements, the Paris Convention and Berne Convention, the TRIPS Agreement provides minimum standards which member countries are bound to respect; however, countries may extend intellectual property protections beyond those standards so long as those protections remain consistent with other agreement terms and provisions.[150] de Carvalho notes that despite the liberalization of its provisions, the TRIPS Agreement does not allow members to "modify obligations established by the Agreement, unless they are authorized by the Agreement itself."[151] He notes further that "this means that implementing legislation may follow legal traditions and customary law, both dictated by repeated practices during a relevant period of time."[152]

Under United States law, the later-in-time doctrine is applicable to the TRIPS Agreement. The United States Supreme Court held in *Breard v. Greene* that:

> although treaties are recognized by our Constitution as the supreme law of the land, that status is no less true of provisions of the Constitution itself . . . "an Act of Congress . . . is on a full parity with a treaty, and that when a statute which is subsequent in time is inconsistent with a treaty, the statute to the extent of conflict renders the treaty null."[153]

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[148] DE CARVALHO, *supra* note 130, at 31; TRIPS Agreement, *supra* note 32, art. 64.

[149] DE CARVALHO, *supra* note 130, at 59.

[150] *Id.* at 60, 62. One concrete example of the minimum standards established by TRIPS is the twenty year patent life protection, which experts agree may be extended by a member country in their own regulations and laws. TRIPS Agreement, *supra* note 32, art. 33.

[151] DE CARVALHO, *supra* note 130, at 64.

[152] *Id.*

[153] Breard v. Greene, 523 U.S. 371, 376 (1998) (quoting Reid v. Covert, 354 U.S. 1, 18 (1957)).

Thus, under the later-in-time doctrine, any law passed by Congress that is inconsistent with a prior treaty agreement supersedes the treaty. The Restatement of Foreign Relations Law also recognizes that United States domestic laws supersede international treaties or laws which cannot be consistently reconciled.[154] However, this does not reduce the obligation of the United States to uphold its international responsibilities, nor does it alleviate any potential consequences of a violation of international law.[155] Further, if a treaty is determined to be inconsistent with the United States Constitution, the treaty cannot come into effect.[156] At this time, the TRIPS Agreement has been given full effect by the United States and domestic laws have consistently afforded even greater protections than the minimum requirements under the TRIPS Agreement.[157]

Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., vacated the order of the Ninth Circuit Court of Appeals dismissing a claim of intellectual property theft against the defendant, Grokster.[158] Plaintiffs, Metro-Goldwyn-Mayer Studios, alleged Grokster, a software distribution company, committed copyright infringement by distributing their free software which allowed peer-to-peer file sharing by direct computer communication.[159] Although Grokster's software was legal, it allowed users to share video, music, and other digital, copyright-protected files without proper authorization.[160] The Court noted the established principle that "[o]ne infringes contributorily by intentionally inducing or encouraging direct infringement."[161] The Court held in this case that, because Grokster knowingly distributed this software for the purpose of encouraging illegal file sharing, and because there was "evidence of the distributors' words and deeds going beyond distribution," Grokster showed intent "to cause and profit from third-party acts of copyright infringement."[162] This case is

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[154] Restatement (Third) of Foreign Relations Law of the United States § 115(1)(a) (1987).

[155] *Id.* § 115(1)(b).

[156] *Id.* § 115(3).

[157] *See* Part I of this article which discusses domestic intellectual property laws and their protections.

[158] Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 545 U.S. 913, 941 (2005).

[159] *Id.* at 920-21.

[160] *Id.* at 920-22.

[161] *Id.* at 930.

[162] *Id.* at 941. The Court remanded the case for further proceedings on the merits of MGM's claim and deemed it had substantial evidence to survive summary

a good example of the strict compliance United States courts require with laws protecting intellectual property and the high expectations of domestic enforcement of intellectual property protections.

3. Dispute Settlement Understanding

Annex 2 of the Uruguay Round Agreements details the dispute resolution mechanisms under the TRIPS Agreement.[163] The Dispute Settlement Understanding establishes the specific procedures for the WTO's settlement of disputes.[164] Under this mechanism, when a violation is discovered, a complainant country must first consult with the alleged violating member and try to reach a mutual agreement.[165] If no agreement is reached within sixty days of the consultation request and if the complainant does not believe a mutual agreement is likely, the complainant may request a panel.[166] A panel normally consists of three experts to whom both parties agree. The WTO Secretariat appoints the panel, which may be comprised of WTO staff, researchers, or WTO trade officials.[167] The panel considers the case using written and oral submissions and, if necessary, through consultation with experts.[168] The panel will issue an interim fact report and a draft report, followed by a final report. This process takes six to nine months before the panel reaches the final disposition.[169] Within sixty days thereafter, the Dispute Settlement Body ("DSB") must adopt the panel's final report.[170]

Either party to the dispute may appeal legal issues or interpretations made by the panel, but may not appeal any findings of fact.[171] On appeal, the WTO appellate body will consider the merits of the appeal and must complete proceedings within sixty or ninety days.[172] The permanent WTO appellate body is comprised of seven WTO members, who serve a term of four years. The appellate body is

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judgment. *Id.* at 940-41.

[163] Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 33 I.L.M. 1225, 1226 (1994) [hereinafter DSU].

[164] WATAL, *supra* note 117, at 60.

[165] DSU, *supra* note 163, art. 4.

[166] *Id.* at art. 4(7).

[167] WATAL, *supra* note 117, at 61. *See* DSU, *supra* note 163, art. 8.

[168] WATAL, *supra* note 117, at 61

[169] *Id. See* DSU, *supra* note 163, art. 15.

[170] WATAL, *supra* note 117, at 61. *See* DSU, *supra* note 163, art. 16.

[171] WATAL, *supra* note 117, at 61-62.

[172] *Id.* at 62. *See* DSU, *supra* note 163, art. 17.

"broadly representative of membership in the WTO."[173] Three members of the appellate board, appointed by the DSB, hear an appeal.[174] The parties to the dispute must accept the appellate body's report unreservedly.[175] Although the entire dispute resolution process should take between eighteen to twenty months from the filing of the complaint to the appellate body's adoption of the report, generally these cases take much longer.[176] If a party is found to have violated the TRIPS Agreement, the panel recommends that the party's actions be brought into conformity with the Agreement. Although these "recommendations" seem advisory, the violator must immediately comply with them, in a mutually agreeable time frame, not to exceed eighteen months.[177] Failure to comply in a timely manner may result in mutually agreed compensation. Retaliation, such as withdrawal of trade, is not allowed under the TRIPS Agreement, unless express authorization is provided from the DSB after a party fails to agree to appropriate compensable damages.[178]

4. Reprisals

Because of their commitments to the WTO dispute resolution mechanisms under the TRIPS Agreement, members must comply with the above-outlined processes and procedures, rather than seek unilateral reprisals against allegedly violating countries. de Carvalho notes that of all the TRIPS Agreement complaints that have been filed in its ten years of existence, approximately half deal with patent infringements.[179] Of the twelve requests for consultations by the DSB that have been filed thus far, the United States was the complainant in seven cases and the respondent in two.[180] Only one of the complaints lodged at this time has been against China, and most have been resolved by mutual agreement or dismissed by the panel or appellate body.[181] In one case, a complaint by the United States against Canada

[173] WATAL, *supra* note 117, at 62.
[174] *Id.* at 62.
[175] *Id.*
[176] *Id.* Although there are a number of factors that may contribute to this increased length of time to complete the dispute resolution process, Watal postulates often panel selection, logistical delays, and extensions of time are the major contributors. *Id.*
[177] *Id.* at 62-63.
[178] *Id.* at 63.
[179] DE CARVALHO, *supra* note 130, at 412.
[180] *Id.* at 412-15.
[181] Press Release from the Office of the United States Trade Representative,

for failure to grant patents a term of protection greater than seventeen years was resolved in favor of the United States.[182] In its eleven-year history in the WTO, the DSB has approved retaliatory measures in only two instances, which were unrelated to intellectual property rights.[183] However, the majority of intellectual property infringement cases under the TRIPS Agreement that undergo the WTO dispute resolution mechanism are settled by mutual agreement. This is a positive result in the respect that the consultations between countries seem to be fruitful and come to agreeable resolution without further legal process.[184] However, there does not seem to be any increased enforcement or protection of intellectual property rights or increased compliance by countries as a result of these processes, as shown by the Special 301 Report results.[185]

D. WTO Cases Under the TRIPS Agreement

Although the United States has filed complaints with the WTO for TRIPS Agreement violations, it has filed only three intellectual property rights violations under the TRIPS Agreement since 2000.[186] In one case, the United States filed a request for consultations on May

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Robert Zoellick, *U.S. and China Resolve WTO Dispute Regarding China's Tax on Semiconductors* (July 8, 2004), http://www.ustr.gov (follow "WTO" hyperlink; then follow "Dispute Settlement" hyperlink). Part III.D of this article will discuss the case in greater detail.

[182] DE CARVALHO, *supra* note 130, at 414.

[183] WATAL, *supra* note 117, at 63. *See* World Trade Organization Dispute Settlement-Index of Disputes Issues, http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#trips (last visited May 1, 2007). The two cases referred to by Watal included the complaint brought forward by the United States and Canada against the European Communities (WT/DS26, 48), which challenged the importation of meat from animals to which six growth hormones had been given. This case was brought in 1996 and has yet to be completely resolved. World Trade Organization Dispute Settlement-The Disputes-DS26, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm (last visited May 1, 2007). The second case is known as the "bananas case." In 1999, Mexico, Panama, Honduras, Guatemala, and the United States requested consultations against the European Communities ("EC"). The complaint centered around the EC "Regime for the Importation, Sale and Distribution of Bananas." In both of these cases, the DSB authorized retaliatory action. World Trade Organization Dispute Settlement-The Disputes–DS158, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds158_e.htm (last visited May 1, 2007).

[184] *Cf.* U.N Charter art. 33.

[185] United States Trade Representative, Special 301 Report (2006). Part III.E of this article will address the Special 301 Report.

[186] World Trade Organization Dispute Settlement-The Disputes, *supra* note 183.

30, 2000, against Brazil with respect to its insufficient patent protections. The United States asserted that Brazil's 1996 industrial property law was inconsistent with Brazil's obligations under the TRIPS Agreement.[187] Brazil's law established a "local working requirement" for the privilege of exclusive patent rights, which the United States asserted would impose compulsory licensing requirements on patents if the patents were not "worked" in Brazil.[188] The United States claimed that this requirement violated Articles 27 and 28 of the TRIPS Agreement.[189] Article 27 of the TRIPS Agreement, Section 1, provides that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[190] Thus, Brazil's restriction of a "local working requirement" violated the TRIPS Agreement requirement that prohibits member discrimination against imported patented subject matter.[191] Further, Article 28 allows the owner of a patent right "where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."[192] The United States argued that Brazil's definition of "failure to be worked as failure to manufacture or incomplete manufacture of the product or failure to make full use of the patented process to be inconsistent with their obligation under TRIPS."[193] Although the DSB assigned a panel to hear the dispute, the parties reported they came to a mutually satisfactory agreement on July 5, 2001.[194]

The United States also instituted consultations on May 30, 2000, against Argentina with regard to certain patent laws which the United States argued were inconsistent with TRIPS Agreement requirements under Articles 27 and 28.[195] Argentina's laws allegedly

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[187] World Trade Organization Dispute Settlement, Dispute DS199: Brazil-Measures Affecting Patent Protection, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (last visited May 1, 2007).

[188] *Id.*

[189] *Id.*

[190] TRIPS Agreement, *supra* note 32, art. 27(1).

[191] World Trade Organization, Dispute DS199, *supra* note 187.

[192] TRIPS Agreement, *supra* note 32, art. 28(1)(b).

[193] World Trade Organization, Dispute DS199, *supra* note 187.

[194] *Id.* Information about the details or documents between the parties involved detailing how the dispute was resolved was not available.

[195] World Trade Organization Dispute Settlement, Dispute DS196: Argentina-

failed to protect patent rights and test data in many respects, including denial of certain exclusive protective rights, exclusion of micro-organisms and other patentable material from protection, absence of safeguard provisions for compulsory licenses, and improper limitations on transitional patents resulting in the denial of TRIPS protection to those patents.[196] An agreement was reached between the United States and Argentina in 2002.[197]

On March 18, 2004, the United States filed its most recent dispute with respect to intellectual property rights infringement under the TRIPS Agreement against China,[198] which remains the largest producer of counterfeit goods.[199] The United States Trade Representative, Robert B. Zoellick, reports that the fastest growing semiconductor market is in China and its exports of the same are worth over $2 billion to American manufacturers.[200] China is also the third largest consumer of integrated circuits globally.[201] Exports of integrated circuits to China from the United States are supplemented by a seventeen percent Value Added Tax ("VAT"), although circuits produced in China are taxed considerably less because they receive a partial refund of that seventeen percent.[202] Thus, circuits from the United States cost comparatively more and in some cases the VAT tax on Chinese circuits may be as low as three percent after the refunds.[203] The USTR reports that China also gives a partial refund to circuits manufactured abroad, but designed in China.[204] These tax breaks conflict with the 1994 GATT Protocol on the Accession of the People's Republic of China, as the WTO explicitly prohibits members from discriminating against foreign goods.[205] As a result, the United

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Certain Measures on the Protection of Patents and Test Data, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm (last visited May 1, 2007). The United States also argued the laws were inconsistent with Articles 31, 34, 39, 50, 62, 65, and 70. *Id.*

[196] *Id.*

[197] *Id.* Further detail on the settlement terms was not provided.

[198] World Trade Organization Dispute Settlement, Dispute DS309: China—Value-Added Tax on Integrated Circuits, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds309_e.htm (last visited May 1, 2007).

[199] *See* discussion *supra* Part II.D.

[200] Press Release from the Office of the USTR, *supra* note 181.

[201] *Id.*

[202] World Trade Organization, Dispute DS309, *supra* note 198.

[203] Press Release from the Office of the USTR, *supra* note 181.

[204] *Id.*

[205] World Trade Organization, Dispute DS309, *supra* note 198. *See generally* Part III.B.

States instituted a WTO action against China and other TRIPS members including Japan, Mexico and the European Communities joined the consultations.[206] By July 14, 2004, China had resolved its problem with the United States.[207] The United States notified the DSB that "China agreed to amend or revoke the measures at issue to eliminate the availability of VAT refunds on integrated circuits produced and sold in China and on integrated circuits designed in China but manufactured abroad by November 1, 2004, and September 1, 2004, respectively."[208] China therefore has changed its policy and no longer unfairly favors its products while disfavoring trade partners.

The resolution of this dispute represents a significant step forward for the United States and all WTO and TRIPS Agreement members in the realm of dispute resolution. The United States' claim against China was one of the more significant disputes for three main reasons: (1) it was the first action taken by any country against China; (2) it was financially crucial to the protection of a valuable industry and segment of industrial intellectual property for the United States; and (3) it represented the joint efforts of many member countries who voluntarily became parties to the action. As reported earlier, China is the major infringer of intellectual property rights globally. China is responsible for the greatest quantity of counterfeit products in the market, which costs the United States billions of dollars every year. For too long China has been allowed to continue this action through the inaction of other member countries, including the United States. The United States allowed the problem to intensify despite China's repeated failure to honor bilateral and multilateral agreements attempting to resolve the problems. However, enforcement in China itself remains weak and must be addressed by the Chinese government, which has jurisdiction over the infringers and can exact criminal and high civil penalties. Further, the resolution of the semiconductor VAT issue was vital to the continued viability of intellectual property in the United States. It was a significant step that other member countries such as Mexico and the European Communities joined the action against China in the WTO. Making joint international efforts to combat blatant intellectual property and trade infringements will certainly be a key component in addressing the ways these rights can be better protected in the future.

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[206] World Trade Organization, Dispute DS309, *supra* note 198.
[207] *Id.*
[208] *Id.*

E. The 2006 Special 301 Report

As a part of the United States' ongoing efforts to target and alleviate global intellectual property theft, the "Special 301" provision of the amended Trade Act of 1974 mandated that the United States Trade Representative conduct yearly investigations of foreign countries' protection of intellectual property rights.[209] A country may be designated as a "Priority Foreign Country" if it has exceptionally egregious practices and a negative impact on the protection of U.S. intellectual property goods.[210] A country may also be designated a Priority Foreign Country if it fails to make significant progress in negotiations or if it fails to engage in good faith negotiations to address its adverse practices and policies.[211] Once a country has been designated as a Priority Foreign Country, the USTR must determine whether or not to begin a Special 301 investigation regarding the Priority Foreign Country status within thirty days of that designation.[212] If an investigation is conducted, the USTR must re-evaluate the offenses of that country within six months. At that time, the USTR may institute applicable Section 301 bilateral trade sanctions.[213] The USTR may also designate countries under the Special 301 "Priority Watch List" or the "Watch List."[214] The designation of Priority Watch List indicates a country has failed to provide sufficient intellectual property protections or enforcement mechanisms, or suffers from a lack of market access for those reliant upon intellectual property rights protection.[215] A Watch List designation means the USTR has found specific problems regarding market access, intellectual property enforcement, or protection.[216] Additionally, the USTR may conduct "Out-of-Cycle Reviews" at any time throughout the year and at that time may change the status of a country or identify a country under the appropriate designation.[217]

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[209] Trade Act of 1974, 19 U.S.C. § 2242 (2006).

[210] *Id. See also* Office of the United States Trade Representative, Special 301 Report (2006), http://www.ustr.gov (follow "Trade Sectors" hyperlink; then follow "USTR Focus on Intellectual Property and Innovation" hyperlink; then follow "2006 Special 301 Report" hyperlink).

[211] Special 301 Report, *supra* note 210, "Background on Special 301."

[212] *Id.*

[213] U.S. Department of State, The U.S. Special 301 Process, http://usinfo.state.gov/journals/ites/0598/ijee/ipfact1.htm (last visited May 1, 2007).

[214] Special 301 Report, *supra* note 210, "Background on Special 301."

[215] *Id.*

[216] *Id.*

[217] The U.S. Special 301 Process, *supra*, note 213.

The 2006 Special 301 Report investigated eighty-seven countries.[218] The USTR reported that China's disregard and lack of enforcement of intellectual property rights continues to be problematic.[219] The USTR stated that "[a]lthough this year's Special 301 Report shows positive progress in many countries, rampant counterfeiting and piracy problems continue to plague both China and Russia, indicating a critical need for stronger intellectual property protection in China and Russia."[220] The USTR determined that China will continue to remain on the Priority Watch List under heightened scrutiny.[221] The USTR recognized that China had made some progress towards correcting the abuse of intellectual property rights, specifically with anti-piracy campaigns; however, that progress was not sufficient to bring the country into compliance with WTO standards. The USTR reported that "overall piracy and counterfeiting levels in China remained unacceptably high."[222] The USTR characterized China's copyright infringement levels at "85 to 93 percent, indicating little to no improvement."[223] The USTR took into account economic losses in the United States due to China's lack of intellectual property protection and the overall threat to safety that counterfeit products presented.[224] Under the TRIPS Agreement, Article 63, to which China is a party, countries must be transparent as to the rights provided and enforcement exercised.[225] China, however, remains unwilling to make its intellectual property rights regime appropriately transparent.[226] Further, China is required to maintain criminal enforcement of intellectual property infringement under Article 61 of the TRIPS Agreement in order to deter criminals from future violations.[227] Again, China falls short of this obligation, as previously discussed with regard to the recent Supreme People's Court and Supreme People's Procuratorate declarations.[228]

As previously discussed, although China has passed laws to bring itself into compliance with international WTO requirements,

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[218] Special 301 Report, *supra* note 210, "Executive Summary."
[219] *Id.*
[220] *Id.*
[221] *Id.*
[222] Special 301 Report, *supra* note 210, "Priority Watch List."
[223] *Id.*
[224] *Id.*
[225] *See* the TRIPS Agreement, *supra* note 32, art. 63.
[226] Special 301 Report, *supra* note 210, "Priority Watch List."
[227] *See* the TRIPS Agreement, *supra* note 32, art. 61.
[228] *See supra* note 107 and text.

China fails to enforce these laws by neither prosecuting infringers nor instituting appropriate deterring punishments. In fact, the USTR investigation found that "China's own 2004 data showed that it channeled more than 99 percent of copyright and trademark cases into its administrative systems and turned less than one percent of cases over to police."[229] The USTR has identified this lack of criminal enforcement as a major reason for China's overall lack of intellectual property rights protections.[230] China has made many empty promises but its lack of enforcement of its own laws as well as its failure to comply with the standards set forth by the TRIPS Agreement and obligations as a member of the WTO continues to cost American companies billions in lost intellectual property revenues.

There are a number of countries on the Priority Watch List, including Argentina, Brazil, India, Ukraine, and Russia.[231] Russia remained on the Priority Watch List for "serious concerns about the continued increase in optical disc pirate production [in Russian plants] and the growth of Internet piracy on Russian websites."[232] These deficiencies explain why the USTR did not change Russia's current status.

Currently, forty-eight countries are on the Priority Watch List, Watch List, or Section 306 Monitoring.[233] Included on the Watch List are Canada, Mexico, the Dominican Republic, Costa Rica, and Guatemala.[234] Although Costa Rica recently signed the Dominican Republic-Central America-United States Free Trade Agreement ("CAFTA-DR") with the United States, Costa Rica remains on the Watch List because the USTR determined that this country continues to have problems "with respect to copyright piracy and trademark counterfeiting."[235] The Dominican Republic similarly remains on the Watch List for its slow progress on many intellectual property protection issues, despite its obligations under CAFTA-DR.[236]

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[229] Special 301 Report, *supra* note 210, "Priority Watch List."

[230] *Id.*

[231] *Id.*

[232] *Id.*

[233] *Id.*

[234] Special 301 Report, *supra* note 210, "Watch List."

[235] *Id.* Part III.F of this article provides a detailed analysis of the CAFTA-DR Agreement.

[236] *Id.*

F. CAFTA-DR

Nuno Pires de Carvalho notes that, although many believe the primary purpose of the TRIPS Agreement is the protection of intellectual property rights, protection is actually an incidental, and the Agreement's primary purpose is to promote free trade.[237] The Agreement's purpose is understandable when one considers that the TRIPS Agreement was adopted as a part of the creation of the WTO. This correlation only reinforces the important link between intellectual property and trade. For instance, protecting industrial designs clearly influences textile trade, just as the protection of geographical indications affects agriculture.[238] Protecting global intellectual property rights will help further international trade.

On August 5, 2004, the United States signed the CAFTA-DR Free Trade Agreement ("FTA") with Costa Rica, Guatemala, Nicaragua, the Dominican Republic, and Honduras.[239] Free trade agreements create free trade areas, "under which member countries agree to eliminate tariffs and non-tariff barriers on trade in goods within the FTA, but each country maintains its own trade policies, including tariffs on trade outside the region."[240] By securing markets for goods produced in member countries, the agreements promote economic growth and facilitate trade between countries.[241] Such agreements also seek to increase global economic growth and trade, stabilize trade to shield domestic manufacturers from unfair trade

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[237] DE CARVALHO, *supra* note 130, at 40.

[238] *Id.* at 41.

[239] J.F. Hornbeck, Specialist in International Trade and Finance: Foreign Affairs, Defense and Trade Division, The Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR) 1 (April 4, 2005) (unpublished Congressional Research Service Report for Congress, on file with The Library of Congress code RL31870), *available at* http://www.opencrs.com/document/RL31870 /2005-04-04%2000:00:00. *See also* 19 U.S.C. §§ 4001-4111 (2006); CAFTA-DR, 43 I.L.M. 514, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral /CAFTA/CAFTA-DR_Final_Texts/Section_Index.html?ht= [hereinafter CAFTA-DR]. CAFTA-DR was approved by El Salvador, Honduras, Nicaragua, and Guatemala respectively in 2006. *See* U.S. Government Export Portal, U.S.-CAFTA-DR Free Trade Agreement-How Can U.S. Companies Benefit, http://www.export. gov/fta/complete/cafta/index.asp?dName=CAFTA.

[240] William H. Cooper, Specialist in International Trade and Finance: Foreign Affairs, Defense and Trade Division, Free Trade Agreements: Impact on U.S. Trade and Implications for U.S. Trade Policy 2 (August 1, 2006) (unpublished Congressional Research Service Report for Congress, on file with The Library of Congress code RL31356) *available at* http://www.opencrs.com/document/RL31356.

[241] *Id.* at 3.

practices, and maintain control over international trade to enhance national security.[242]

The United States House and Senate passed legislation implementing CAFTA-DR on July 28, 2005, and the CAFTA-DR Free Trade Agreement came into force on January 1, 2006.[243] Chapter 15 of CAFTA-DR addresses the protection of intellectual property rights and the detail provided to this area of law is much greater than that in free trade agreements of years past, including the North American Free Trade Agreement.[244] Although CAFTA-DR has been criticized with regard to its potential effects on developing countries and their access to products such as pharmaceutical patents for HIV-AIDS drugs, etc., its protection of intellectual property data in the United States exceeds current standards.[245] CAFTA-DR specifically addresses protection of trademarks, internet domain names, geographical indications, and copyrights and related rights. CAFTA-DR makes specific and detailed protection provisions for all of these areas of intellectual property and incorporates a number of other treaties including the TRIPS Agreement.[246] Countries party to the CAFTA-DR must accede to these other international intellectual property treaties.[247] Further, Article 15.11 delineates the rights and duties of members to the treaty in the event of an infringement of this agreement. Parties are subject to civil penalties, including payment of damages and profits received, attorneys' fees and costs, and seizure, or destruction of improper goods.[248] CAFTA-DR also provides for criminal procedures and remedies for any party's willful violation of intellectual property rights through production and dissemination of counterfeit or pirated goods.[249] The remedies that may be provided include monetary payment, imprisonment, and seizure among others.[250] Most significantly, the protections of the CAFTA-DR go

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[242] *Id.*

[243] H.R. 3045, 109th Cong. (2005); S. 1307, 109th Cong. (2005). The House of Representatives passed the legislation by a narrow margin of 217 to 215. H.R. 3045. The Senate passed the bill by nearly an equally close margin of 54-45. S. 1307.

[244] CAFTA-DR, *supra* note 239, ch. 15; *see also* North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289 (pts. 1-3); 32 I.L.M. 605 (pts. 4-8.) (entered into force Jan. 1, 1994).

[245] Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 85-86 (2004).

[246] CAFTA-DR, *supra* note 239, ch. 15.

[247] *Id.*

[248] *Id.* at ch. 15, art. 15.11(7)-(11).

[249] *Id.* at ch. 15, art. 15.11(26)(a).

[250] *Id*. at ch. 15, art. 15.11(26)(b)(c).

beyond those provided by the WTO and are many steps closer to meeting the needs of American businesses.[251]

The United States is correct in using free trade agreements such as CAFTA-DR to seek an increase in global recognition of intellectual property theft, global enforcement of intellectual property rights, and stiff monetary and criminal penalties for infringers. These agreements provide the United States with some leverage that is not only important for the economy in the context of free trade but also in the protection of the multi-billion dollar intellectual property industry.

In considering the success of CAFTA-DR, the status of the Dominican Republic, Costa Rica, and Guatemala in the Special 301 Report should be of particular concern.[252] Despite the higher protection requirements that bilateral free trade agreements and other treaties give to intellectual property rights, those protections are meaningless without strict enforcement and adherence to the agreement by all parties. It is clearly not enough that agreements and treaties purport to give greater protections to intellectual property holders if countries consistently fail to bring themselves into compliance with their obligations and duties to their fellow treaty signers. Although the level of infringements on intellectual property rights by the Dominican Republic, Costa Rica, and Guatemala are not near the level of China's infringements, a large problem remains in these countries and action must be taken to correct this issue. It seems unwise that the United States entered into lucrative agreements with these countries despite their already failing intellectual property protections. The United States should have insisted on more evidence of compliance before signing the CAFTA-DR, which would have perhaps given these countries greater incentives. The USTR Special 301 Report does commend each country for its efforts to increase intellectual property protections—but it also commends China for the same.[253] Implementing new legislation to increase protection and enforcement does take time. Thus, while it is fair to give these countries some leeway in addressing these problems, most experts agree improvement is not occurring fast enough and more must be done.

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[251] J.F. Hornbeck, *supra* note 239, at 21-23.
[252] *See* Special 301 Report, *supra* note 210, "Watch List."
[253] *Id.* at "Priority Watch List," "Watch List."

IV. FUTURE EFFORTS TO CURTAIL GLOBAL INTELLECTUAL PROPERTY THEFT

The United States government has undertaken a number of initiatives to combat current levels of intellectual property theft. The U.S. Department of Commerce announced three new initiatives to combat intellectual property theft on September 21, 2005.[254] Secretary of Commerce Carlos Gutierrez unveiled a new Small Business Outreach program that will work with American companies and assist them in protecting intellectual property.[255] The formation of a Global Intellectual Property Academy was also announced to coordinate various agencies from other governments to provide training to assist developing countries in understanding and enforcing intellectual property rights.[256] The Administration will appoint Intellectual Property Rights Experts to promote intellectual property rights and infringement enforcement in problematic countries such as China and Russia.[257]

In July 2005, the Administration appointed a new Coordinator of International Intellectual Property Enforcement to "work with agencies across the Administration to develop policies to address international intellectual property violations and enforce intellectual property overseas."[258] Chris Israel, Deputy Chief of Staff for the Secretary of Commerce, leads the National Intellectual Property Law Enforcement Coordination Council's ("NIPLECC") international efforts to enforce intellectual property rights and is a key coordinator of the STOP! Initiative, another new program.[259] Both of these programs address intellectual property law issues. Congress created NIPLECC in 1999 to harmonize U.S. and international attempts at enforcing intellectual property laws.[260] However, according to testimony by Loren Yager, Director of International Affairs and Trade, at a Senate hearing in 2005, NIPLECC "has struggled to define its

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[254] Press Release, Hon. Carlos Gutierrez, *supra* note 14.

[255] *Id.*

[256] *Id.*

[257] *Id.*

[258] Press Release, Hon. Carlos Gutierrez, *supra* note 51.

[259] *Id*.

[260] *U.S. Efforts Have Contributed to Strengthened Laws Overseas, but Significant Enforcement Challenges Remain: Testimony Before the Senate Comm. on Homeland Sec. and Gov. Affairs, Subcomm. on Oversight of Gov. Management, the Fed. Workforce, and the District of Columbia*, 108th Cong. 10 (2005) (statement of Loren Yager, Director International Affairs and Trade).

purpose and has had little discernable impact."[261] Criticisms from within the group have found NIPLECC to be unfocused, understaffed, and under-funded.[262]

STOP! began in October 2004 as a joint project between the Department of Homeland Security, U.S. Department of Justice, USTR, U.S. Department of Commerce, and the Bush Administration.[263] STOP! combines the efforts of these departments as well as the Food and Drug Administration and the State Department to achieve five major goals.[264] STOP! seeks to enforce intellectual property rights laws against criminal offenders, prevent counterfeit goods from crossing the borders into the United States, increase knowledge of American companies as to how to protect their intellectual property rights, keep counterfeit goods from getting into mainstream market supplies, and strengthen joint international efforts to curtail intellectual property theft.[265] A STOP! hotline exists for companies seeking intellectual property rights information or to report intellectual property rights related issues.[266] Thus far, the STOP! program seems to be making progress, particularly in its coordination efforts with American companies.[267]

International efforts at curtailing intellectual property theft remain weak, as illustrated by the results of the 2006 Special 301 Report.[268] Although the United States' enforcement efforts have increased, the efforts of its foreign trading partners have not. As Yager noted in her testimony:

> Although U.S. law enforcement does undertake international cooperative activities to enforce intellectual property rights overseas, executing these efforts can prove difficult. For example, according to DHS and Justice officials, U.S. efforts to investigate IPR violations overseas are complicated by a lack of jurisdiction as well as by the fact that U.S. officials must convince foreign officials to take action.[269]

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[261] *Id.*
[262] *Id.* at 11.
[263] *Id.* at 12.
[264] *Id.*
[265] *Id.*
[266] *Id.* at 13
[267] *Id.*
[268] *See* discussion of Special 301 Report, *supra* note 210, Part III.E.
[269] Statement of Loren Yager, *supra* note 260, at 16.

Thus, without recognition of the problem and cooperation by foreign governments, solving the problem of international intellectual property theft will be impossible. Yager also notes that, despite costs to the United States economy, intellectual property theft is not on the priority list of foreign affairs issues.[270] Economically, consumers are attracted to pirated goods such as digital media, because of the cheap upfront cost, while the incentives are huge for those in the pirating industry.[271]

Although many in the federal government do not recognize intellectual property theft as a major priority, there are some who do, such as the few members of Congress who voted to remove the United States from the realm of WTO dispute resolution.[272] On November 17, 2005, two bills were introduced in the House of Representatives to address intellectual property rights. House Concurrent Resolution 303, sponsored by Oregon Representative Peter DeFazio, was a bill "[u]rging the United States Trade Representative to take action to ensure that the People's Republic of China complies with its obligations to protect intellectual property rights."[273] The bill noted that despite China's bilateral commitments made to the United States in 1992, 1995, and 1996, and despite its succession to the WTO and the TRIPS Agreement, China continued to violate international intellectual property standards.[274] The bill took notice of the fact that China's infringements resulted in severe losses to the American economy and that manufacturers, the Administration, and the USTR have taken careful notice of the specific problems with China.[275] Further, the bill found China's actions or lack of them unjustifiable.[276] The bill "urges the United States Trade Representative to take action under Section 301 of the Trade Act of 1971 . . . including the imposition of bilateral tariffs."[277] The bill urged the USTR to file complaints with the WTO to force China to comply with its international obligations.[278] This measure was referred to the House Ways and Means Committee for consideration.[279] It has not been

[270] *Id.* at 17.
[271] *Id.*
[272] *See* Part III.A: The World Trade Organization.
[273] H.R. Con. Res. 303, 109th Cong. (2005).
[274] *Id.*
[275] *Id.*
[276] *Id.*
[277] *Id.*
[278] *Id.*
[279] *Id.*

renewed in the 110th Congress.[280] Based on the text of the legislation, if the measure was renewed and passed both the House and Senate, it would have no real impact in holding China accountable for its lack of protection and empty promises because as a concurrent resolution, it lacks the force of law.

Similarly, Representative Darrell Issa from California introduced House Concurrent Resolution 230 with the purpose of expressing the opinion of Congress that the "Russian Federation should provide adequate and effective protection of intellectual property rights, or it risks losing its eligibility to participate in the Generalized System of Preferences (GSP) program."[281] This measure passed the House 421 to 2 and passed the Senate on December 22, 2005.[282] Much like the resolution relating to China, this measure recognized the burdens posed on the United States economy by Russian theft of intellectual property and stated that the Russian government fails to adequately regulate blatant intellectual property theft in that country.[283] This measure has strong language condemning the acts of Russia. Again, although the measure may temporarily draw attention to the problem, as a concurrent resolution, it lacks the force of law. At best, the measure may shed more light on the problem of intellectual property theft with the intention of forcing the USTR, Congress, and the Administration to make the problem a priority.

Finally, eight industrialized nations who formed the Group of Eight ("G8"), recently convened and stated G8 would increase efforts to fight global counterfeiting and piracy, in recognition that organized crime often has a hand in such large scale operations.[284] The G8, composed of the United States, United Kingdom, Canada, Germany, Russia, Italy, Japan, and France, vows to increase studies of the problem, to increase detection, deterrence, and enforcement procedures and regulations, and to work closely with other government officials to increase awareness and international bonds to fight intellectual property theft.[285] Again, this is a significant international step in the right direction to bring together key countries to fight the problem and increase awareness and compliance.

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[280] *Id.*

[281] H.R. Con. Res. 230, 109th Cong. (2005).

[282] *Id.*

[283] *Id.*

[284] Press Release, G8, G8 Vows to Increase Fight Against Intellectual Property Theft (July 8, 2005), http://usinfo.state.gov/ei/ Archive/ 2005/Jul/08-989233.html.

[285] *Id.*

V. CONCLUDING REMARKS

The problem of global intellectual property theft has an enormous impact on the United States. In addition to the economic costs to businesses and the economy, counterfeit goods cost Americans jobs and negatively impact international relationships. China and Russia continue to be the top producers of counterfeit goods and rank among the worst countries for intellectual property theft.

The TRIPS Agreement represented a substantial step forward in terms of international laws protecting intellectual property rights. While dispute settlement through the WTO under the TRIPS Agreement has resolved some issues, only a limited number of disputes have been filed, and overall the impact has been weak. The 2006 Special 301 Report supports this conclusion, specifically with regard to China and Russia, who have failed to make significant intellectual property rights improvements. The United States continues to move forward in its mission to increase intellectual property protections through the use of its bilateral free trade agreements, most recently with the CAFTA-DR.

Further, the United States Congress continues to move forward with new legislation and administrative initiatives aimed at protecting intellectual property rights in this country and abroad. However, implementation and enforcement of these ideas is still questionable. It is yet to be seen if such initiatives will have an actual impact. Although there are no easy answers to this problem, the first step is international awareness and the banding together of countries to pressure those countries refusing to play by the rules. Both the United States and foreign legislatures need to make addressing this dilemma a priority. It is important to continue to work with countries such as China to educate and assist the government with enforcing its domestic and international intellectual property rights laws and obligations. The key to better protection of valuable intellectual property rights, whether in the United States or abroad, is strong enforcement of both domestic and international laws.

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MOST VALUABLE PATENT: THE USE OF NATURAL PHENOMENA IN PATENTS

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The power of patents has always struck a tenuous balance between encouraging innovation and sanctioning monopolies. Justice Bradley's much-referenced quote explains this tension:

> The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge and makes a step in advance in the useful arts. Such inventors are worthy of all favor. It was never the object of those laws to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures. Such an indiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention.[1]

The tension becomes particularly poignant when the invention incorporates a judicial exception. The three judicial exceptions to

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[1] Atl. Works v. Brady, 107 U.S. 192, 200 (1883).

what constitutes patentable material are laws of nature, abstract ideas, and natural phenomena. This article will highlight the natural phenomena judicial exception. Phenomena of nature are facts of nature or elements that exist in nature which are merely objects of discovery and not invention.[2] As the Supreme Court has noted, Newton could not have patented gravity nor could Einstein have patented $E=mc^2$.[3] But in *Diamond v. Diehr*, the Court conceded that incorporating such phenomena in a *process* or using phenomena in an *application* does not render an invention unpatentable.[4] The multitude of patents and applications that use genetic and biological elements in process and method patents have many practitioners questioning the wisdom of the Court's decision. The recent decision by the Court to address these patents in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.* ("*LabCorp*"),[5] followed by a sharp pivot and dismissal of the original grant of certiorari,[6] has left the issue in flux.

This article will discuss the use of phenomena of nature in patents. Part I will give an overview of the *LabCorp* case. Part II will highlight the issues and concerns the public, academics, and practitioners have regarding patents that use phenomena of nature as part of a process or method. Part III will discuss the current Supreme Court test and provide an analysis of an alternative test. Part IV will conclude with a summary of why natural phenomena are still important elements in the patent system and the author's opinion on how concern over their use should be addressed.

I. LABCORP: THE SUPREME COURT PUNTS

This part will first outline the facts of the underlying Federal Circuit case, and then move to the analysis the court used in its determination. This part will conclude with an overview of the dissent in the Supreme Court's dismissal of the original grant of certiorari.

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[2] Diamond v. Diehr, 450 U.S. 175, 188 n.11 (1981). Justice Douglas described phenomena of nature as follows: "[t]hey are manifestations of laws of Nature, free to all men and reserved exclusively to none." *See* Funk Bros. Seed Co. v. Kalo Inoculant, 333 U.S. 127, 130 (1948). The author notes that *Diamond v. Diehr* is generally referred to as *Diehr* and will be for the remainder of the article.

[3] *Diehr*, 450 U.S. at 185 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[4] *Id.* at 187 (emphasis added).

[5] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 601 (2005).

[6] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006).

The Federal Circuit case of *Metabolite Laboratories, Inc. v. Laboratory Corporation of America Holdings*[7] started as many patent litigations start: one company accused the other of infringing one or more patent claims in one or more patents. The patent at issue in this case was patent 4,940,658 ('658) that had been licensed to Metabolite.[8] The '658 patent claimed the use of a total homocysteine test and a total homocysteine-methylmalonic acid test.[9] These tests are used by doctors to determine if their patients are suffering from cobalamin (B_{12}) or folate (folic acid) vitamin deficiencies.[10] A deficiency of either cobalamin or folate can lead to various diseases, but both are easily treated with vitamin supplements.[11] The patent characterizes the tests disclosed in the claims as more efficient than the previous diagnostic devices that were in use.[12] Metabolite and LabCorp had entered into a contract that sub-licensed the use of Metabolite's total homocysteine test to LabCorp.[13] LabCorp however, began to use Abbott Laboratories' total homocysteine test and stopped paying royalty fees to Metabolite.[14] Metabolite then accused LabCorp of both indirectly infringing Metabolite's patent and violating the contract between the two companies.[15] Both the District Court and the Federal Circuit agreed with Metabolite and found LabCorp guilty of infringement.[16]

In its decision, the Federal Circuit interpreted Claim 13[17] as encompassing "a method for detecting a vitamin deficiency."[18] Additionally, the court interpreted the term "correlating" to refer to the doctor's comparison of the total elevated homocysteine levels against

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[7] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

[8] *Id.* at 1358.

[9] *Id.* at 1358. The total homocysteine test became the point of litigation in *LabCorp*. Claim 13 encompasses the total homocysteine test. *Id.* at 1358-59.

[10] *Id.* at 1358.

[11] *Id.*

[12] U.S. Patent No. 4,940,658 (issued July 10, 1990).

[13] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1359 (Fed. Cir. 2004).

[14] *Id.*

[15] *Id.*

[16] *Id.* at 1358.

[17] The text of Claim 13 is as follows: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." U.S. Patent No. 4,940,658, *supra* note 12.

[18] *Metabolite Labs., Inc.*, 370 F.3d at 1362.

the normal homocysteine levels.[19] As "correlating" is part of Claim 13, this comparison is part of the method claimed in the patent. Therefore, infringement occurred when the assay of homocysteine levels was completed and the results were sent to doctors who compared the homocysteine levels from the assay to normal homocysteine levels to determine if their patients were suffering from cobalamin or folate deficiencies.[20]

The Federal Circuit did not address whether the inclusion of homocysteine in this method allowed unpatentable subject matter to be patented in violation of 35 U.S.C. § 101. Although LabCorp did not expressly press the Federal Circuit to include that question in its analysis,[21] LabCorp did argue that if the court found Claim 13 was valid, then any scientific concept could be patented in a "vague, two step 'test-plus-correlate' claim."[22] The Federal Circuit refused to address the issue. However, the Supreme Court originally did grant a writ of certiorari to address whether the use of homocysteine in the method was unpatentable.[23] The question presented was:

> Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.[24]

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[19] *Id.* at 1363-64.

[20] *Id.* at 1364. *See also* Brief for the United States as amicus curiae at 22, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3533248, at *22 [hereinafter U.S. Brief].

[21] *Metabolite Labs., Inc.*, 370 F.3d at 1365-66. LabCorp argued that the '658 patent was invalid on different grounds, including "indefiniteness, lack of written description and enablement, anticipation, and obviousness" but it did not assert that the subject matter was unpatentable under 35 U.S.C. § 101 (2006). *Id.*

[22] Corrected Brief for Appellant Laboratory Corp. of America Holdings at 38, Metobolite Labs. Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004) (No. 03-1120), 2003 WL 24305314, at *38.

[23] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 601 (2005).

[24] Petition for a Writ of Certiorari at i, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (Nov. 3, 2004) (No. 04-607), 2004 WL 2505526, at *i (alteration in original).

Three of the Justices believed the original question warranted an answer and would have kept the grant of certiorari in place.[25]

The dissent in the Supreme Court's dismissal of the grant of certiorari makes clear that the Court will have to address the issue of the inclusion of phenomena of nature in method or process patents soon. From the dissent's point of view, not reaching a decision in *LabCorp* "threatens to leave the medical profession subject to the restrictions imposed" on these method patents using phenomena of nature.[26]

The dissent begins its argument by outlining the precedent and justifications for the phenomena of nature patent exclusion. Justice Breyer first points to the *Diamond v. Diehr*[27] principle of law that "laws of nature, natural phenomena, and abstract ideas" are all excluded from patent protection.[28] The dissent notes that the justification for excluding "laws of nature" is that "sometimes *too much* patent protection can impede . . . the constitutional objective of patent and copyright protection."[29] The dissent goes on to commend the Court's decision to exclude phenomena of nature as "reflect[ing] a basic judgment" that allowing such patents would "interfere with . . . development and the further spread of useful knowledge itself."[30] In reviewing past decisions, the dissent appears to highlight the strength of the phenomena of nature patent exclusion as justification for hearing the *LabCorp* case, even in the face of several procedural problems.[31] Justice Breyer gives three distinct reasons why the Court should have heard the *LabCorp* case.[32] First, the effect of patents that include natural phenomena could hinder the "special public interest"

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[25] *Lab. Corp. of Am. Holdings*, 126 S.Ct. at 2921 (2006) (Breyer, J., dissenting).

[26] *Id.* at 2928. The dissent goes on to predict that the patents will "inhibit doctors from using their best medical judgment; . . . force doctors to spend unnecessary time and energy to enter into license agreements; . . . divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; . . . [and] raise the cost of healthcare while inhibiting its effective delivery." *Id.* at 2928-29.

[27] Diamond v. Diehr, 450 U.S. 175 (1981).

[28] *Id.* at 185.

[29] *Lab. Corp. of Am. Holdings*, 126 S.Ct. at 2922 (Breyer, J., dissenting) (emphasis in original).

[30] *Id.* at 2923.

[31] *Id.* at 2925-26. The dissent acknowledges that there are two valid, procedural reasons for not deciding the *LabCorp* case. First, the petitioner did not argue 35 U.S.C. § 101 in the lower courts. *Id.* at 2925. Second, the Federal Circuit has not been given a chance to consider and make a decision on these types of patents. *Id.*

[32] DONALD S. CHISUM, 1-1 CHISUM ON PATENTS § 1.03 (2006).

of the medical profession to provide the highest standard of care.[33] Therefore, a decision is needed to protect the standard of care. Second, a decision is also needed to alleviate "legal uncertainty in the area."[34] Third, the debate between specialist courts and generalist courts regarding the balance of the patent system would benefit from a decision from the highest generalist court, the Supreme Court.[35]

One specific issue the dissent has regarding the *LabCorp* decision is the Federal Circuit's interpretation of the '658 patent's Claim 13 which makes the claim so broad that it encompasses "every homocysteine test that a doctor reviewed"[36] simply because every doctor will look at a total homocysteine assay and, in his or her mind, compare the results against the normal levels of homocysteine.[37] Even without this expansion, the dissent would invalidate the claim because Justice Breyer, with "little doubt," considered the correlation between total homocysteine and cobalamin or folate deficiencies a natural phenomenon.[38] The inclusion of this phenomenon of nature in the midst of a method does not validate the claim because it is still "no more than an instruction to read some numbers in light of medical knowledge."[39]

II. WHY IS THIS PLAY IMPORTANT?

To impress why the issue of patenting natural phenomena is important, this part will discuss concerns identified in different segments of society. Specifically, this part will discuss the concerns of the public, academic commentators, and the participants in *LabCorp*. This part will begin with the concerns of the public person

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[33] *Lab. Corp. of Am. Holdings*, 126 S. Ct. at 2928-29 (Breyer, J., dissenting).

[34] *Id.* at 2929. Justice Breyer goes on to cite the United States' amicus brief assertion that there will be a "substantial number of patent claims" affected by a decision regarding these types of patents. *Id.* These issues are not central to the topic of this article and will not be discussed by the author.

[35] *Id.*

[36] *Id.* at 2924.

[37] *Id.* The Federal Circuit in its decision even noted the testimony of Dr. Sally Stabler when she stated that "it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency." *Metabolite Labs.*, 370 F.3d at 1364.

[38] *Lab. Corp. of Am. Holdings*, 126 S. Ct. at 2927 (Breyer, J., dissenting). Justice Breyer also refers to the Brief for the United States as Amicus Curiae as supporting the contention that the correlation between homocysteine levels and vitamin deficiencies is a phenomenon of nature. *Id.*

[39] *Id.* at 2928.

over patents that include natural phenomena incorporating the paradigm example of a natural phenomenon, DNA. The part will then discuss other issues that commentators have identified that are important when considering these types of patents. Lastly, the part will deal with the issues raised in the briefs filed in *LabCorp*.

One commentator has divided the concerns of the public into two overriding issues: the subject matter itself and social justice.[40] The concern over the subject matter of the patent is primarily the idea that pieces of nature were not invented by man and thus man should not be able to patent nature.[41] If, for example, a man were allowed to patent DNA, then that patent would allow him to own, or have dominion over, a living organism, since DNA is the building block of life.[42] Cases such as *Ex Parte Allen*[43] and the Harvard mouse patent[44] only heightened fear that life can be owned. George Annas identifies this fear of "commodifying life" as the underlying fear surrounding DNA patents.[45] The social justice concern is rooted instead in the fear that those who are attempting to patent DNA will exploit people groups.[46] Annas uses the example of the Human Genome Diversity Project collecting DNA from "vanishing tribes" where the tribes were given no royalties or consideration for the products created from the tribes' DNA.[47] The social justice concern also applies to the idea found above; it is not fair to society for one patent owner to "own" a living organism or some other part of nature.

The public's perception of patents issued on a genetic sequence make those patents the paradigm of the phenomenon of nature problem. Genes exist in nature and are therefore "free to all men."[48] However, the isolated and purified sequence is patentable because the

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[40] George Annas, *Molecules vs. Information: Should Patents Protect Both?, Address at the Symposium on Bioinformatics and Intellectual Property Law* (Apr. 27, 2001), 8 B.U. J. SCI. & TECH. L. 190, 207 (2002).

[41] *Id*.

[42] *Id.*

[43] *Ex Parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (1987). The patent at issue in *Ex Parte Allen* was an attempt to patent polyploidy oysters. *Id.* at 1425-26. The U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences found that "Section 101 [of the Patent Act] includes man-made life forms." *Id.* at 1426.

[44] U.S. Patent No. 4,736,866 (filed June 22, 1984).

[45] Annas, *supra* note 40, at 208.

[46] *Id.* at 209.

[47] *Id.*

[48] Michael J. Malinowski & Radhika Rao, *Legal Limitations on Genetic Research and the Commercialization of its Results*, 54 AM. J. COMP. L. (SUPP.) 45, 49 (2006).

inventor has in some way manipulated the natural phenomenon[49] so that it is no longer a phenomenon of nature but a "product of human ingenuity."[50] This product can be the subject of a patent and therefore can be owned by a patent holder. The fear of humans being owned is constantly reinforced in the public arena. For example, the highly recognizable author Michael Crichton wrote an Op-Ed piece for the *New York Times* in which he stated that "[twenty] percent of the genome is now privately owned."[51] With these types of statements, the fears of social justice and commodifying life continue to grow.

In the face of the public's fears of social injustice associated with the ownership of life, the Patent and Trademark Office ("PTO") has been unresponsive. Its position is that "[f]rom a patent law standpoint, genes are treated just like any other chemical found in nature."[52] This statement is indicative of the PTO's attitude concerning natural phenomena outside of the genetic context. If the invention falls under a mandate from Congress and does not fall under a judicial exception to the Patent Act, then the invention is patentable. According to academics, there are both monetary and developmental problems with this approach.[53] These two elements are intertwined, encouraging each other and making the larger problem more pressing. However, in this article the author will discuss each problem separately.

Patent protection, as discussed earlier,[54] must walk a fine line between encouraging development and granting monopolies. The fear is that patents that use natural phenomena are cutting off future avenues of development while granting larger monopolies than the patent-bargain ever anticipated. Future development and innovation is tied to a constant source of public domain information that Peter Lee has categorized in his article as "upstream" knowledge.[55] This

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[49] *Id.* at 48-49. *See also* M. Scott McBride, *Bioinformatics and Intellectual Property Protection*, 17 BERKELEY TECH. L.J. 1331, 1341 (2002).

[50] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[51] Michael Crichton, *This Essay Breaks the Law*, N.Y. TIMES, Mar. 19, 2006, at 13. To emphasize the amount of information available to the public concerning patents on the genome, the author conducted several LexisNexis searches of news articles from the last year that contained either the terms "patent" and "genome" or "patent" and "DNA." Each search yielded over 3,000 results.

[52] Andrew Pollack, *Patenting a Human Gene As if It Were an Invention*, N.Y. TIMES, June 28, 2000, at C1.

[53] *Infra*, text p. 260-62 and accompanying notes.

[54] *Supra* text p. 253.

[55] Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on*

upstream knowledge is essential because it is the foundational knowledge that is used to create the patentable "downstream" inventions.[56] One way that upstream knowledge can be monopolized is by patenting research tools.[57] These tools produce basic, or upstream, knowledge that is necessary for new innovations.[58] In the case of *LabCorp*, the total homocysteine assay is a research tool producing upstream knowledge that has been monopolized by Metabolite, and therefore stifles downstream innovation. Lee suggests that the hindrance on innovation occurs because patents on research tools create patents on the fundamental inputs into new tools.[59] In the context of *LabCorp*, the problem is that the patent covers an assay *of* homocysteine. Therefore, according to Lee's characterization of these patents, homocysteine would be the input that has essentially been covered by the patent on the research tool (i.e., the assay).

In the same vein, the monopolies created through patent rights give patent holders the power to demand royalties from any new developments that may use the method or process. While the ability to stop others from using or making one's invention is an essential element of the patent-bargain, the effect is to stifle new developments by driving up the costs of innovations such that they are prohibitively expensive. The patents on isolated genes, assays, and other tools used in research and patient care allow fees to be tacked on to the new product even when the new product has no actual relation to the gene or assay.[60] In *LabCorp*, the patent on the assay for total homocysteine could theoretically allow Metabolite to extract a royalty payment from every laboratory that completes a homocysteine assay because the results could be used to determine a vitamin deficiency. According to Christopher Hazuka, that is exactly what has happened to embryonic stem cell research.[61]

The Wisconsin Alumni Research Foundation owns the two patents that cover significant areas of embryonic cell lines.[62]

Biotechnology Research Tools, 19 HARV. J.L. & TECH. 79, 81 (2005).

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] Andrew Marks, *Molecules vs. Information: Should Patents Protect Both?, Address at the Symposium on Bioinformatics and Intellectual Property Law* (Apr. 27, 2001), 8 B.U. J. SCI. & TECH. L. 190, 205-06 (2002).

[61] Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157 (2002).

[62] *See* U.S. Patent No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998);

Therefore, any research into the use of human embryonic cells must have approval from, and pay money to, the Wisconsin Alumni Research Foundation.[63] While not research tools as Lee envisioned them, these cell lines are still upstream tools necessary for creating downstream innovation. For the innovation to take place, money must change hands. If it does not, research stops thereby stifling innovation. This is how the two parts of the problem, development and money, encourage one another.

Players in the current market, whatever that market is, must adapt to the power of patents over development and profit in order to survive. For example, the fear and respect for the power of the patent has become a driving force in the pharmaceutical industry with every company trying to patent as much as it can so that the next company cannot.[64] Another interesting example of an industry responding to the power of the patent is the Motion Picture Association of America, Inc. ("MPAA"). According to its website, the MPAA has its roots as a trade organization that now acts as an advocate for the companies involved in theatrical film and lobbies for "strong protection of creative works."[65] The MPAA has recently responded to the PTO's request for comments regarding its interim guidelines. The MPAA called upon the PTO to address "issues specific to patents involving creative and artistic works."[66] The MPAA is concerned that the PTO might begin granting patents on claims that cover "artistic content" without fully considering the implications of such claims.[67] The MPAA's interest in the possibility of patents being issued on some forms of creative works, which usually fall under copyright law, demonstrates how strong the power of the patent is regarded.

In every argument, there must be two sides. One side, as stated above, is that using natural phenomena in patents stifles development. The other logical side of the argument is that the patents Lee calls upstream patents, or simply patents that incorporate phenomena of

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U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001).

[63] Hazuka, *supra* note 61, at 158-59.

[64] Marks, *supra* note 60, at 212.

[65] Motion Picture Association of America, About Us, http://www.mpaa.org/AboutUs.asp (last visited Mar. 21, 2007).

[66] Comment from the Motion Picture Association of America, Inc. to the U. S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75, 451 (Dec. 20, 2005), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/mpaa.pdf.

[67] *Id.*

nature, will actually "accelerate research and development."[68] Unfortunately, the author has not found any law review or journal articles that take this position. Even Metabolite's Brief for Respondents does not take this position. Instead, almost all participants in *LabCorp*, either as parties or as amici curiae, focused on other issues.

The foundation for Metabolite's arguments is that (1) the issue of subject matter patentability was never brought as a defense at the lower court level, (2) the '658 patent follows all the correct forms, and (3) that the Supreme Court would have to overturn precedent allowing patents of this type in order to overturn the Federal Circuit's decision.[69] Likewise, the briefs filed in support of the respondents rest first on the procedural grounds for not reaching subject matter patentability and second on the contention that Claim 13 is in the form required by *Diehr*.[70]

One *amicus* brief does come close to arguing that patents on processes or methods that include phenomena of nature are a positive development in patent law.[71] The Boston Patent Law Association ("Boston Law") notes in its brief that without the patent, the information that elevated levels of homocysteine correlate to vitamin deficiencies would not be known to the public.[72] However, the majority of the brief defends the correlation as patentable subject matter.[73] Boston Law directs the Court to two criteria that the PTO

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[68] Lee, *supra* note 55, at 81-82.

[69] Brief for Respondents at 43-44, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303905, at *43-44 [hereinafter Brief for Respondents].

[70] *See, e.g.*, Brief for Perlegan Sciences, Inc. and Mohr, Davidow Ventures as Amicus Curiae Supporting Respondents at 5, 126 S.Ct. 2921 (2006) (No. 04-607) 2006 WL 303908, at *5 [hereinafter Perlegan Brief]. The brief outlines the Supreme Court precedent concerning process patents that contain a law of nature or phenomenon of nature. The brief then goes on to compare Claim 13 to the facts of those Supreme Court precedent cases to show that Claim 13 is only doing what the Court has already allowed. *Id.* at *6-7. The brief also counsels the Court to look at the transformation language found in Diamond v. Diehr, 450 U.S. 175, 183 (1981), to support Claim 13. *Id.* at *8-9.

[71] Brief for Boston Patent Law Association et al. as Amicus Curiae Supporting Respondents at 14, Lab. Corp. of Am. Holdings v. Metabolite Labs. Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303909, at *14 [hereinafter Boston Brief]. The Boston Brief also outlines that the affirmation of Claim 13 "will not hinder innovation, and the public will continue to be served by scientific and technological progress." *Id.* at *16.

[72] *Id.* at *14.

[73] *Id.* at *3.

recently put forth in its Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility[74] ("Interim Guidelines") to bolster the claim that the subject matter is patentable. These criteria refer to the two ways the PTO suggests that a claim can be identified to determine if the claim falls under an excluded subject matter.[75] Boston Law directs the Court to the "transformation" and "useful, concrete and tangible result" criteria found in the Interim Guidelines through the *Diehr* holding to support Boston's contention that Claim 13 is patentable.[76]

Boston Law's brief also attempts to draw a comparison between Claim 13 and claims to medical devices because those devices "are also premised on scientific principles."[77] The brief asserts that the "[e]xclusivity conferred on a patented medical process should be treated no differently from the exclusivity conferred on patented medical devices" because medical devices are "also premised on scientific principles" just as are medical processes.[78] However, the author notes that medical devices that use scientific principles are more like the downstream innovations Lee identified[79] than the upstream knowledge Claim 13 appears to encompass.[80] Generally, Metabolite and its supporters treat the question of whether phenomena of nature should be allowed in patents as moot. Instead, the threshold question is whether a phenomenon of nature has been applied correctly in a process that performs a function.[81]

The amicus curiae briefs in support of the petitioner LabCorp have taken a more aggressive approach by confronting the issue of natural phenomena in patents directly.[82] In confronting the issue, the

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[74] Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 OFF. GAZ. PAT. & TRADEMARK OFFICE 142 (Nov. 22, 2005), *available at* http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm [hereinafter *Interim Guidelines*].

[75] *Id.* A more exhaustive discussion concerning the Interim Guidelines can be found *infra* pp. 272-273.

[76] Boston Brief, *supra* note 71, at *5-6. Note that Boston Law does not refer to the Interim Guidelines until after it has directed the Court's attention to *Diehr*, 450 U.S. 175 (1981).

[77] Boston Brief, *supra* note 71, at *15.

[78] *Id.*

[79] *See* Lee, *supra* note 55, at 81-82.

[80] *Id.*

[81] *See, e.g.*, Perlegan Brief, *supra* note 70, at *9.

[82] *See, e.g.*, Brief for American Clinical Laboratory Association as Amicus Curiae Supporting Petitioner at i, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (Dec. 23, 2005) (No. 04-607), 2005 WL 3543098, at *i ("The Disputed Patent Claim Is Invalid Because It Seeks To Protect Nothing More Than A

individual briefs raise different concerns regarding the inclusion of natural phenomena in patents.

The American Medical Association's ("AMA") brief argues that the construction of Claim 13 is so broad that it covers the natural phenomena of elevated levels of homocysteine in relation to vitamin deficiencies with none of the necessary limitations.[83] One of the AMA's concerns is that patents on "basic scientific principles . . . erode the quality of patient care by limiting the knowledge" available to physicians when treating their patients.[84] In addition to the threat to patients, the AMA also identifies a threat to a physician's professional obligation to disseminate knowledge.[85] The AMA accuses the patent system of having created a system that rewards physicians for sharing "medical knowledge, skills and techniques [with] colleagues for reasons of personal gain" instead of for the general good of health care and the patient's well-being.[86]

Similarly, the American Clinical Laboratory Association ("Clinical Laboratory") argues that the elevated levels of homocysteine and its relation to vitamin deficiencies is a natural phenomenon that the two-step assay claim is taking out of the public domain.[87] The problem Clinical Laboratory identifies is that once a correlation between a naturally occurring condition and the source of that condition is patented, future clinical testing will be significantly curtailed, even if the test had not been developed at the time of the patent.[88] Clinical Laboratory's concern is that any new or improved test related to some sort of correlation "would be entirely at the

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Naturally Occurring Biochemical Relationship - A Quintessentially Unpatentable Discovery") [hereinafter Clinical Lab. Brief]; Brief for AARP as Amicus Curiae Supporting Petitioner at iii, *id.* (Dec. 23, 2005), 2005 WL 3597809, at *iii ("The Court Should Invalidate Claim 13 Because It Improperly Claims a Mental Process of Recognizing a Phenomenon of Nature") [hereinafter AARP Brief]; Brief for American Medical Association, et al. as Amici Curiae Supporting Petitioner at iii, *id*. (Dec. 23, 2005), 2005 WL 3597812, at *iii ("Claim 13 Improperly Claims Non-Patentable Subject Matter") [hereinafter AMA Brief].

[83] AMA Brief, *supra* note 82, at 18-20, 2005 WL 3597812, at *18-20.

[84] *Id.* at 13, 2005 WL 3597812, at *13.

[85] *Id.* at 13-14, 2005 WL 3597812, at *13-14.

[86] *Id.* at 14, 2005 WL 3597812, at *14.

[87] Clinical Lab. Brief, *supra* note 82, at 4-7, 2005 WL 3543098, at *4-7.

[88] *Id.* at 8, 2005 WL 3543098, at *8. The AMA refers to over 1,100 clinical test codes that correspond to even more actual tests all of which can be categorized as testing correlations such as the correlation found in *LabCorp*. *Id.* at 8-9, 2005 WL 3543098, at *8-9.

mercy" of the owner of the patent for that correlation.[89] As the AMA identified in its brief, this would affect patient care.[90]

Attacking from a different angle, the AARP Brief argued that Claim 13 was a patent on the *mental process* of recognizing a natural phenomenon and correlating that information with the possibility of a vitamin deficiency.[91] AARP reached this conclusion by noting that the correlation step of Claim 13 is carried out by a physician who looks at the test results and establishes a relationship between the results and the patient's condition.[92] In addition to the concern that mental processes are not patentable subject matter, the AARP was also concerned with the same issues as the AMA and Clinical Laboratory: a patent on a mental process used in diagnosis and patient treatment "threatens public health and interferes with the practice of medicine."[93]

LabCorp picked up on this threat and argued that the lower court's interpretation of Claim 13 will mean that "merely thinking about a scientific correlation is enough to infringe" the patent.[94] LabCorp went further and attempted to draw a connection between the "correlation" in Claim 13 and "equations" such as $E=mc^2$ and the Pythagorean theorem, which academics and jurists agree are not patentable.[95] The only concern or issue that LabCorp brought to the attention of the Court is the simple, but effective, public policy argument that a "monopoly over a basic tool of science hinders . . . innovation."[96] According to LabCorp, the dissemination of scientific principles among academics and physicians will be adversely affected by patents on correlations that use medical facts and mental process, much to the detriment of the medical community and the patients.[97]

The playbooks of the amici curiae briefs are fairly predictable. The respondents and their supporters cite form and predictability over concerns of patenting natural phenomena. The petitioner and its supporters cite the need for medical innovation and putting the

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[89] *Id.* at 9, 2005 WL 3543098, at *9.

[90] *See supra* notes 83-86 and accompanying text.

[91] AARP Brief, *supra* note 82, at 26-27, 2005 WL 3597809, at *26-27.

[92] *Id.* at 6, 2005 WL 3597809, at *6 (citations omitted). The brief also references the original trial where the correlation is referred to as being "all done in the mind." *Id.* at 6, 2005 WL 3597809, at *6 (internal citations omitted).

[93] *Id.* at 17, 2005 WL 3597809, at *17.

[94] Brief for Petitioner at 24, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543099, at *24.

[95] *Id.* at 25, 2005 WL 3543099, at *25.

[96] *Id.* at 43, 2005 WL 3543099, at *43.

[97] *Id.* at 45-47, 2005 WL 3543099, at *45-47.

patients' needs over exclusive patent rights on a scientific principle. The announcers are the academics that are concerned with the self-fulfilling cycle of development and money. While on the sidelines, the public is concerned that it will one day be the subject of a patent. The Supreme Court has been primed for the next play.

III. THE SUPREME COURT HAS THE BALL: WILL IT RUN?

The Supreme Court signaled to the PTO that phenomena of nature are patentable when included in a process or method patent claim.[98] Therefore, it is up to either Congress to referee this game or the Supreme Court to give a new play to the PTO, and to set the boundaries on these patents. This part will present the current test the Supreme Court uses then will discuss the proposed approach from the United States Brief and the support this approach has received from the PTO. Finally, this part will analyze the proposed test and discuss why this is the test the Supreme Court should use when it again has control of the ball.

The Supreme Court itself has blurred the boundary between what is patentable and what is unpatentable in the realm of natural phenomena. In *Parker v. Flook*, the Court stated that "a process is not unpatentable simply because it contains a law of nature."[99] But the Court then clarifies that the idea that "post-solution activity . . . can transform an unpatentable principle into a patentable process that exalts form over substance."[100] Likewise, the Court again noted, three years later, that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process."[101] The Court in *Diehr* stipulated that claims must be read as a whole to prevent courts from dissecting claims and eliminating known steps such as natural phenomena.[102] The Court's most definite statement concerning natural phenomena and patents was made in *Diehr*: "[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[103] The current test centers on the need for the patentable innovation within the invention to overcome the

[98] Parker v. Flook, 437 U.S. 584, 590 (1978). This case is generally referred to as *Flook* and will be referred to as such for the remainder of this article.

[99] *Id.*

[100] *Id.*

[101] Diamond v. Diehr, 450 U.S. 175, 191-92 (1981).

[102] *Id.* at 188.

[103] *Id.* at 187 (emphasis in original).

unpatentable natural phenomenon within the invention. The Supreme Court's decisions have allowed the PTO to escort a patent into the "end-zone" when the invention has applied a natural phenomenon to create something more then a mere discovery of a natural phenomenon.[104]

The United States proposed a new game plan for patents that include a natural phenomenon or any judicial exception to subject matter patentability. The amicus curiae brief filed by the United States agreed with the respondents and their supporters insomuch as the petitioner failed to raise a 35 U.S.C. § 101 defense at the lower court level.[105] However, the United States recommended that the Court remand the case to the Federal Circuit for a factual determination of whether Claim 13 "encompass[ed] all 'substantial practical application[s]' of the natural relationship."[106] The Solicitor General contended that if Claim 13 is interpreted to include all the practical applications of the relationship between homocysteine and vitamin deficiencies then the claim would create "a monopoly over a basic scientific relationship"[107] in violation of the Supreme Court's holding in *Gottschalk v. Benson*.[108]

The Court in *Benson* considered a patent application that attempted to patent an invention for a "method for converting binary-coded decimal ("BCD") numerals into pure binary numerals."[109] This method had not been limited to a specific result or machinery, but instead could be applied to any "general-purpose digital computer of

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[104] Julian David Forman, Comment, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 659 (2002).

[105] U.S. Brief, *supra* note 20, at 6, 2005 WL 3533248, at *6.

[106] *Id.*

[107] *Id.* at 17, 2005 WL 3533248, at *17.

[108] 409 U.S. 63 (1972). This case is generally referred to as the *Benson* decision and will be referred to as such in the remainder of the article. The United States amicus curiae brief also references the Interim Guidelines from the PTO that were referenced by Boston Law. U.S. Brief, *supra* note 20, at 20, 2005 WL 3533248, at *20. *See also* Boston Brief, *supra* note 71, at 5-6, 2006 WL 303909, at *5-6. However, the Solicitor General is citing the pre-emption portion of the Interim Guidelines, not the "transformation" and "useful, concrete and tangible result" portion cited by Boston Law. *Compare* U.S. Brief, *supra* note 20, at 20, at 2005 WL 3533248, *20 *and* Boston Brief, *supra* note 71, at 5-6, 2006 WL 303909, at *5-6. In a footnote, the Solicitor General takes note that the issue that would raise a "transformation" analysis is not before the Court. U.S. Brief, *supra* note 20, at 21 n.4, 2005 WL 3533248, at *21 n.4.

[109] *Benson*, 409 U.S. at 64.

any type."[110] The Court took note that although this was a process or method claim that used a natural phenomenon as part of the process or method, the claim was still "so abstract and sweeping" that it would cover any use of the binary decimals converted to numerals.[111] According to the Court, the "practical effect" of such a patent would "wholly pre-empt" the field and "would be a patent on the algorithm itself."[112] The Court found that the patent application was directed to the judicial exception of abstract ideas.[113] This decision though has since been broadened to apply to all the judicial exceptions, including phenomena of nature.[114]

The Court's decision in *Benson* made clear that while patents could include a process that *used* a natural phenomenon, if the patent was essentially a patent *on* the natural phenomenon, then the patent would be invalid.[115] For the Solicitor General, that decision is the real test Claim 13 must pass: Is the patent on Claim 13 a "monopoly over a basic scientific relationship?"[116] The Solicitor General appears to respond to that question in the affirmative.[117]

The United States brief concluded that Claim 13 was interpreted to be a monopoly over the correlation through its analysis of the prior decisions. The Solicitor General first focused on the Federal Circuit's claim construction.[118] The United States concluded that the Federal Circuit's interpretation of "correlate" held that "anyone who thinks about the relationship between elevated total homocysteine and cobalamin or folate deficiency after obtaining the results of a total homocysteine assay infringes the patent claim."[119] The Solicitor General then pointed out that the jury awarded damages for all the homocysteine tests LabCorp performed, regardless of the doctors' reasons for ordering the tests.[120] According to the United States, this award indicated that the "jury necessarily concluded that no substantial non-infringing uses of the total homocysteine assays"

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[110] *Id.*

[111] *Id.* at 68.

[112] *Id.* at 71-72.

[113] *Id.*

[114] *See generally*, *Interim Guidelines*, *supra* note 74, at IV.C.3.

[115] Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972) (emphasis added).

[116] U.S. Brief, *supra* note 20, at 20-21, 2005 WL 3533248, at * 20-21 (contending that if the Court does hear *LabCorp*, the section 101 issue will be whether Claim 13 "asserts 'a monopoly over a basic scientific relationship'").

[117] *Id.* at 22-23, 2005 WL 3533248, at *22-23.

[118] *Id.* at 22-24, 2005 WL 3533248, at *22-24.

[119] *Id.* at 22, 2005 WL 3533248, at *22.

[120] *Id.*

existed.[121] The Solicitor General also noted that the Federal Circuit affirmed the district court's permanent injunction against LabCorp from performing any homocysteine tests.[122] In making this decision, the Federal Circuit "concluded that *any* assay for total homocysteine would infringe [C]laim 13, regardless of the reason a doctor ordered it."[123] The Solicitor General's conclusions are significant because they demonstrate that Claim 13 does create a monopoly over the scientific principle that homocysteine levels correlate to vitamin deficiencies. Therefore the claim is invalid under *Benson*.[124]

The United States was not the only amicus curiae that supported this test on judicial exceptions found in patents. In its brief, the American Heart Association counseled the Court to use a test similar to the Solicitor General's test: whether the claim "would confer a private exclusionary right on all, or a substantial part of, a natural phenomenon or law of nature."[125] This test again implicates the Court's decision in *Benson*.[126] The pre-emption approach espoused by the United States and American Heart Association is a significantly different play than tests other participants, amici curiae and parties alike, have encouraged the Supreme Court to use. This play may be the game winner.

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[121] U.S. Brief, *supra* note 20, at 23, 2005 WL 3533248, at *23.

[122] *Id.* at 23-24, 2005 WL 3533248, at *23-24.

[123] *Id.* at 24, 2005 WL 3533248, at *24 (emphasis in original).

[124] The respondents have strongly denied that Claim 13 has pre-empted the use of homocysteine levels. The respondents have stated that the natural phenomenon, i.e, the correlation between the vitamin deficiency and the homocysteine level, is safely within the public domain because "[t]he act of assaying body fluids for total homocysteine for reasons other than diagnosing vitamin deficiencies would not infringe." Brief for Respondents, *supra* note 69, at 38. Respondents also asserted that they "[did] not claim a monopoly to the correlation." *Id.* at 31.

[125] Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 11, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3561169, at *11 [hereinafter Heart Association Brief].

[126] The Heart Association Brief does not cite *Benson* directly for this principle but highlights several Court decisions. *Id.* at 12-15, 2005 WL 3561169, at *12-15. The Heart Association Brief does cite a Court of Customs and Patent Appeals judge who consolidated the decisions of the Supreme Court prior to 1979 into one statement: "The common thread throughout [this Court's] cases is that [patent] claims which *directly or indirectly preempt* natural laws or phenomena are proscribed, whereas claims which merely *utilize* natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful end results define statutory inventions." *Id.* at 16, 2005 WL 3561169, at *16 (citing *In re Bergy*, 596 F.2d 952, 988 (C.C.P.A. 1979) (Baldwin, J., concurring)) (alterations in Heart Association Brief).

The concept of pre-emption to help determine if an invention that includes a natural phenomenon is patentable did not start with *Benson*.[127] The pedigree of the pre-emption test reaches back to the Telegraph Case of 1853 when the Supreme Court denied Morse the broad patent he was attempting to validate.[128] However, the actual use of a pre-emption analysis in *Benson* has been called "nonsense."[129] Even if the pre-emption analysis should not have been used in *Benson*, the effect of the analysis is still felt in other Supreme Court cases and Federal Circuit cases. The Federal Circuit's analysis in 1994 was "to see whether the claimed subject matter as a whole is a disembodied mathematical concept . . . which in essence represents nothing more than a 'law of nature,' 'natural phenomenon,' or 'abstract idea.'"[130] The court went on to cite *Diehr*, explaining that if the claimed subject matter did represent an unpatentable subject matter then "*Diehr* precludes the patenting of that subject matter."[131] The Supreme Court distinguished *Diehr* from *Benson* and *Flook* when it pointed out that the respondents in *Diehr* did "not seek to pre-empt the use of [the natural phenomenon]."[132] The United States in its *amicus* brief noted that neither *Diehr* nor *Flook* focused on questions about pre-emption.[133] However, the fact that both cases addressed the pre-emption analysis signifies that pre-emption has at least been accepted in part as grounds for refusing to grant a patent on an invention including a natural phenomenon. The degree to which the pre-emption analysis has been accepted can be inferred by its inclusion in the PTO Interim Guidelines of November 22, 2005.[134]

According to the PTO, the "principal objective [of the Interim Guidelines] is to assist examiners in determining . . . whether a claimed invention falls within a judicial exception to statutory subject matter."[135] The Interim Guidelines assist the patent examiners by providing them with the PTO's "current understanding of the law"

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[127] *See, e.g.*, Heart Association Brief, *supra* note 125, at 12-15, 2005 WL 3561169, at *12-15. (highlighting Supreme Court cases).

[128] O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853). *See also*, Heart Association Brief, *supra* note 125, at 12, 2005 WL 3561169, at *12.

[129] CHISUM, *supra* note 32, at § 1.03[6][c].

[130] *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994).

[131] *Id.*

[132] Diamond v. Diehr, 450 U.S. 175, 187 (1981).

[133] U.S. Brief, *supra* note 20, at 21 n.4, 2005 WL 3533248, at *21 n.4 (citing *Diehr*, *Flook*, and *Benson*).

[134] *Interim Guidelines*, *supra* note 74.

[135] *Id.*

regarding subject matter patentability.[136] It is important to note that the Interim Guidelines do not have the force of law and do not *have* to be followed by the patent examiners.[137] However, the Interim Guidelines are considered the official view of the PTO.[138]

Under the Interim Guidelines, when an examiner considers the subject matter of the invention under § 101, he or she should determine whether the subject matter falls within the judicial exceptions to patentability (laws of nature, natural phenomena, and abstract ideas).[139] The examiner is to first consider whether the invention falls into one of these judicial exceptions or is a practical application of the laws of nature, natural phenomena, or abstract idea which has been incorporated in the claims.[140] The examiner can identify a practical application of a judicial exception to subject matter if the invention "'transforms an article or physical object to a different state or thing" or if it "otherwise produces a useful, concrete and tangible result."[141] The examiner should also consider whether the invention pre-empts one of the judicial exceptions to § 101.[142] The PTO cites to *Diehr* and *Benson* to explain to the examiners what to consider.[143] Specifically, the examiners "must ensure that [the invention] does not in reality 'seek[] patent protection for that formula in the abstract.'"[144] The PTO also informs examiners that "[o]ne may not patent a process that comprises every 'substantial practical application' of an abstract idea, because such a patent 'in practical

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[136] *Id.* at I.

[137] *Id.* ("These Guidelines…do not have the force and effect of law…[A]ny failure by USPTO personnel to follow the Guidelines is neither appealable nor petitionable."). To clarify, the Manual of Patent Examining Procedure (MPEP) also does not have the force of law even though it does "outline[] the current procedures which the examiners are required or authorized to follow." U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE Foreword (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r5_Foreword.pdf.

[138] *See generally*, *Interim Guidelines*, *supra* note 74 (discussing in Foreword and Introduction that the examiners should use the Interim Guidelines when they examine patent applications).

[139] *Id.* at IV.C.

[140] *Id.* at IV.C.1.

[141] *Id.* at IV.C.2. The Interim Guidelines also provide guidance on what is a "useful result," "tangible result," and a "concrete result."

[142] *Id.* at IV.C.3.

[143] *Id.*

[144] *Interim Guidelines*, *supra* note 74, IV.C.3 (citing Diamond v. Diehr, 450 U.S. 175, 191 (1981) (second alteration in original).

effect would be a patent on the [abstract idea].'"[145] The PTO's interpretation of the pre-emption analysis and its inclusion in the Interim Guidelines is another indication that the pre-emption test is a legitimate play.

The pre-emption test appears to be supported by Supreme Court precedent, the PTO, and the Solicitor General. However, it is not supported by all the players. The PTO requested comments from the public concerning these Interim Guidelines and even extended the comment time to take into account the decision from the Supreme Court in *LabCorp*.[146] Some who responded voiced concerns over the pre-emption approach and its place in the examiners' patentable subject matter determinations under § 101. Intellectual Ventures, a business based on "creat[ing] and invest[ing] in new inventions,"[147] considered the pre-emption test more of a subjective "final check" than a condition to patentability as it is used in the Interim Guidelines.[148] Similarly, Rick Nydegger, a patent attorney, considered the pre-emption test to be a "final, separate inquiry" in the § 101 analysis.[149] The American Intellectual Property Law Association ("AIPLA") also disagreed with the PTO including the pre-emption test as part of the § 101 analysis.[150] In AIPLA's view, *Flook* had already overruled the pre-emption test, therefore the test had no place in any section of the code governing patents.[151] Brian Hickman, a registered

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[145] *Id.* (citing *Benson*, 409 U.S. at 64) (second alteration in original).

[146] Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 71 Fed. Reg. 34,307, 34,308 (Jun. 14, 2006).

[147] Comment from Intellectual Ventures, LLC, to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 1 (July 31, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/iv.pdf [hereinafter Intellectual Ventures Comment]

[148] *Id.* at 6.

[149] Comment from Rick Nydegger to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), II (Aug. 4, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/nydegger.pdf.

[150] Comment from the American Intellectual Property Law Association to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 4 (July 28, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/aipla.pdf.

[151] *Id.* However, Chisum has interpreted *Flook* as following *Benson*'s treatment of abstract ideas which has been extended to all judicial exceptions of § 101.

patent agent, was somewhat more lenient in his comments on the pre-emption test.[152] Hickman demoted the pre-emption test to a "theoretical requirement" that possibly deserved "a paragraph, or a footnote" in the Interim Guidelines.[153]

Not all of the comments the PTO received were negative. While the National Institutes of Health ("NIH") expressed concern over the pre-emption test as it applies to "diagnostic methods and assays,"[154] it did not attempt to completely discredit the pre-emption test. The NIH did not believe the Interim Guidelines' current pre-emption test provided enough guidance for examiners when the invention contains diagnostic or assay methods like the patent in *LabCorp*[155] and recommended instead that the framework of the test be changed. [156] On the other hand, the Association of American Medical Colleges ("AAMC") strongly supported the pre-emption test.[157] The AAMC even recommended that the test "play a decisive role" in any § 101 analysis.[158]

There will be disagreement over using the pre-emption test more aggressively when there are valuable patents at stake. However, the Supreme Court should use the pre-emption test to determine if subject matter that falls under a judicial exception to § 101, such as phenomena of nature, is being removed from the public domain. The current test, focusing on the overall process or method instead of the

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CHISUM, *supra* note 32, at § 1.03.

[152] Comment from Brian Hickman to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), (May 19, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/hickman.pdf.

[153] *Id.*

[154] Comment from the National Institutes of Health to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 2 (Jul. 31, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/nih.pdf. This concern arises from the possible tension between *Diehr* (consider the claims as a whole) and *Flook* (a pre-existing relationship is never patentable). *Id.* at 2-3 (internal citations omitted).

[155] *Id.*

[156] *Id.* at 4-6.

[157] Comment from the Association of American Medical Colleges to the U. S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 3 (July 31, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/aamc.pdf.

[158] *Id.*

natural phenomenon included in the process, works well to exclude patents that truly are patents on laws of nature, natural phenomena, and abstract ideas. True to the innovative spirit the patent system fosters and encourages, inventors and patent attorneys have found ways to circumvent the current test. The pre-emption test will cut off one of those avenues of circumvention.

Another important factor, as the United States Brief pointed out, is that the Supreme Court has already accepted and affirmed the pre-emption analysis.[159] There are four different teams deciding how the patent system is run: Congress, the Supreme Court, the Federal Circuit Court of Appeals, and the PTO. The Supreme Court will be more likely to endorse a test that the Federal Circuit currently uses, the PTO has incorporated into its Interim Guidelines, and Congress has not legislated away, than a new or different test that has not garnered as much support from the other teams. While this may be a general observation concerning the balance between Congress, the Supreme Court, the lower courts, and administrative agencies, tension between the branches of government is more pronounced in the field of patent law where there is the ongoing discussion between generalists and specialists that Justice Breyer referred to in *LabCorp*.[160]

Although there may be problems with the implementation of the pre-emption test by the PTO, the test itself is a necessary defense to patents that may be taking scientific principles out of the public domain. The pre-emption test requires the examiners to think beyond the four corners of the patent application and consider the further implications of the claims. This may make the test more subjective, as Intellectual Ventures suggested.[161] Subjectivity in the patent system will negatively influence the predictability of patent applications and therefore may affect the willingness of companies to devote resources to innovation. The respect companies have for the power of the patent should overcome any hesitancy over researching a new drug, medical device, or diagnostic tool.[162] Just as innovation has continued to flourish under the current test, innovation will continue to flourish under the pre-emption test.

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[159] U.S. Brief, *supra* note 20, at 20, 2005 WL 3533248, at *20 (citing *Benson*, *Diehr*, and *Flook* as well as the Interim Guidelines to support the pre-emption test).

[160] *Lab. Corp. of Am. Holdings*, 126 S.Ct. at 2929 (Breyer, J., dissenting).

[161] Intellectual Ventures Comment, *supra* note 147, at 6.

[162] *See supra* notes 64-67 and accompanying text.

IV. CONCLUSION

One commentator believes that simple reliance on the "common law prohibition against patenting natural laws, natural phenomena, and abstract principles" as well as the "policy interest in keeping knowledge and other foundational elements of research freely available in the public domain" will be enough to reverse the trend of phenomena of nature found in patents.[163] As demonstrated above, all players believe that the common law prohibition is to their benefit. They also all agree that none of the judicial exceptions, including natural phenomena, should be directly patented. The current test, simply allowing a method or process to be patented as long as the natural phenomenon found within the steps is an application that produces a "new and useful end,"[164] has not been able to keep necessary information in the public domain. Therefore, either the Supreme Court or Congress must step up to the line. The ideal course of events would be for the Federal Circuit to take this issue out of the hands of either team and begin making decisions based on *Benson* and guided by the Interim Guidelines. The more likely course of events is that the Supreme Court will be asked to grant the petition for a writ of certiorari in a case where the petitioner has argued that the subject matter was unpatentable under § 101 because it pre-empted the use of a phenomenon of nature or some other judicial exception. When this occurs, the Supreme Court should look to its precedent and applies the pre-emption test. The Supreme Court should be able to leave in place the protections that the patent system affords inventors to encourage research while at the same time make the standard for using natural phenomena in inventions harder to meet. The pre-emption test is the game-winning play that will provide incentives for inventors and protection for natural phenomena.

[163] Lee, *supra* note 55, at 82.
[164] *Benson*, 409 U.S. at 67 (internal citations omitted).

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