SYRACUSE SCIENCE & TECHNOLOGY LAW REPORTER

VOLUME 21 FALL 2009

TABLE OF CONTENTS

Sex, Privacy, and Webpages: Creating a Legal Remedy for Victims of Porn 2.0
Ariel Ronneburger……. 1

The FDA Safe Harbor Provision After Proveris
Adam Sibley…… 36

Virtual Inheritance: Assigning More Virtual Property Rights
Olivia Y. Truong……. 57

Obvious Fallacy: Improving the Standard of Obviousness for Chemical Compounds to More Accurately Reflect Common Practice in the Art
Alison M. Taroli…….. 87

Review of "The Stem Cell Dilemma: Beacons of Hope or Harbingers of Doom?" by Leo Furcht, M.D. and William Hoffman
Heather Giglio……. 118

Review of "Against Intellectual Monopoly" by Michele Boldrin and David K. Levine
Susan C. Azzarelli…… 130

SYRACUSE SCIENCE & TECHNOLOGY LAW REPORTER

VOLUME 21 FALL 2009

SYRACUSE SCIENCE & TECHNOLOGY LAW REPORTER

VOLUME 21 FALL 2009 ARTICLE 1, PAGE 1

SEX, PRIVACY, AND WEBPAGES: CREATING A LEGAL REMEDY FOR VICTIMS OF PORN 2.0

Ariel Ronneburger*

I. INTRODUCTION

Cecilia Barnes' online profile included her name, workplace contact information, and nude photographs. The pictures, posted on a web page hosted by Yahoo! Inc., received so much attention that they motivated a number of men who did not know Ms. Barnes to find her at work.[1] Given her Internet exposure, Ms. Barnes probably should not have been surprised by these visits. However, Ms. Barnes never posted these photos herself—her ex-boyfriend did.[2] After Ms. Barnes informed Yahoo! that she had not consented to the online profile containing her nude photographs, the company still failed to remove the profile from its website. The Oregon District Court determined that Yahoo! was not liable for any harm caused by the dissemination of Ms. Barnes' photographs and personal information.[3] While the Ninth Circuit Court of Appeals later determined that Ms. Barnes had a cause of action against Yahoo!, this decision was based solely on the fact that the company had promised Ms. Barnes that it would

* J.D., Hofstra University School of Law, M.A., State University of New York at Stony Brook, B.S., Cornell University. The author wishes to thank Holning Lau, Associate Professor of Law at the University of North Carolina at Chapel Hill Law School, for all his help and encouragement in the writing of this Article.

[1] *Barnes v. Yahoo! Inc.*, No. Civ. 05-926-AA, 2005 WL 3005602, at *1 (D. Or. Nov. 8, 2005), *overruled by Barnes v. Yahoo! Inc.*, 570 F. 3d 1096 (9th Cir. 2009).

[2] *Id.*

[3] *Id.* at *4.

remove the pictures from its site.[4] The Ninth Circuit opinion is unfortunately under-protective because, based on its reasoning, services like Yahoo! can avoid liability simply by refraining from making any promises to assist victims like Ms. Barnes.[5]

Stories like Ms. Barnes' are not uncommon.[6] Moreover, the rise of so-called "Porn 2.0" will likely increase the online distribution of nude photographs featuring people who did not consent to the images' circulation.[7] Derived from the term "Web 2.0," which is used to define Internet-based interactive communities,[8] the term Porn 2.0 describes websites that allow users to post pornography that they themselves have created.[9] With Porn 2.0, it is increasingly easy for Internet users to post pornographic images or videos of people who did not consent to the materials' circulation.

---

[4] *Barnes*, 570 F. 3d at 1107-09.

[5] *Id.*

[6] *See, e.g.*, Carol Ann Alaimo, *Adultery Penalty, FBI Probe Dog Huachuca Chaplain*, ARIZ. DAILY STAR, Feb. 11, 2007, at A1, A1 (A married Army chaplain posted nude photographs of a woman on various sex sites. The woman, believing that she was the man's fiancée, had sent him the photos while he was overseas and did not intend for anyone else to see them); *Ex-Boyfriend Guilty in Extortion*, SEATTLE TIMES, Dec. 31, 1999, at B2, B2 (A man was convicted of extortion for threatening to post his ex-girlfriend's nude photos online. The man also claimed he had already posted some of the photographs online); *Teen Charged with Posting Ex-Girlfriend's Nude Photo on MySpace* (May 1, 2008), http://www.thedenverchannel.com/technology/ 16117242/detail.html? rss=den&psp=news (a Wisconsin teen broke into his ex-girlfriend's MySpace account and posted nude photos of her).

[7] Sunny Freeman, *Porn 2.0, and its Victims*, THE TYEE, July 6, 2007, http://thetyee.ca/Mediacheck/ 2007/ 07/06/Porn2-0/.

[8] Ann Bartow, *Pornography, Coercion, and Copyright Law 2.0*, 10 VAND. J. ENT. & TECH. L.799, 801 (2008).

[9] Jacqui Cheng, *Porn 2.0 is Stiff Competition for Pro-Pornographers*, ARS TECHNIA, June 6, 2007, http://arstechnica.com/news.ars/ post/20070606-porn-2-0-is-stiff-competition-for-pro-pronographers.html.

There is little that victims of the Porn 2.0 phenomenon can do. Such victims generally have no recourse against websites like Yahoo!, due to the Communications Decency Act ("CDA"), a federal statute that grants immunity to online service providers[10] for content uploaded by users.[11] In some places, victims like Ms. Barnes can sue their ex-boyfriends and ex-girlfriends for tort damages in state court; however, it is unlikely that monetary damages paid by the person who uploaded the pictures can adequately compensate for the effects of their actions—the potentially widespread dissemination of private images, which could permanently remain on the Internet for anyone to see.

Legal scholars have proposed various ways to prevent or regulate the posting of pornographic images of non-consenting individuals. These methods include conditioning copyright of pornographic videos and images on a showing of consent of the model or actor,[12] and imposing contract liability on ex-lovers who spread confidential information and photographs.[13] These methods, however, are inadequate. They do not provide victims with any way to have the photos removed from the website, nor do they impose any liability on service providers who ignore complaints that the provider is hosting videos or images of people who did

[10] A "service provider" is merely a source of third party information and media. The service provider does not create content itself, but allows for its third parties (users of the website) to upload and display their own content. An "information content provider," in contrast, plays an active role in the creation of material presented on its website. *See infra* notes 48-50.

[11] *Barnes v. Yahoo! Inc.*, No. Civ. 05-926-AA, 2005 WL 3005602, at *1 (D. Or. Nov. 8, 2005), *overruled by Barnes v. Yahoo! Inc.*, 570 F. 3d 1096 (9th Cir. 2009); *see also* Communications Decency Act of 1996, 47 U.S.C. § 230 (2006) (Section 230 of the Act provides broad immunity for third-party content to providers of Internet services).

[12] Bartow, *supra* note 8, at 834-38.

[13] Andrew J. McClurg, *Kiss and Tell: Protecting Intimate Relationship Privacy Through Implied Contracts of Confidentiality*, 74 U. CIN. L. REV. 887, 908-35 (2006).

not consent to their distribution. Further, the proposals do not address posters who do not seek copyright protection and who are not ex-lovers.

The problem of regulating the world of Porn 2.0 thus persists. This paper addresses this problem by proposing an amendment to the CDA, creating potential liability for service providers who fail to at least investigate claims of non-consented pornography. The proposed amendment is modeled on The Online Copyright Infringement Liability Limitation Act ("OCILLA") portion of the Digital Millennium Copyright Act ("DMCA"). If a service provider is on notice that it is hosting copyrighted material, OCILLA requires the service provider to remove the material from its servers in order to obtain safe harbor from copyright infringement charges.[14] Thus, service providers must act upon notice of hosting copyrighted material.[15] According to this Article's proposed amendment to the CDA, online service providers would have a similar duty to act upon notice that they are hosting nude images of unconsenting individuals.

The remainder of this Article unfolds in three parts. Part II discusses the rise of Porn 2.0 and the need to regulate the uploading and distribution of pornography depicting people who have not consented to its circulation. This Part also examines service provider immunity under the CDA and explains how this law bars claims against service providers that host non-consented pornography. Part III describes the different proposals made by legal scholars to both control the

[14] Online Copyright Infringement Liability Limitation Act ("OCILLA"), 17 U.S.C. § 512(c) (2006). The Digital Millennium Copyright Act ("DMCA") was passed in 1998 to create harsher penalties for copyright infringement on the Internet. Title II of the DMCA, referred to as "OCILLA", creates a safe harbor for online service providers who promptly act upon actual knowledge of copyrighted material that has been posted by a third-party user. If these procedures are followed, the service provider will not be held liable for the infringing activities of a third party. *See id.* § 512, 1201-05, 1301-32.

[15] *Id.*

spread of user-generated amateur pornography and protect its victims. Additionally, this Part explains why these solutions will not solve all the problems posed by the widespread popularity of Porn 2.0. Part IV discusses the DMCA, which imposes on service providers a duty to investigate claims of copyright infringement, and also requires service providers to remove copyrighted materials from their websites in order to obtain immunity from claims of contributory infringement.[16] This Part also makes a novel proposal, arguing for an amendment to the CDA. This amendment, modeled after the DMCA, would require service providers to investigate claims of hosting non-consented pornography and subsequently remove such images or videos, in order to obtain immunity in suits over third-party content. This Article then concludes that amending the CDA to extend potential liability to service providers is the best way to regulate Porn 2.0.

II. PORN 2.0, ITS VICTIMS, AND THE CDA

In the past decade, the popularity of interactive Internet sites has given rise to a number of websites that allow members to share personal pornographic materials.[17] This phenomenon, known as Porn 2.0, has provided a mechanism for users to post photos and videos not only of themselves, but also of people who have not consented to the online distribution of these images.[18] While victims of non-consented postings of pornography have attempted to sue the websites hosting the material, courts have found that the CDA grants service providers immunity

[16] 17 U.S.C. § 512(c).

[17] Freeman, *supra* note 6.

[18] *Id.*

from liability for third-party content.[19] Accordingly, Porn 2.0 sites have become instruments for revenge and humiliation, and the victims of these sites have been left with little legal remedy.[20]

A. *The Rise of Porn 2.0 and Its Consequences*

Interactive pornographic websites are part of what has become known as Web 2.0.[21] Web 2.0 consists of sites that promote the development and exchange of information between users, such as blogs, social networking sites like MySpace and Facebook, interactive projects like Wikipedia, and video-sharing sites such as YouTube.[22]

While Web 2.0 technologies have facilitated communication among people all over the world, and even played a large role in the 2008 presidential campaign,[23] they have also led to the development of Porn 2.0 sites.[24] Two of the most successful of these sites are YouPorn and PornoTube, both of which enable users to upload pornographic videos that are then searchable and viewable by anyone on the site.[25] These sites are extremely popular. The website Alexa, which tracks Internet traffic, shows that YouPorn is the fifty-second most visited site in the world.[26]

---

[19] *See Barnes v. Yahoo! Inc.*, No. Civ. 05-926-AA, 2005 WL 3005602, at *1 (D. Or. Nov. 8, 2005), *overruled by Barnes v. Yahoo! Inc*., 570 F. 3d 1096 (9th Cir. 2009).

[20] Freeman, *supra* note 7.

[21] Bartow, *supra* note 8, at 816.

[22] Ross D. Silverman, *Enhancing Public Health Law Communication Linkages*, 36 J.L. MED & ETHICS 29, 36-37 (2008).

[23] David Carr & Brian Stelter, *Campaigns in a Web 2.0 World*, N.Y. TIMES, Nov. 2, 2008, at B1.

[24] Freeman, *supra* note 7.

[25] *Id.*

The advent of Porn 2.0 raises serious questions over the issues of privacy and consent. A 2006 survey by *Cosmopolitan* magazine revealed that 15% of women admit to having made a sex tape, creating the possibility of these tapes being circulated on the Internet.[27] It has been reported that there are at least 250 YouPorn videos containing pornography of "ex-girlfriends," presumably women whose ex-lovers have now posted supposedly private sex tapes online seeking revenge through public humiliation.[28] The blog "Ex Girlfriend Pictures"[29] allows users to submit photos of ex-girlfriends for "revenge or bragging rights," and contains a plethora of pictures of nude women, lying on beds and spreading their legs underneath comments such as "I love her perky little tits and that little pink snatch is looking as sweet as nectar."[30] Additionally, a Google search for the term "ex girlfriend photos" yields some 2,480,000 results, mostly pages that cater to those who want to upload pornographic images of women they have dated.[31]

Fear of an ex-lover uploading private images and videos online is prevalent among people who have participated in the creation of homemade pornography. On Yahoo! Message Boards, there are threads started by young women asking other members what to do about ex-boyfriends who are currently threatening to post nude photos, and other threads by women

---

[26] YouPorn.com – Traffic Details from Alexa, http://www.alexa.com/siteinfo/youporn.com# (last visited Nov.12, 2009).

[27] Freeman, *supra* note 7.

[28] *Id.*

[29] Ex Girlfriend Pictures – Real Ex Girlfriends and Ex Wives Nude, http:www.exgfpics. com/blog (last visited Nov. 15, 2008).

[30] Ex Girlfriend Pictures – Spicy Ex Girlfriend Nude in Mirror, http://www.exgfpics. com/blog/index.php/2008/ 11/06/spicy-ex-girlfriend-nude-in-mirror/ (last visited Nov. 15, 2008).

[31] Ex-Girlfriend Photos – Google Search, http.www.google.com (search for "ex girlfriend photos") (last visited Nov. 15, 2008).

asking what to do now that their private photos have already been leaked online.[32] Indeed, posting these photos does seem to be a popular form of revenge, as many sites promote the sharing of pictures and videos of ex-boyfriends or girlfriends as a form of punishment for a bad break-up.[33]

Once uploaded, the material on these sites is available to anyone who logs on. Though sites like YouPorn have disclaimers that mandate the consent of all parties involved in a pornographic video.[34] According to pornography law expert Janine Benedet, many of these images are posted without authorization.[35] Benedet describes this as "a devastating attack. There is no legal mechanism for victims to get their pictures back once they're out there, despite the fact that there is lingering harm."[36]

It is the sexual nature of this attack that makes it so damaging. The Internet can be used to assault a person's reputation in a variety of ways, such as through the posting of defamatory comments.[37] However, posting sexual images of unconsenting individuals is particularly harmful. Both law and culture continue to distinguish between sexual expression and other forms of expression. Indeed, Supreme Court jurisprudence treats sexual expression as a category unto itself.[38] Likewise, society particularly condemns those whose sexual photographs have

---

[32] Posting of Bina to http://au.answers.yahoo.com/question/index?qid=20080320060501AA Fvp7Q (Mar. 2008); Posting of L ~ to http://answers.yahoo.com/question/index?qid= 20081002230322AArW1bc (Oct. 2008).

[33] *See, e.g.*, Ex Girlfriend Pictures – Real Ex Girlfriends and Ex Wives Nude, *supra* note 29.

[34] YouPorn.com – Terms of Service, http://youporn.com/terms (last visited Nov. 15, 2008).

[35] Freeman, *supra* note 7.

[36] *Id.*

[37] *See*, Zeran v. Am. Online, Inc., 129 F.3d 327, 329-330 (4th Cir. 1997).

been circulated online, whether by themselves or by others. For example, Arlington, Oregon mayor Carmen Kontur-Gronquist was forced to step down after she posted a photo of herself in a bra and underwear, taken years before she became mayor, on her private MySpace page.[39] Though the photo was hardly pornographic, many in Arlington felt that Kontur-Gronquist's decision to pose in this way was evidence that she was not fit to be mayor.[40] Similarly, an award-winning Texas high school teacher was fired after a co-worker discovered online photos of the teacher where her breasts were visible,[41] while a Texas probation officer was recently placed on administrative leave because nude photographs she took as a college student were found online.[42] Thus, it is the particular taboo that society places on sexual expression that makes the unauthorized posting of such images or videos so injurious. While the mere dissemination of pornographic images can be detrimental to one's reputation and career, the

[38] The Supreme Court has maintained different standards for the regulation of sexual material as opposed to other forms of speech. The Court held that the government may regulate sexual expression when a work appeals to a "prurient interest in sex," as defined by contemporary community standards, portrays sex in a patently offensive way, and lacks any literary, artistic, political, or scientific value. Miller v. California, 413 U.S. 15, 39 (1973). In contrast, the Supreme Court has been more protective of other forms of speech, even when such speech would likely be considered offensive by many members of the public. Cohen v. California, 403 U.S. 15, 21 (1971) (upholding a man's First Amendment right to wear a jacket that said "Fuck the Draft," in opposition to the Vietnam War).

[39] Mike Celizic, *Ousted Mayor Defends Racy MySpace Pics*, MSNBC, Mar. 3, 2008, http://today.msnbc.msn.com/id/23445683/.

[40] *Id.*

[41] Heather L. Carter et al., *Have You Googled Your Teachers Lately? Teachers' Use of Social Networking Sites*, 89 PHI DELTA KAPPAN 681, 683 (2008).

[42] *Texas Probation Officer Karla Escobar Fired for Nude Internet Photos. Is this Fair? Take our Poll*, GUANABEE, Oct. 14, 2008, http://guanabee.com/2008/10/texas-probation-office-karla-e.php.

people who participate in pornography of this sort lack a legal remedy when these materials are disseminated without their consent.[43]

Although some commentators might place the blame on individuals who took part in creating amateur pornography by claiming that they should have exercised more discretion by not posing nude for their partners in the first place, victims of Porn 2.0 should be protected nonetheless. They should be protected, because placing trust in one's intimate partner is understandable; and because our legal culture places a strong emphasis on principles of consent.

Trust is an inherent component to many, if not most, intimate relationships.[44] Because placing trust in one's intimate partner is so common, victims of Porn 2.0 should not be blamed for wrongly trusting their partners. In some regards, the law already protects individuals who misplace trust in their intimate partners, instead of blaming the individuals for trusting in the first place. For example, commentators have argued that one of the purposes of domestic violence laws is to protect individuals against their misplaced trust.[45] Protecting victims of Porn 2.0 would function in the same vein.

The law should also protect, rather than blame, victims of Porn 2.0, because the American legal system values consent; victims of Porn 2.0 are victims precisely because their

---

[43] *See* Freeman, *supra* note 7.

[44] *See* Orly Rachmilovitz, *Bringing Down the Bedroom Walls: Emphasizing Substance over Form in Personalized Abuse*, 14 WM. & MARY J. WOMEN & L. 495, 499-502, 539-42 (2008) (discussing dynamics of trust as a oft-cited justification for domestic violence policies and providing background on social science literature on trust). One of the reasons trust is often so strong between couples is because individuals' identities are often intertwined with that of their partners. *See id*. at 539 (discussing the relationship between trust and identity); Holning Lau, *Transcending the Individualist Paradigm in Sexual Orientation Antidiscrimination Law*, 94 CAL. L. REV. 1271 (2007) (discussing how coupled relationships influence the identity of individuals).

[45] *See* Rachmilovitz, *supra* note 44, at 500 (summarizing literature on domestic violence and trust).

images have been posted without their consent. Strong rape laws in the United States reflect the legal culture's emphasis on consent. For example, in order to prevent clouding fact-finders' assessments of consent in rape cases, the Federal Rules of Evidence generally bar the presentation of a rape victim's prior sexual conduct.[46] Such provisions serve to protect rape victims, based on principles of consent, rather than blame victims for their sexual history.[47] Similarly, creating a remedy for the victims of Porn 2.0 would value consent and not blame the victims for their sexual history.

B. *Service Provider Immunity Under the CDA*

Despite the fact that the online posting of pornographic images could be particularly damaging, there remains inadequate legal recourse for those who discover their supposedly private photos have been spread throughout the Internet. Victims of Porn 2.0 have no mechanism to have the material removed from the website, and the CDA provides immunity to service providers for third-party content, even when the people depicted in the photos or videos did not consent to their posting.

---

[46] *See* FED. R. EVID. 412 (barring evidence of rape victim's sexual history, unless it is being offered in a criminal case to show consent with the particular defendant or that another person was the perpetrator).

[47] It should be noted that unfortunately, in practice, judges and juries are sometimes still biased against rape victims, placing blame on the victims. *See* Christine Chambers Goodman, *Protecting the Party Girl: A New Approach for Evaluating Intoxicated Consent*, 2009 B.Y.U. L. REV. 57, 65, 76 (2009). As a result, legal scholars have been arguing, based on principles of consent, for even stronger rape protections. *See, e.g.*, *id* at 65 (proposing that, in determining whether sexual intercourse was consensual, the jury's focus should not be on whether there was a clear expression of dissent, but that only "some evidence of dissent, even mild evidence of dissent, should be adequate to put the defendant on notice that any continued action towards sexual intercourse may be non-consensual or forced."); Allison West, *Tougher Prosecution When the Rapist is Not a Stranger: Suggested Reform to the California Penal Code*, 24 GOLDEN GATE U. L. REV. 169, 195-98 (1994) (arguing that laws must be revised so that rapes involving two people who are well-acquainted with one another are not considered less serious than when the perpetrator is a stranger).

The CDA distinguishes, for purposes of liability, between service providers and information content providers. A service provider is a passive conduit for web pages and media that are entirely provided by its user; the service provider does not create the offending content itself. This content, created by website designers or uploaded to Web 2.0 sites by users, is considered third-party content.[48] In contrast, an information content provider is someone who is "responsible, in whole or in part, for the creation or development of" the content displayed on a website.[49] Websites may be both service providers, presenting images and videos that have been entirely created and posted by third parties, as well as information content providers, creating or contributing to some material.[50]

The CDA was passed in 1996 to "promote the continued development of Internet and other interactive computer services and other interactive media."[51] Because Congress felt that imposing liability for the actions of third parties on service providers would require websites to heavily regulate the actions of users and thus limit the development of online communities as a form of mass communication,[52] Section 230 of the CDA states that, "[n]o provider or user of an

[48] Communications Decency Act of 1996, 47 U.S.C. § 230(f)(3) (2002).

[49] *See*, *Fair Housing Council of San Fernando Valley, et al. v. Roommates.com, et al.*, 521 F.3d 1157,1162 (9th Cir. 2007).

[50] *Id.* An example of a service provider is a website that allows users to post messages to one another. The users of the site create the content, while the website itself provides only a passive means of communication. *See id.* at 1163; *Cubby, Inc. v. CompuServe, Inc*., 776 F. Supp. 135, 140 (S.D.N.Y. 1991). A content provider is any website whose owners create the content displayed on the website. For example, Roommates.com was held to be a content provider, because it had created the questions that users of the site were required to answer to register with the site. *Roommates.com*, 521 F.3d at 1164.

[51] Communications Decency Act of 1996, 47 U.S.C. § 230(b)(1) (2002).

[52] *Barnes v. Yahoo! Inc.*, 2005 U.S. Dist. LEXIS 28061 at *2 (2005), *overruled by Barnes v. Yahoo! Inc.*, 570 F. 3d 1096 (9th Cir. 2009).

interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider."[53] This section has been interpreted to mean that the CDA precludes claims that attempt to hold a service provider liable for the information that a third-party user has distributed through the service.[54]

A number of claims seeking to hold service providers liable for the acts of third parties have been dismissed due to the CDA.[55] Even when notice has been given to a service provider regarding pornographic third-party content that has been posted without the consent of all parties involved, service providers are still granted immunity under the CDA. In *Barnes v. Yahoo!*, Ms. Barnes, after discovering her ex-boyfriend had posted nude photos of her on a fake profile he had created, repeatedly sent letters to Yahoo!, telling the Internet company that she had not consented to the posting of the images or profile, and asking that they be removed. Yahoo! failed to respond to these letters, and it was only after Ms. Barnes threatened to go to a local news channel to do a story about the situation, that a Yahoo! representative contacted her and told her the profiles would be removed from the site.[56] When the company failed to remove the profile and

[53] 47 U.S.C. § 230(c)(1). Communications Decency Act of 1996, 47 U.S.C. § 230(c)(1) (2002).

[54] *See, Barnes, supra* note 52, at *5.

[55] *See, e.g., Carafano v. Metrosplash.com Inc*., 339 F.3d 1119, 1122-24 (9th Cir. 2003) (holding that, because of the Communications Decency Act ("CDA") an Internet dating service could not be held liable for defamation based upon a fake profile that had been created by a third-party user); *Zeran v. Am. Online, Inc*., 129 F.2d 327, 334-35 (4th Cir. 1997) (holding that the CDA precludes service providers from being liable for defamation based upon messages posted by a third-party); *Doe v. MySpace, Inc*., 474 F. Supp. 2d 843, 846-50 (W.D. Tex. 2007) (holding that the interactive website MySpace could not be held liable for negligence due to the CDA, when a minor was sexually assaulted by an adult she met through the site); *Barnes*, 2005 U.S. Dist. LEXIS 280614 (holding that the CDA barred Yahoo! from being held liable for nude photos a man had posted of his ex-girlfriend).

[56] *Barnes*, 2005 U.S. Dist. LEXIS 28061 at *1.

pictures, Ms. Barnes sued Yahoo!, alleging that it breached a duty it had assumed when its representative promised to have the material deleted.[57] The District Court of Oregon dismissed the suit, holding that, because Section 230 of the CDA prevented Yahoo! from being treated as the publisher of the photographs, it was immune from liability for the actions of Ms. Barnes' ex-boyfriend.[58]

While the Ninth Circuit ultimately held that Ms. Barnes had a cause of action against Yahoo!, the court based its decision on the theory of promissory estoppel.[59] A Yahoo! employee had told Ms. Barnes that her photos would be removed from the website, and the court determined that this promise was legally enforceable against the company.[60] The Ninth Circuit's decision thus offers little help to victims of Porn 2.0, as website employees will now be careful not make promises similar to the one Yahoo! made to Ms Barnes.

While the CDA does not always grant websites immunity, the situations in which the provision is inapplicable do not provide relief to the victims of user-generated pornography. The immunity clause of the CDA does not apply to service providers if the service provider is acting as an information content provider.[61] Since websites can be both passive service providers and active content providers, it is possible that a website may be granted immunity under the CDA for content generated by third parties, while the immunity clause will not apply to other materials

---

[57] *Barnes*, 2005 U.S. Dist. LEXIS 28061 at *2.

[58] *Id.* at *4.

[59] *Barnes*, 570 F. 3d at 1107-09.

[60] *Id.*

[61] 47 U.S.C. § 230(c)(1); Fair Hous. Council of San Fernando Valley v. Roommates.com, LLC, 521 F.3d 1157, 1162 (9th Cir. 2008).

that the website played a role in creating.[62] However, this does little for Porn 2.0 victims like Ms. Barnes, whose photos were posted on Yahoo! by a third party user, her ex-boyfriend, while Yahoo! retained its CDA immunity by remaining a service provider only.

Recently, the Ninth Circuit Court of Appeals held that the immunity clause of the CDA did not apply to the website Roommates.com, and thus did not protect the site from a claim that it violated the Fair Housing Act ("FHA").[63] The website, which matches people looking for a place to live with people who have space to rent out, required users to fill out profiles describing their own sexual orientation, as well as their preference in a roommate's sex, sexual orientation, and whether they would bring children to the home.[64] Users provided answers to these questions using drop-down menus.[65] This information was then used to filter listings so that only those who met the described criteria would receive email notifications about available housing. For example, if person stated that she preferred her roommate be a straight female, a lesbian looking for housing would not receive an alert about this housing opportunity. This conduct was alleged to be a violation of the FHA because it ultimately made it more difficult for people to find housing based on discriminatory factors.[66] Roommates.com tried to argue it was immune from liability because it was not responsible for the content of users' profiles, and could not be

[62] 47 U.S.C. § 230(c)(1); Fair Hous. Council of San Fernando Valley v. Roommates.com, LLC, 521 F.3d 1157, 1162 (9th Cir. 2008).

[63] *Fair Hous. Council of San Fernando Valley*, 521 F.3d at 1175-76.

[64] *Id.* at 1161-62.

[65] *Id.* at 1165.

[66] *Id.* at 1167.

considered a publisher of the content.[67] However, the Court held that, because Roommates.com created the questions and the drop-down menu, the website had in fact acted as an information content provider, and could not claim immunity under the CDA against charges of discriminatory filtering of housing opportunities.[68]

The *Roommates.com* holding does little to help those in Ms. Barnes' situation; sites like YouPorn and PornoTube do not contribute to the creation of the videos that they host; these sites act as service providers, passively hosting third-party content.[69] Thus, even though the effects of having unauthorized pornography posted online could be devastating, the CDA permits service providers to turn a blind eye to the fact that their Terms of Service are being violated, and their websites being used as tools for revenge and humiliation.

III. EXISTING PROPOSALS TO REGULATE PORN 2.0 AND PROPOSED REMEDIES FOR ITS VICTIMS

Legal scholars have attempted to develop ways to regulate the spread of amateur, user-generated pornography and, thereby, to protect the interests of those involved. One of these proposals is granting copyright protection to pornographic materials only if all of the people in the video or pictured have consented to its creation and circulation.[70] However, this fails to address situations in which the person spreading the pornography is not concerned with copyright protection, but rather with revenge or humiliation. Another proposal focuses on creating implied or express contracts of confidentiality between couples, where a cause of action arises should one member of the couple share private information about, and images of, the other

[67] *Fair Hous. Council of San Fernando Valley*, 521 F.3d at 1162.

[68] *Id.* at 1175-76.

[69] *See* Freeman, *supra* note 7.

[70] Bartow, *supra* note 8, at 834-38.

on the Internet.[71] This proposed regulation, however, does not protect those who have had images spread by either someone they never had a long-term relationship with or someone who they do not know.

A. *Copyright*

Recently, Professor Ann Bartow proposed a method of regulating Porn 2.0 focused on conditioning copyright registration and enforcement for pornography on a showing that all parties involved consent to both the creation and distribution.[72] Under Professor Bartow's regulation scheme, the creator of a pornographic video or image could never seek a copyright infringement claim against someone who allegedly copied her work, unless she could show that her original work was created with the consent of the persons featured in it.[73]

Professor Bartow points out that, under current copyright law, only the copyright holder has the ability to control the use of photos and videos. Since the copyright in an image or work of art is always granted to the creator rather than the subject of the work, only the creator has a legal right to control its use, while the subjects of the pornographic materials have no ownership rights. [74] Accordingly, the subjects of pornographic videos and images have no ability to control their distribution.[75] Copyright does play a role in pornography. Porn purveyors often search through sites like YouPorn and PornoTube to find content they themselves produced, and then

[71] *See* McClurg, *supra* note 13, at 908-35.

[72] Bartow, *supra* note 8, at 802.

[73] *Id.*

[74] *Id.* at 835.

[75] *Id.*

take action against the infringer.[76] By conditioning copyright protection on a showing of consent by all the parties involved, a pornographer will only be able to pursue such an infringement claim if she can make a showing that all the parties depicted in the photographs or videos consented to the creation of the material and its widespread circulation.[77] In proposing this regulation scheme, Bartow focuses only on creators of Porn 2.0 who are actually interested in obtaining a copyright in their work and would seek to enforce that right.[78]

The weakness of this proposal's ability to protect victims of Porn 2.0 is reflected in some of the examples provided by Professor Bartow. She tells the story of a student who recently discovered that nude photographs of her were taken, without her consent, in a university locker room and subsequently posted on the Internet, while the "legal system, as [the student] experiences it, offers her nothing."[79] It is unlikely that anyone would seek some kind of copyright protection in a photograph taken, presumably from a cell phone, of a girl changing into a bathing suit in a locker room. And because the copyright is owned by the creator of the image, the student herself could not exert any type of ownership over the photograph.[80] Thus, Professor Bartow's regulation scheme would provide no relief to this student.

Therefore, conditioning copyright registration and enforcement on a showing of consent of the subjects depicted would be unlikely to effectively regulate the Porn 2.0 industry and

---

[76] Bartow, *supra* note 8, at 834. Despite the efforts to remove copyrighted material on sites like YouPorn, copyrighted material of porn actress Jenna Jameson still remains on the site. *See also* Freeman, *supra* note 7.

[77] *See* Bartow, *supra* note 8, at 834-38.

[78] *Id.*

[79] *Id.* at 816.

[80] *Id.* at 836.

protect its victims. Someone seeking revenge on an ex-lover is probably not interested in obtaining a copyright, and a copyright would only protect the owner's right to an infringement claim. The subject of the pornographic material would still be left with little recourse after her image is distributed throughout the internet community.

B. *Implied and Express Contracts of Confidentiality*

Legal scholars have also analyzed contract law as a potential source of regulating user-generated Internet pornography. Professor Andrew McClurg proposed that implied or express contracts of confidentiality between partners may give rise to a cause of action if an ex-lover leaks private information or photographic images on the World Wide Web.[81] Courts have already allowed those whose private information is shared on the internet to file suit against their ex-lovers, claiming damages for "publicizing embarrassing personal details."[82]

Professor McClurg, arguing that this tort liability is not adequate protection, proposed that contracts of confidentiality arise between couples in "intimate relationships," which he defines as "a course of romantic dealing between two adults in which the parties intend to form or at least investigate the possibility of forming an ongoing, stable relationship."[83] Thus, intimate relationships do not include purely physical relationships, such as one-night stands.[84] In these relationships, "private, embarrassing information" is shared between the couple, which

[81] *See* McClurg, *supra* note 13, at 908-34.

[82] *Id.* at 892-96.

[83] *See id.* at 917.

[84] *Id.*

may include secrets that could be embarrassing if widely known, sexual information, as well as "sexy pictures."[85]

Contracts of confidentiality are formed between the couple and the information shared between the couple becomes part of this contract. The contract may be implied, inferred from the interactions between the couple while they are together.[86] An implied contract of confidentiality, as Professor McClurg would define it in this situation, only covers "the dissemination of private, embarrassing information through an instrument of mass communication."[87] Thus, breaches of this contract can only occur if one member of the couple uses some kind of widespread media, such as the Internet, to spread private information about the other. This distinction is based on the differences between person-to-person communication and mass communication—face-to-face conversations are fleeting and often quickly forgotten, while Internet postings can be permanent and easily circulated.[88]

Professor McClurg also proposes that parties could form an express contract, ensuring that each member of the relationship owes a duty to the other to keep information private.[89] An

[85] McClurg, *supra* note 13, at 923-28.

[86] *Id.* at 908-17.

[87] *Id.* at 924.

[88] *See id.* at 927.

[89] Professor McClurg proposes the following as a model express contract that could be signed by both parties to a relationship:

> The undersigned parties, for the valuable consideration of society, companionship and all of the other many services and benefits mutually conferred by intimate partners, enter into this agreement of confidentiality as part of an intimate relationship they have established. The parties agree . . . that private information and acts be shared and take place in an atmosphere of mutual trust in which each party can rely on the other not to disclose to third parties private, embarrassing

express contract would avoid the difficulties of ascertaining the terms of an implied contract, and the parties can also determine in advance the kind of damages that will be sought in the event there is a breach.[90]

While contract claims rarely give rise to emotional distress damages, in situations where a breach was "of such a kind that serious emotional disturbance was a particularly likely result," recovery for emotional distress may be allowed.[91] Professor McClurg asserts that the kind of emotional harm resulting from the breach of a contract of confidentiality is likely to meet this description, because intimate relationships are grounded in emotion. Under this theory, damages, determined on a case-by-case basis, could be awarded to a man or woman who is the victim of a breach of confidentiality by an ex-lover.[92]

The potential liability for damages that could occur if a contract of confidentiality between an intimate couple is breached might deter someone from spreading an ex-lover's private information or photographs, and it could help compensate the victim of the breach for humiliation he or she has suffered. However, implied contracts may be hard to prove in court and it may be difficult for a judge to discern whether the parties were ever in a serious

---

> information about the other acquired in the course of the relationship. . . . [Private, embarrassing information] includes information relating to mental and physical health, sexual activities, personal finances, quirks and eccentricities, indiscretions, and immodest or sexually oriented photographs or video in any format.
>
> McClurg, *supra* note 13, at 933 (internal citation omitted).

[90] *Id.* at 929, 936-37.

[91] *Id.* at 935 (citing RESTATEMENT (SECOND) OF CONTRACTS § 353 (1981)).

[92] *Id.* at 935-36.

relationship.[93] Further, it is hard to imagine a couple actually sitting down and signing an express agreement that stipulates to what so many people expect out of a relationship—that private information will be kept between the couple. If one partner requested the other to sign this kind of contract, it could raise issues about trust and potentially damage the relationship.[94] Thus, it seems unlikely that express contracts of confidentiality would actually be utilized by couples.

Even if breach of a contract of confidentiality allows the victim to recover damages from an ex-boyfriend or girlfriend, the money he or she receives will not be able to compensate for what happens after the information is shared. For example, if a man posts nude photographs of his ex-girlfriend on the internet, she might be able to recover a substantial sum of money if she is successful in a breach of an implied contract of confidentiality claim.[95] However, these photos may have been downloaded by hundreds of people all over the world, and may be reposted to different internet sites.[96] The woman's nude images may still be viewed by anyone and could still effect her career and reputation, even years after she won the breach of contract lawsuit. It is the sharing of private information that is the real harm caused by a breach of an ex-lover's promise of confidentiality, and although monetary damages may be able to compensate

---

[93] *See* Elizabeth S. Scott, *A World Without Marriage*, 41 FAM. L.Q. 537, 549-50 (2007) (discussing the difficulty of proving implied contract claims with regard to property in relationships where the couple chose to live together in a marriage-like relationship but yet never made their relationship legally binding).

[94] Richard H. Singer, Jr., *A Primer on Preparing Premarital Agreements*, N.J. LAWYER, Aug. 2003, at 54, 55. Similar issues are raised by prenuptial agreements, which "can have a chilling effect on the parties' love for each other at a very critical time in their relationship."

[95] *See* McClurg, *supra* note 13, at 908.

[96] *Id.* at 927.

somewhat, they cannot erase the websites on which the private information or photographs have been shared or the minds of those people who have viewed it.

Professor McClurg's proposal would also offer no protection to the student described in Professor Bartow's article, as the student did not have any kind of relationship with the person who uploaded nude photos of her on the Internet—she did not even know who had taken the pictures.[97] Contracts of confidentiality thus offer no real way of regulating the unauthorized spread of pornographic images. They cannot provide adequate protection to all people who may be the victims of such acts.

IV. AMENDING THE CDA TO IMPOSE A DUTY TO ACT UPON NOTICE

While existing proposals for regulating Porn 2.0 provide inadequate relief to most people who find their supposedly-private images posted online, amending the CDA can provide a more significant remedy. The CDA should be amended to require service providers to act upon knowledge that it is hosting unauthorized pornography. The CDA currently grants immunity to interactive service providers for content posted by third-parties by preventing these providers from being treated as the publishers of this information.[98] However, these service providers may be liable for hosting copyrighted material posted by a third party without the permission of the owner.[99] The OCILLA requires service providers to act upon the knowledge that copyrighted material has been uploaded to its website in order to avoid liability.[100] Similarly, the CDA should be amended to require that service providers investigate claims of non-consented

---

[97] *See* Bartow, *supra* note 8, at 816.

[98] Communications Decency Act of 1996, 47 U.S.C. § 230(c)(1) (2006).

[99] *See* Online Copyright Infringement Liability Limitations Act, 17 U.S.C. § 512(c) (2006).

[100] *See id.*

pornography and subsequently remove it from its website. This change will provide better protection for victims of Porn 2.0.

A. *Safe Harbor for Online Service Providers under the DMCA*

The DMCA was signed into law by President Bill Clinton on October 28, 1998, in order to protect copyright holders against the threat of infringement that was beginning to grow as a result of the widespread use of the Internet.[101] The Act made criminal actions that "circumvent a technological measure that effectively controls access to a [copyrighted work]."[102] Thus, the production or dissemination of any technology that allows users to circumvent digital copyright protection is barred by the DMCA.[103] Further, the Act imposes civil or criminal liability on those who violate its provisions. A first offense is punishable by a fine of up to $500,000 or imprisonment of up to five years, or both.[104] Subsequent offenses are punishable by a fine of up to $1,000,000 or imprisonment of up to ten years, or both.[105]

The immunity granted to service providers under the CDA has "[n]o effect on intellectual property law," such as copyright law.[106] This provision suggests that service providers could potentially be liable for contributory copyright infringement. Contributory copyright

---

[101] Brandon Brown, Note, *Fortifying the Safe Harbors: Reevaluating the DMCA in a Web 2.0 World*, 23 BERKELEY TECH. L.J. 437, 443 (2008); U.S. Copyright Office, The Digital Millennium Copyright Act of 1998 (Dec. 1998), http://www.copyright.gov/legislation/dmca.pdf.

[102] Digital Millennium Copyright Act, 17 U.S.C. § 1201(a)(1)(A) (2006).

[103] Brown, *supra* note 101, at 443; Declan McCullagh, *Congress Readies Broad New Digital Copyright Bill*, CNET NEWS, Apr. 24, 2006, http://news.cnet.com/2100-1028_3-6064016.html.

[104] 17 U.S.C. § 1204(a)(1).

[105] *Id.* § 1204(a)(2).

[106] Communications Decency Act of 1996, 47 U.S.C.§ 230(e)(2) (2006).

infringement occurs when one party, with the knowledge that another party is committing copyright infringement, "induces, causes, or materially contributes to the infringing conduct of another."[107] This means that an online service provider might be considered a contributory infringer if it knowingly hosts copyrighted material posted by a third-party user. While the third party has committed direct copyright infringement by posting the material, the online service provider is a contributory infringer if it has actual knowledge of this infringement and continues to host the third-party content.[108]

However, the DMCA contains its own provision giving safe harbor to service providers, so that they may avoid claims of contributory copyright infringement for the acts of third parties.[109] Title II of the DMCA, known as OCILLA, creates immunity for online service providers for the copyright-infringing acts of third-party users if the service providers either do not know about the copyright infringement, or if they comply with the procedure set out in OCILLA after gaining knowledge of infringement.[110] The "notice and takedown" procedure described in OCILLA requires that a service provider, upon receiving "knowledge or awareness" of infringing material on its network, must "act[] expeditiously to remove, or disable access to,

[107] Gershwin Publ'g Corp. v. Columbia Artists Mgmt., Inc., 443 F.2d 1159, 1162 (2d Cir. 1971).

[108] *See* Laura Rybka, ALS Scan, Inc. v. Remaro Communities, Inc.: *Notice and ISPS' Liability for Third Party Copyright Infringement*, 11 DEPAUL-LCA J. ART. & ENT. L. & POL'Y 479, 492 (2001).

[109] *See* 17 U.S.C. § 512 (c).

[110] *Id*; David Haskel, *A Good Value Chain Gone Bad: Indirect Copyright Liability in* Perfect 10 v. Visa, 23 BERKELEY TECH. L.J. 405, 415 (2008).

the material."[111] Additionally, to qualify for safe harbor, the service provider must designate an agent who receives all notifications of alleged copyright infringement.[112]

Adequate notification of copyright infringement under the DMCA includes a physical or electronic signature of someone authorized to act on behalf of the owner of the copyright, an identification of the copyrighted work allegedly being infringed, contact information for the complaining party, a statement of good faith belief that copyright infringement is occurring, and a statement that all the information in the notification is accurate under penalty of perjury.[113] After the designated agent receives the claim of copyright infringement, the agent must decide whether the notification meets the required standards, and determine whether the material should be removed.[114] Removing the material in a timely fashion will allow the service provider to avoid any contributory copyright infringement claim for the infringement committed by a third party.[115]

After the material is deleted from the site, the agent must notify the alleged infringer that the material has been removed.[116] The alleged infringer may then file a counter-notification, arguing a good faith belief that the material was mistakenly removed.[117] The service provider must then wait ten to fourteen days; if a copyright infringement suit is not filed within this time,

---

[111] OCILLA, 17 U.S.C. § 512(c)(1)(A)(iii) (2006).

[112] *Id.* § 512(c)(2).

[113] OCILLA, 17 U.S.C. § 512(c)(3)(A).

[114] *See id.* § 512(c).

[115] *See id.*

[116] *Id.* § 512(g)(2)(A).

[117] *Id.* § 512(g)(3).

the material may be placed back on the website.[118] However, if the service provider fails to act and copyright infringement has occurred, it may be liable for contributory infringement.[119]

Though the DMCA provides a way for copyright holders to protect their ownership rights, it only keeps such materials off of websites to the extent that an infringement suit ensues. Thus, only those with the means to pursue a lawsuit will be able to keep their copyrighted work from being infringed upon.[120]

Porn 2.0 sites such as YouPorn have DMCA disclaimers, providing information on whom to contact if material posted on the site is infringing a copyright, and what proper notification of this infringement must include.[121] These sites thus provide mechanisms for contacting the site about potential infringements, even giving the contact information of an agent who will investigate these claims.[122]

The DMCA has been subjected to some criticism on multiple fronts since it was enacted, and any new legislation modeled on its provisions should address those criticisms. Analysis of takedown notices received by online service providers has indicated a high percentage of flawed claims. Moreover, service providers have generally been quick to act on these claims, and more

[118] *See* OCILLA, 17 U.S.C. § 512(g)(C).

[119] Rybka, *supra* note 108, at 492.

[120] *See* Copyright Claim Dispute: Filing a Counter Notice, http://www.google.com/support/youtube/bin/answer.py?answer=59826 (last visited Dec. 18, 2008).

[121] YouPorn.com – DMCA Notice of Copyright Infringement, http://www.youporn.com/dmca (last visited Nov. 18, 2008).

[122] *See id.*

hesitant to put back material that may have been taken down in error.[123] However, other analyses have concluded that despite misuse of some DMCA provisions, the measure "has achieved some success in balancing its two principal goals: protection of the rights of copyright owners and limited liability of online service providers."[124] Despite some problems, the DMCA, with some modifications, is still a worthy model for an amendment to the CDA.

B. *Amending the CDA to Provide Notice and Takedown Measures Similar to the DMCA*

The CDA and the DMCA both provide immunity to service providers for the actions of third-party users.[125] However, the immunity provided for contributory copyright infringement under the DMCA is provisional; it is based upon the service providers' compliance with specific procedures, which include removing the allegedly copyrighted material from the website.[126] The CDA should be amended to include a similar provision, granting immunity to websites for third-party conduct only when these sites react to the notification that they are hosting unauthorized pornography.

A "notice and takedown" amendment to the CDA would function in a similar way to the DMCA provision with the same name. This amendment would require every website considered to be a Porn 2.0 site—that is, those that permit third parties to upload user-generated

---

[123] Jennifer M. Urban & Laura Quilter, *Efficient Process or "Chilling Effects"?Takedown Notices under Section 512 of the Digital Millennium Copyright Act*, 22 SANTA CLARA COMPUTER & HIGH TECH L.J. 621, 681-83 (2006).

[124] Joshua Urist, Note, *Who's Feeling Lucky? Skewed Incentives, Lack of Transparency, and Manipulation of Google Search Results under the DMCA*, 1 BROOK. J. CORP. FIN. & COM. L. 209, 227 (2006).

[125] *See* Communications Decency Act of 1996, 47 U.S.C. § 230(c) (2006); 17 U.S.C. § 512(c).

[126] OCILLA, 17 U.S.C. § 512(c) (2006).

pornography—to have a link providing information on how to contact an agent regarding posts of unauthorized content. In providing such notification, the complaining party would be required to provide contact information, a description of the content allegedly posted without consent and information on how to locate the image or video on the website (for example, the direct web site link to the material), a good faith statement that this is a legitimate claim and that all the information provided is truthful.

After the agent receives a complaint of non-consented pornography, the agent would notify the poster that the material has been removed. Then the original poster would have ten days to reply; if the website does not receive a response within the ten day period, the material will not be restored to the site. If the original poster chooses to respond, he will have to provide evidence that all the people in the pornographic material that was removed had consented both to its production and its dissemination on the Internet. This proposal differs from the DMCA, in that the person who submits the complaint is not required to file a lawsuit in order to permanently remove the material.[127] Thus, people would be able to protect their privacy even if they do not have the time and resources to commit to a lawsuit.

If the website fails to provide visitors with adequate information regarding how to contact an agent regarding third-party postings, or its appointed agent ignores a claim of unauthorized pornography, the CDA would no longer provide a safe haven to online service providers, and they could face potential liability for hosting these unauthorized photos.

[127] *See* OCILLA, 17 U.S.C. § 512(g)(C).

An amendment to the CDA would open the door to claims such as Ms. Barnes' against Yahoo!.[128] This includes suits for negligently breaching a duty the service provider assumes when it receives notification of the unauthorized photos.[129] And, although the law is somewhat murky on exactly what remedy victims of Porn 2.0 have against the person who posted the photos,[130] courts have imposed fines,[131] and could potentially consider the action an invasion of privacy.[132] Under a "notice and takedown" provision of the CDA, services providers who violated the specified procedure after notification could potentially be liable for contributing to such an invasion, and also might be required to pay damages to the plaintiff. Service providers would thus be contributorily liable for whatever cause of action the plaintiff pursues against the poster.

Victims of Porn 2.0 require a mechanism to have their unauthorized pictures or videos removed from a website. This could be accomplished by creating a provision to the CDA that would grant online service providers immunity for the actions of third parties only after the service provider, on notice that it is hosting unauthorized postings of pornography, moves to take down such material. Not only would websites like YouPorn be required to post information on how people may contact the site about unauthorized postings, but service providers would have incentive to take such claims seriously.

---

[128] Barnes v. Yahoo! Inc., No. Civ. 05-926-AA, 2005 WL 3005602, at *2 (D. Or. Nov. 8, 2005), *overruled by* Barnes v. Yahoo! Inc., 570 F. 3d 1096 (9th Cir. 2009).

[129] *Id*.

[130] *See* McClurg, *supra* note 13, at 894.

[131] Lisa Sink & Jeanette Hurt, *Posting Nude Photos of Ex-Girlfriend Brings Fine: Man Also is Ordered to Serve One Year in Jail for Lying Under Oath During Case*, MILWAUKEE J. SENTINEL, May 22, 2001.

[132] *See* Bartow, *supra* note 8, at 816.

C. *Addressing Counterarguments*

There are several likely counterarguments against this proposed amendment to the CDA. This proposal would not be able to entirely prevent the spread of potentially damaging photos and videos on the Internet, since "notice and takedown" procedures would come into effect only after the images have already been disseminated and, most likely, viewed by many people. While the "notice and takedown" CDA amendment would still not be able to curb a website user's ability to download pictures off a Porn 2.0 site to their home computers, or prevent a user from uploading the image or video to yet another amateur pornography web page, it would at least provide victims of unauthorized postings with a way to begin to regain their privacy. If the victim knows of other sites hosting the material, he or she can notify all of these websites, which would then have a duty to investigate the claim and possibly remove the uploaded content. Though people will likely have viewed the content on the website before it is removed, the "notice and takedown" CDA amendment can help do away with the permanency that comes along with embarrassing Internet postings.[133]

There are also those who would argue that victims of pornography should not be granted special protections of this kind, or that existing recourses are sufficient. However, sexuality has often been treated as a special case in matters of law, subject to special protections and regulations.[134] Sexual assault is considered an especially grievous crime, and rape is one of the very rare cases when "deadly force" has been deemed justified as a defense against a non-lethal

[133] *See* McClurg, *supra* note 13, at 927.

[134] *See supra* note 37. *But see* Gayle S. Rubin, *Thinking Sex: Note for a Radical Theory of the Politics of Sexuality*, *in* PLEASURE AND DANGER: EXPLORING FEMALE SEXUALITY 267, 274 (Carole S. Vance ed., 1984).

assault.[135] Moreover, consent is often a particularly important consideration when it comes to sex-based offenses. In criminal rape cases, consent is the focus of the trial—the defense often argues that the alleged victim consented to intercourse, while the prosecution must prove non-consent beyond a reasonable doubt.[136] Additionally, the crime of statutory rape is based on a minor's legal incapacity to consent to sex with an adult.[137] Thus, it makes sense to consider the consent of both parties when one partner posts sexually explicit photographs on the Internet.

Other arguments against this proposed amendment would likely address the potential chilling effect on speech of "notice and takedown" provisions. Such criticisms have already been leveled against the DMCA.[138] However, while immunity was granted to service providers under the CDA in order to "to promote the continued development of the Internet,"[139] this development must not be to the detriment of individual privacy. Because society often views those who take part in sexual expression with particular disdain, a breach of privacy through Porn 2.0 has particularly devastating consequences, often leading to the loss of both a person's career and reputation,[140] thus the victims of Porn 2.0 need a mechanism of protection. The Internet, and even amateur pornography websites, will still be able to flourish if pornographic websites remove unauthorized postings. The "notice and takedown" CDA amendment would

---

[135] Kimberly Kessler Ferzan, *Self Defense and the State*, 5 OHIO ST. J. CRIM. L. 449, 451 (2008).

[136] Corey Rayburn, *To Catch a Sex Thief: The Burden of Performance in Rape and Sexual Assault Trials*, 15 COLUM. J. GENDER & L. 437, 462 (2006).

[137] *See* Russell L. Christopher, *Should Being a Victim of a Crime be a Defense to the Same or a Different Crime?*, 28 PACE L. REV. 783, 791 (2008).

[138] *See* Urban & Quilter, *supra* note 123, at 681-83.

[139] Communications Decency Act of 1996, 47 U.S.C. § 230(b)(1) (2006).

[140] *See supra* notes 37-43 and accompanying text.

only force Porn 2.0 websites to ensure that users are actually complying with the site's Terms of Service, which typically require that all parties involved in pornographic material consented to its posting.[141]

A "notice and takedown" CDA amendment will thus provide a way for victims of Porn 2.0 to notify an online service provider that its Terms of Service are being broken, and have the unauthorized images taken off the website. This Amendment, by actually forcing service providers to remove material that has been posted by third-party users without the consent of the persons involved, regulates Porn 2.0 in a way that other proposals do not.[142] Removing the information from these sites will preclude people from viewing it in the future, and, accordingly, will limit the amount of harm caused by the unauthorized postings.

V. CONCLUSION

With the rising popularity of online interactive communities, Porn 2.0 has become a widespread phenomenon, with sites like YouPorn being ranked among the most-visited websites in the world.[143] By allowing users to upload their own homemade pornography, these sites open the doors for extreme violations of privacy. Much of the material posted on these sites has likely been uploaded without the consent of all the parties involved.[144] The victims of unauthorized

[141] *See* YouPorn.com – Terms of Service, *supra* note 34.

[142] *See supra* Section III.

[143] YouPorn.com – Traffic Details from Alexa, *supra* note 26.

[144] Freeman, *supra* note 7.

pornographic Internet postings have little legal recourse, as the CDA grants immunity to online service providers for the actions of third parties.[145]

Legal scholars have proposed different ways to control Porn 2.0 and provide relief to those who do not consent to being a part of these websites. Professor Ann Bartow believes that copyright protection for pornography should be conditioned on a showing of the consent of all parties involved.[146] However, this method assumes that people who make unauthorized postings of pornography actually want copyright protection for the pornographic material they post. This will not always be the case. It seems that one great motivation for such postings is revenge on an ex-lover.[147] Additionally, Professor Andrew McClurg has proposed implying a contract of confidentiality in intimate relationships that protects private, embarrassing information from being shared through forms of mass communication such as the Internet.[148] This would allow the ex-girlfriend or boyfriend of someone who has posted nude photographs or videos on the Internet to pursue a claim for damages.[149] This proposal, however, would provide no relief to Porn 2.0 victims who did not have an intimate relationship with the person who posted the photos, nor would it provide a mechanism for the removal of the pornographic materials.

An adequate remedy for Porn 2.0 victims can be modeled after the DMCA, which grants service provider immunity for contributory copyright infringement only if a service provider,

---

[145] *See* Barnes v. Yahoo! Inc., No. Civ. 05-926-AA, 2005 WL 3005602, at *1 (D. Or. Nov. 8, 2005), *overruled by* Barnes v. Yahoo! Inc., 570 F. 3d 1096 (9th Cir. 2009).

[146] Bartow, *supra* note 8, at 834-38.

[147] Bartow, *supra* note 8, at 813; Freeman, *supra* note 7.

[148] McClurg, *supra* note 13, at 908-35.

[149] *Id.* at 935-36.

after being informed of infringing activity on its servers, moves to take the material down.[150] Modeling an amendment to the CDA after the "notice and takedown" provision of the DMCA would require service providers to investigate claims of unauthorized pornography postings and remove materials that were posted without the consent of all parties involved, or else face potential liability for hosting this content. This would enable Porn 2.0 victims to put a halt to people viewing supposedly private videos and images that have now been posted on the Internet.

A "notice and takedown" amendment to the CDA would provide a protection for individual privacy in the context of a law that aids the development of the Internet. It would allow private moments to remain private, in an age where it has become increasingly easy to ruin careers and personal relationships through the digital world.

[150] OCILLA, 17 U.S.C. § 512(c) (2006).

SYRACUSE SCIENCE & TECHNOLOGY LAW REPORTER

VOLUME 21 FALL 2009 ARTICLE 2, PAGE 36

The FDA Safe Harbor Provision After *Proveris*

Adam Sibley

Abstract

The "FDA safe harbor provision," enacted as part of the Hatch-Waxman Act and codified at 35 U.S.C. § 271(a), excepts from infringement uses of patented inventions that are solely and reasonably related to submissions to the FDA. Over the past twenty years, the Supreme Court has broadened this safe harbor to include medical devices and upstream research, in cases such as *Eli Lilly v. Medtronic*, 496 U.S. 661 (1990), and *Merck KGaA v. Integra Lifesciences I*, 545 U.S. 193 (2005). Throughout this broadening evolution, the Supreme Court has fashioned analytical tests as well as specific definitions for various applicable terms, such as "patented invention." However, in August 2008, the Federal Circuit brought an abrupt halt to this trend in its decision in *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008). Although the result in *Proveris* might well be correct, the opinion displays obvious tensions with Supreme Court precedent and leaves many questions unanswered.

Table of Contents

Introduction 37
Part I: Statutory Experimental Use Exception 39
  Eli Lilly & Co. v. Medtronic, Inc. 44
  Merck KGaA v. Integra Lifesciences I 46
Part II: Analysis of Proveris Scientific Corp. v. Innovasystems, Inc. 48
Part III: Recommendations 54

The FDA Safe Harbor Provision After *Proveris*

Adam Sibley[1]

Introduction

In the United States, a patent offers its holder a negative right to exclude others from practicing the encompassed invention.[2] However, over the years, both Congress and the courts have allowed various non-licensed uses of patented inventions and have excepted[3] these actions from infringement.[4]

One exception to infringement is known as the Food and Drug Administration Safe Harbor ("FDA safe harbor") and is embodied in the Hatch Waxman Act.[5] Since the Act's enactment in 1984, the courts have seemingly broadened the statute's scope of applicability to

---

[1] Law student at the University of Virginia School of Law, Class of 2010.

[2] 35 U.S.C. § 154(a)(1) (2006) (granting, in part, "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States[.]"); JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 14 (2nd ed. 2006).

[3] Courts and commentators have interchangeably labeled this exclusion as either an exception or an exemption. *See* Madey v. Duke Univ., 307 F.3d 1351, 1361 (Fed. Cir. 2002) ("[W]e have referred to the defense [to infringement] in a variety of ways."); *see also* Denise W. DeFranco, *The Experimental Use Exception: Looking Towards a Legislative Alternative,* 6 J. HIGH TECH. L. 93, 97-98 n.4 (2006) (electing to consistently use "exception"). Similarly to the DeFranco article, this paper will refer to the defense as an exception.

[4] Infringement is described in 35 U.S.C. § 271(a) (2006) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

[5] Codified in part at 35 U.S.C. § 271(e)(1) (2006) (excepting from infringement activities that are "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products").

include various upstream drug testing and medical devices[6]. Nevertheless, this trend of expansion came to an abrupt halt in August 2008 when the United States Court of Appeals for the Federal Circuit ("Federal Circuit")[7] handed down its ruling in *Proveris Scientific Corp. v. Innovasystems, Inc.*[8] This holding restricted the applicability of the FDA safe harbor to only except infringement on those devices that are subject to a required approval process under the Federal Food Drug and Cosmetic Act (FDCA).[9]

While the end result of *Proveris* may be reasonable, the holding leaves many questions unanswered. Since many research tools[10] are not subject to FDCA approval, does *Proveris*

[6] 21 U.S.C. § 321(h) (2006) (defining a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes").

[7] The Federal Circuit, amongst the Circuit Courts of Appeal, has sole appellate jurisdiction for patent cases. *See* 28 U.S.C. § 1295(a)(1), (a)(4)(A), (a)(6) (2006) (granting the Federal Circuit exclusive jurisdiction over appeals from district court cases arising under 28 U.S.C. § 1338, appeals from the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office, and review of determinations from the United States International Trade Commission); 28 U.S.C. § 1338 (2006) (noting that federal district courts have original jurisdiction for cases arising under the patent laws).

[8] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008).

[9] The FDCA is a federal law that regulates the manufacture, use or sale of drugs and other products. 21 U.S.C. §§ 301-399a, 355(a) (2006).

[10] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999) (final notice) (defining research tools as "tools that scientists use in the laboratory, including cell lines monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines"); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860

preclude most research tools from the safe harbor provision? What if a research tool is subject to FDCA approval, but is merely used as a research tool and not for its FDCA use? Was this holding merely fact-specific, and would an entity be excepted under the safe harbor if it made an infringing device for solely in-house use (and not for sale as that in *Proveris*)? In order to answer these and other questions, the courts will either need to make the test laid out in *Proveris* more robust, or resort back to a more flexible analysis.

Thus, this paper will discuss the present state of the FDA safe harbor and its applicability. Part I will discuss the statutory exception in the Hatch Waxman Act and its interpretation by the courts. Part II will present an analysis of the recent Federal Circuit case, *Proveris Scientific Corp. v. Innovasystems, Inc.*[11] Part III will offer recommendations and suggestions on how the courts should approach future cases under the FDA safe harbor provision.

Part I: Statutory Experimental Use Exception

At the present time, when a drug manufacturer wishes to commercialize a generic drug, it may file an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA).[12] As a result, the generic drug maker is not required to show the safety and efficacy of

(Fed. Cir. 2003) *vacated, remanded by* Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (citing the definition outlined in 64 Fed. Reg. at 72,092).

[11] *Proveris*, 536 F.3d 1256.

[12] 21 U.S.C. § 355(j) (2006).

the drug;[13] instead, it only needs to show that its generic is the bioequivalent to (same active ingredients as) the previously marketed drug.[14]

However, things were not always as easy for a generic manufacturer. Prior to the Hatch Waxman Act, the generic manufacturer had to wait until after the patent expired[15] on a pioneer (new) drug[16] before undergoing experiments to prove bioequivalence.[17] The practical result was

---

[13] 21 U.S.C. § 355(j)(2)(A) (2006).

[14] 21 U.S.C. § 355(j)(2)(A)(ii), (2)(A)(iv), (8)(B) (2006). The general FDA Drug Approval Process for a new drug is as follows:

- Initial Step: Perform preclinical testing in animals; obtain the pharmacological profile, the acute toxicity data, and short-term toxicity data; submit an Investigational New Drug (IND) application to the FDA (the FDA has 30 days to review).
- Phase I: Perform clinical pharmacological studies on humans to obtain information on the safety and pharmacological activity of the drug (this Phase last an average of 6 months to 1 year).
- Phase II: Concentrated studies in patients with the specific conditions that the drug is meant to address in order to determine intended efficacy (average of 2 years).
- Phase III: These are the open trials that last approximately 3 years and occur on multiple health centers. The Phase III studies are critical for approval by the FDA.
- New Drug Application (NDA): The applicant submits all of the testing data as well as all relevant information regarding manufacturing, packaging, and product assurance. This application is reviewed for an average of 24 months.
- Phase IV: Includes post-market analysis on the approved drug.

However, a generic drug can be filed under an abbreviated new drug application (ANDA). For a generic drug, the applicant needs to prove bioequivalence to the brand-name drug, but Phase I, II, and III data are not required. Jason C. Cooper, The FDA Approval Process, Lecture Notes, *available at* http://people.musc.edu/~cooperjc/FDAapproval.htm (last visited Oct. 28, 2009).

[15] 35 U.S.C. § 154(a) (2006) (declaring that the patent term for applications filed on or after June 8, 1995 is twenty years from the filing date of the original application); 35 U.S.C. § 154(c) (allowing a patent holder of a patent that was filed before June 8, 1995 to have a term that is the greater of that outlined in § 154(a) or seventeen years from the date the patent is granted).

[16] 21 U.S.C. § 321(p) (2006) (defining a new drug as one "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs").

[17] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984) (finding a generic manufacturer liable for infringement for practicing a patented invention to submit data to the FDA for approval during the patent's active term).

that the generic manufacturer was not able to enter the market immediately after the expiration of the patent, and thus the patent holder gained a *de facto* patent term extension.[18] This delay in generic entry was very valuable to pioneer drug manufacturers and also very costly to consumers.[19]

These patent term distortions in the pre-Hatch Waxman era are illustrated in *Roche Prods., Inc. v. Bolar Pharm. Co.*[20] In *Roche*, the accused infringer (Bolar) made a patented drug and performed safety tests and experiments of bioequivalence while the Roche's pioneer patent was still in force, in violation of Roche's exclusionary rights under 35 U.S.C. § 154(a)(1).[21] This testing was done in order to satisfy Bolar's submission to the FDA.[22] Of note was that Bolar did not plan to market their generic drug while Roche's patent was in force; rather, they wanted to obtain FDA approval during Roche's patent life so that they could effectively market the generic immediately after the patent expired.[23] The court, noting that Bolar did not experiment on the

---

[18] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 670 (1990) ("[T]he patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained."); *Proveris*, 536 F.3d at 1265 ("[T]he de facto extension of effective patent life at the end of the patent term [is] also caused by the FDA premarket approval process.").

[19] Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 172 (2008) ("Generic drugs can capture 80-90% of the market, often within months of entering the marketplace."); CONG. BUDGET OFFICE, THE CONGRESS OF THE U.S., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37 n.2 (1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (stating that, in 1994, 95 percent of drugs with revenues over $40 million whose patents had expired had generic equivalents).

[20] *Roche*, 733 F.2d at 858.

[21] *Id.* at 860.

[22] *Id.*

[23] *Id.*

patented invention but rather experimented with the invention in order to obtain safety and bioequivalence data, held that the experimental use defense did not apply.[24] In addition, the court noted that "Section 271(a) prohibits, on its face, any and all uses of a patented invention."[25] Scholars have noted that the holding in *Roche* was not "extraordinary" and followed the proper analysis with regard to experimental use.[26]

However, the decision was controversial and mere months after the decision in *Roche*, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch Waxman Act, overturning *Roche*.[27] The FDA safe harbor provision of the Hatch Waxman Act is codified in 35 U.S.C. § 271(e)(1) and states:

> It shall not be an infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs.[28]

The legislative history of the Hatch Waxman Act indicates that it was originally meant to be a very limited reversal of the *Roche* decision.[29] The main purpose of the safe harbor provision

---

[24] *Roche*, 733 F.2d at 863.

[25] *Id.* at 861.

[26] Harold C. Wegner, *Post-Merck Experimental Use and the "Safe Harbor"*, 15 FED. CIR. B.J. 1, 13 (2005).

[27] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. § 68(b)-(c), 70(b) (1994); 21 U.S.C. § 301 n.355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

[28] 35 U.S.C. § 271(e)(1) (2006).

[29] Wegner, *supra* note 26, at 13; Rebecca Lynn, Note, *Merck KGaA v. Integra Lifesciences I, Ltd: Judicial Expansion of 271(e)(1) Signals a Need for a Broad Statutory Experimental Use Exemption in Patent Law*, 21 BERKELEY TECH. L.J. 79, 84-85 (2006); *see also* Paul Wiegel, *Was the FDA exemption to patent infringement, 35 U.S.C. § 271(e)(1), intended to exempt a*

was simply to enable generic drug manufacturers to enter the market immediately after patent expiration, by allowing them to begin the regulatory approval process while the patent was still in force.[30] By enacting the safe harbor, Congress was able to eliminate a distortion at the end of a patent term, in which a patentee had previously obtained a de facto patent term extension due to the generic company's inability to enter the market immediately after patent expiration.[31]

When considering the Act, Congress also recognized another distortion at the beginning of the term.[32] Patentees were getting a de facto patent term reduction due to the time consumed in the FDA regulatory approval process.[33] In 1999, the average time for the FDA to review the approval application for a new drug was 12.6 months,[34] and it has been estimated that the average time from "synthesis to approval" is 100 months.[35] Thus, when Congress chose to overrule *Roche* with the safe harbor provision, it chose to offset this change by offering a patent term extension of up to five years for time spent in the regulatory approval process.[36]

---

pharmaceutical manufacturer's activities in the development of new drugs?, 2007 B.C. INTELL. PROP. & TECH. F. 112901 (noting that the exemption was only meant to apply to generic drugs and not new pharmaceuticals).

[30] H.R. REP NO. 98-857(II), at 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2692 (stating that the purpose of the Act was to legalize "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute").

[31] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669-71 (1990).

[32] *Id.* at 669-70.

[33] *Id.*

[34] *FDA Approval Process Slowing*, 36 PSYCHIATRIC NEWS 33 (2001). This statistic only represents the time for the review of the New Drug Application and does not include the previous applications and clinical trials.

[35] Cooper, *supra* note 14.

[36] *Medtronic*, 496 U.S. at 671; *see also* 35 U.S.C. § 156 (2006).

Although the initial purpose of the Hatch Waxman Act might well have been directed at generic drugs,[37] the courts have subsequently expanded that safe harbor doctrine to include upstream testing and medical devices in cases such as *Eli Lilly & Co. v. Medtronic, Inc.*[38] and *Merck KGaA v. Integra Lifesciences I.*[39] These cases and the subsequent expansion of the doctrine are discussed below.

Eli Lilly & Co. v. Medtronic, Inc.

In *Eli Lilly & Co. v. Medtronic, Inc*., Eli Lilly sought to enjoin Medtronic from the "testing and marketing of an implantable cardiac defibrillator, a medical device used in the treatment of heart patients."[40] Eli Lilly claimed that Medtronic was infringing its patents in this process, and Medtronic claimed exemption under the FDA safe harbor in 35 U.S.C. § 271(e)(1).[41] Therefore, the Supreme Court was confronted with the issue of whether or not the FDA safe harbor provision was applicable not only to drugs, but also to medical devices.[42]

However, deciding this issue was not clear-cut for the Court, partly due to the ambiguous nature of the statute.[43] In attempting to analyze § 271(e)(1), Justice Scalia noted that

> No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship. To

[37] Wiegel, *supra* note 29.

[38] *Medtronic*, 496 U.S. 661.

[39] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

[40] *Medtronic*, 496 U.S. at 664.

[41] *Id.*

[42] *Id.* at 663.

[43] *Id.* at 679.

> construe it as the Court of Appeals decided [that "patented invention" in the safe harbor includes medical devices], one must posit a good deal of legislative imprecision; but to construe it as petitioner would [that the safe harbor does not include medical devices], one must posit that and an implausible substantive intent as well.[44]

In eventually finding that § 271(e)(1) included medical devices, the Court found it likely that Congress wished to balance the two distortions at the beginning and end of the patent term by enacting the Hatch Waxman Act.[45] Because medical devices were eligible for patent term extension under § 156 (and patent holders were thus able to negate the previous de facto patent term reduction), the Court was persuaded that Congress would have rationally meant to include medical devices in the safe harbor of § 271(e)(1) (thus symmetrically eliminating the patent holder's de facto patent term extension).[46] Otherwise, a medical device patent holder would gain a patent extension at the end of the term for the time in regulatory approval, without also being subjected to generic competition under the safe harbor.[47] Importantly, the Court defined "patented invention" in § 271(e)(1) to "include all inventions, not drug-related inventions alone."[48]

This opinion is significant for numerous reasons. Firstly, the Court interpreted § 271(e)(1) to include medical devices, and not only drugs, even though it may have been the

---

[44] *Medtronic*, 496 U.S. at 679.

[45] *Id*. at 672-73.

[46] *Id.*

[47] *Id.* at 672-73.

[48] *Id*. at 665.

intent of legislators to only aid generic drugs getting to the market.[49] In addition, the Court's attempt to achieve symmetry between the prior patent term distortions that were present before the Hatch Waxman Act later became the basis of Federal Circuit's analysis in *Proveris*,[50] as described in Part II of this article. The Court's broad definition of "patented invention" in *Medtronic*[51] is also a central inconsistency in the Federal Circuit's holding in *Proveris*,[52] also discussed further in Part II.

After *Medtronic*, the next major Supreme Court case that effectively broadened the FDA safe harbor provision from its original purpose of allowing generic drug testing was *Merck KGaA v. Integra Lifesciences I*.[53]

Merck KGaA v. Integra Lifesciences I

In *Merck*, Integra had an ownership interest in patents on peptide sequences (RGD peptides) that promote cell adhesion.[54] Merck began funding research at the Scripps Institute

[49] H.R. REP. NO. 98-857(II), at 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2692 (noting that the House Committee on the Judiciary described the purpose of the safe harbor as allowing "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute"); H.R. REP. NO. 98-857(II), at 45 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714 (recording that the House Committee on the Judiciary anticipated the effects of the FDA safe harbor on the rights of the patent holder would be "de minimus [sic]"); Wegner, *supra* note 26, at 13 (characterizing the safe harbor as being "designed to create a very narrow statutory override . . . simply to permit the regulatory testing of generic drugs[.]"); Lynn, *supra* note 29, at 84-85 (stating that the purpose of Congress was to affect the regulatory approval process for generic drugs); *see also* Wiegel, *supra* note 29 (noting that the exemption was only meant to apply to generic drugs and not new pharmaceuticals).

[50] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265 (Fed. Cir. 2008).

[51] *Medtronic*, 496 U.S. at 665.

[52] *Proveris*, 536 F.3d at 1265-66.

[53] Merck KGaA v. Integra Lifesciences I, 545 U.S. 193 (2005).

that involved preclinical testing of RGD peptides for use in angiogenesis as well as tumor inhibition.[55] Integra then filed suit against various entities, including Merck, claiming patent infringement.[56] The issue before the Supreme Court was "whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U.S.C. § 271(e)(1)."[57]

In holding that the preclinical research is protected by the safe harbor provision, the Court concentrated on the phrase "reasonably related" in the statute.[58] The Court noted that it is "apparent from the statutory text . . . that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA [Food Drug and Cosmetic Act]."[59] In addition, "[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included."[60] The Court viewed "reasonably related" activity as that for which one "has a reasonable basis for believing that a patented compound may work, through a particular

---

[54] *Merck*, 545 U.S. at 197.

[55] *Id*.

[56] *Id*. at 200.

[57] *Id*. at 195.

[58] *Id*. at 202.

[59] *Merck*, 545 U.S. at 202.

[60] *Id*.

biological process, to produce a particular physiological effect, and uses the compound in research, that if successful, would be appropriate to include in a submission to the FDA."[61]

Thus, the Supreme Court's rulings in *Medtronic* and *Merck* appeared to expand the FDA safe harbor provision in § 271(e)(1). In light of this expansive trend, the Federal Circuit's recent restrictive holding in *Proveris*[62] can be viewed a substantial. Part II, below, will discuss the *Proveris* case and the inconsistencies in its analysis when compared with of *Medtronic* and *Merck*, discussed above.

Part II: Analysis of Proveris Scientific Corp. v. Innovasystems, Inc.

On August 5, 2008, the Federal Circuit handed down its decision in *Proveris Scientific Corp. v. Innovasystems, Inc.*[63] This decision is noteworthy because it is the first Federal Circuit case[64] that has addressed how the FDA safe harbor should be applied in the context of research tools.[65]

Proveris owned a patent ("the '400 Patent") on "a system and apparatus for characterizing aerosol sprays commonly used in various drug delivery devices, such as nasal

---

[61] *Merck*, 545 U.S. at 207.

[62] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008).

[63] *Id.*

[64] See *supra* note 7 for a discussion on Federal Circuit jurisdiction.

[65] *Proveris*, 536 F.3d at 1264 (noting that Innova viewed its device as a research tool). See *supra* note 10 for a definition of "research tools." The definition of research tools is rather broad. Some tools, such as monoclonal antibodies, can be subject to FDA approval; however, others (such as microscopes) are not subject to the FDCA regulatory approval process. *See* Ramon K. Tabtiang & Steven C. Carlson, *A Safe Harbor in a Patent Storm?*, LOS ANGELES DAILY JOURNAL, Sept, 10, 2008, at 7, *available at* http://www.fr.com/news/2008/September/FR%20DJ%20clip%20Proveris%20Case%20Tabtiang%20and%20Carlson%209-10-08%20_3_.pdf.

spray pumps and inhalers."[66] Since "FDA approval is required for inhaler-based drug delivery devices," spray characterization (such as that accomplished by the '400 Patent)[67] is important in the FDA approval process.[68] However, the actual "system and apparatus" disclosed in the '400 Patent are not subject to FDA approval.[69] This invention can be characterized as a research tool because it is used as laboratory testing equipment by scientists.[70]

Innova, the accused infringer, produced an Optical Spray Analyzer (OSA) that it sold to third parties but never used for its own FDA-related research.[71] The OSA was used by third parties to develop data for FDA submissions (such as measurements of the "physical parameters of aerosol sprays"), but the OSA was not itself subject to FDA approval.[72]

Proveris filed an infringement suit against Innova,[73] and the issue eventually presented to the Federal Circuit was "whether section 271(e)(1) immunized the manufacture, marketing or

---

[66] *Proveris*, 536 F.3d at 1258; U.S. Patent No. 6,785,400 (filed Aug. 16, 2000).

[67] The '400 Patent (stating that characterization of the geometry of an inhaler's aerosol spray is the best indicator of the overall performance of the drug delivery device; noting that the most important measurements include the spray angle and geometry as it leaves the device, the cross-sectional ellipticity, the spray uniformity and pattern, and the time-wise development of the spray plume).

[68] *Proveris*, 536 F.3d at 1258.

[69] *Id.*

[70] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, *supra* note 10, at 72,092 n.1; *see also Proveris*, 536 F.3d at 1264 (noting that Innova viewed its device as a research tool, although the court did not conclusively agree, stating "assuming its OSA device is viewed as such [as a research tool]").

[71] *Proveris*, 536 F.3d at 1259, 1264.

[72] *Id.*

[73] *Id.* at 1258.

sale of Innova's OSA, which is used in the development of FDA regulatory submissions, but is not itself subject to the FDA premarket approval process."[74]

In concluding that Innova's OSA was not protected under the safe harbor provision, the court centered its analysis on the phrase "patented invention" in § 271(e)(1).[75] The court modeled its approach after the one taken by the Supreme Court in *Medtronic*.[76] It reiterated the counterbalancing patent term distortions that were addressed by the Hatch Waxman Act and noted that "the first distortion was the reduction of effective patent life caused by the FDA premarket approval process, while the second distortion was the de facto extension of effective patent life at the end of the patent term – also caused by the FDA premarket approval process."[77] The Federal Circuit stated that since Innova's OSA did not require premarket FDA approval, it was not a party that would have been negatively affected by the second distortion prior to the enactment of the Hatch Waxman Act.[78] Therefore, the court held that Congress would not have intended for Innova to be protected by the safe harbor provision if it were not also subject to the second distortion.[79] The court felt that this analysis provided the "same kind of fit, or symmetry" as that proffered by the Supreme Court in *Medtronic*.[80]

---

[74] *Proveris*, 536 F.3d at 1265.

[75] *Id.* at 1265-67.

[76] *Id.* at 1265.

[77] *Id.* (citing *Medtronic*, 496 U.S. at 669-70).

[78] *Id.*

[79] *Proveris*, 536 F.3d at 1265.

[80] *Id.* at 1265-66.

Thus, the Federal Circuit ultimately held that, since Innova's OSA was not the type of invention that Congress intended to be protected under the Hatch Waxman Act, that it was not a "patented invention" under § 271(e)(1).[81] The court did not even reach the issue of whether or not the testing use of the OSA was "reasonably related" to a submission to the FDA.

Although the Federal Circuit's analysis is appealing from the perspective of symmetry, this "fit" may be deceiving. There are inventions that can be used merely to obtain data (in much the same ways as Innova's OSA) that are, however, subject to FDA approval.[82] This could lead to the somewhat anomalous result that the FDA safe harbor would apply to the use of an FDA approved invention as a mere research tool (and not the therapeutic use that was subjected to the regulatory approval process), while leaving the use of other non-regulated research tools non-excepted.[83] One example is monoclonal antibodies which are subject to FDA approval but can also be used as binding agents in drug screening assays.[84] Under a strict reading of the Federal Circuit's test in *Proveris*, the use of a monoclonal antibody as a research tool might have protection under the FDA safe harbor, whereas the use of Innova's OSA as a research tool was not excepted. However, it could be that the court would then be forced to assess whether or not the use of the tool was "reasonably related" to an FDA submission.

In light of the example above, the Federal Circuit might be attempting to force symmetry where it has never completely existed. Even the application of the Supreme Court's holding in

---

[81] *Proveris*, 536 F.3d at 1265-66.

[82] Tabtiang & Carlson, *supra* note 65, at 7.

[83] For the purposes of this example, it is assumed that both the FDA-regulated and the FDA non-regulated inventions are used "solely for uses reasonably related to the development and submission of information under" the FDCA as required by 35 U.S.C. § 271(e)(1) (2006).

[84] Tabtiang & Carlson, *supra* note 65, at 7.

Medtronic, on which the Federal Circuit modeled its symmetry analysis, does not result in perfect symmetry.[85] In *AbTox*, the question before the court was whether or not § 271(e)(1) covered Class II medical devices.[86] Many Class II devices, in comparison to Class III devices (such as the defibrillator in *Medtronic*), undergo a much less rigorous regulatory approval process,[87] and are not eligible for patent extensions under § 156.[88] Despite the asymmetrical result, the Federal Circuit noted that "the phrase 'patented invention' of section 271(e)(1) includes any medical device, regardless of its eligibility for patent term extension under section 156."[89] Thus, when presented with the decision of whether to draw distinctions between different classes of medical devices or to allow asymmetries between § 271(e)(1) and § 156, the Federal Circuit had previously chosen the latter. However, more recently in *Proveris*, the Federal Circuit has reverted back to attempting to force symmetry.

While assessing symmetry in *Proveris*, the court appeared to concentrate on whether or not *Innova's infringing device* was subject to FDA approval.[90] However, the court also found

[85] AbTox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997).

[86] *Id.* at 1028.

[87] The FDA separates devices into three Classes. Class I devices are subject to minimal controls and pose no unreasonable risk of illness or injury. Class II devices are possibly more harmful and must comply with federal special controls (although they may be marketed without approval). Class III devices are potentially the most harmful and are those that are intended for "supporting or sustaining human life" or are substantially "important in preventing impairment of human health." These must be approved by the FDA before marketing. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). *See also* 21 U.S.C. § 360 (k), (m) (2006) (outlining the exemption of certain Class II devices from reporting to the federal government before introducing a medical device into interstate commerce).

[88] *AbTox*, 122 F.3d at 1029.

[89] *Id.* at 1028-29.

[90] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265 (Fed. Cir. 2008).

noteworthy that *Proveris' patented invention* was also not subject to FDA approval.[91] Since it is uncertain whether the court centered its analysis on the infringing device or the patented invention (or both), it remains somewhat unclear how the court would view an infringing application that was not used in a context of FDA approval when the patented invention was subject to FDA approval, or vice-versa.

Similarly, it is not clear whether the Federal Circuit's analysis was centered on the device, the parties, or a combination of both. On one hand, the court notes that Innova was not a *party* that was itself seeking FDA approval, and therefore Congress could not have meant to protect it with the FDA safe harbor.[92] However at other times, the court concentrates on the *device* and not the party by noting that Innova's infringing *device* was not subject to approval under the FDCA, so it was not eligible for protection under the safe harbor.[93] Due to the lack of certainty of the importance of the infringer's mode of use, it is unclear how the *Proveris* decision would have come down if Innova had itself solely used its OSA for FDA submissions.[94] In the end, it is possible that the Federal Circuit's decision was influenced by the fact that Innova did not manufacture the infringing device for its own use, but merely made its OSA to sell to pharmaceutical companies and the FDA.[95] It also appears that the Federal Circuit has redefined

---

[91] *Proveris*, 536 F.3d at 1265.

[92] *Id.*

[93] *Id.* at 1266.

[94] *Federal Circuit: No § 271(e)(1) Safe Harbor for Patented Inventions not Regulated by FDA*, Aug., 8, 2008, http://www.bakerdonelson.com/ContentWide.aspx?NodeID=200&Publication ID=464 (last visited Oct. 28, 2009) (noting a very similar issue in the context of third-party funding).

[95] *Proveris*, 536 F.3d at 1264.

"patented invention" in a way that is directly contrary to that laid out by the Supreme Court. As noted above, the Supreme Court in *Medtronic* defined "patented invention" in § 271(e)(1) to "include all inventions, not drug-related inventions alone."[96] However, in *Proveris*, the Federal Circuit limits the definition of "patented invention" to only include those inventions that require FDCA approval.[97] In light of the Supreme Court's trend of broadening the safe harbor provision,[98] the Supreme Court might well have intended all inventions to be included under the safe harbor.

Part III: Recommendations

However the FDA safe harbor is interpreted, it likely will result in various inconsistencies.[99] As Justice Scalia noted, "[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship."[100] That being said, the Federal Circuit has created unnecessary confusion in *Proveris* by not following the prior trends and decisions of the Supreme Court as well as its own earlier holding.

In view of the inconsistent definition of "patented invention,"[101] it would be advantageous for the Federal Circuit to abandon its definition and resort to the broader view of

---

[96] Eli Lilly v. Medtronic, 496 U.S. 661, 665 (1990).

[97] *Proveris*, 536 F.3d at 1265-66.

[98] *Medtronic*, 496 U.S. 661 (broadening the safe harbor provision to include medical devices); *Merck*, 545 U.S. 193 (interpreting the safe harbor to encompass preclinical testing of new drugs).

[99] *Medtronic*, 496 U.S. at 679.

[100] *Id.*

[101] *Compare Medtronic*, 496 U.S. at 665 (stating that patented inventions "include all inventions, not drug-related inventions alone"), *with Proveris*, 536 F.3d at 1265-66 (restricting patented

the Supreme Court in *Medtronic*.[102] This would result in a more consistent definition, and would also allow for any safe harbor analysis to take place under the "solely" and/or "reasonably related" prongs of § 271(e)(1) versus attempting to force symmetry in instances where it simply does not fit. Therefore, the same outcome could have been reached by the Federal Circuit in *Proveris* by determining that the relation between the measuring tool and the physical parameters of the aerosol sprays was too attenuated to be considered "reasonably related" to an FDA submission.[103] This type of analysis would offer more flexibility with regard to widely-varying fact scenarios and would be more amenable to application than a more rigid and "symmetrical" test of whether or not the technology is a "patented invention."

Similarly, the court in *Proveris* could have reached the same result by centering its analysis on the "solely" text of § 271(e)(1). Since Innova's intentions and actions were simply to obtain commercial revenue from the infringing product versus itself using it for FDA-related research, it could be argued that its sole use was not reasonably related to FDA submissions.

By concentrating on the "solely" and "reasonably related" text of § 271(e)(1), the court would appropriately focus on the question of why the accused infringer used the patented invention instead of directing its attention to whether or not the infringed device is subject to

---

inventions under 271(e)(1) to only those that are subjected to the regulatory approval process under the FDCA).

[102] Although I have not found any sources or publications directly advocating for the abandonment of the definition of "patented invention" outlined in *Proveris*, some commentators have noted the inconsistency. *See* Tabtiang & Carlson, *supra* note 65, at 7 (stating that "[b]y constricting the category of 'patented invention' to only those that require FDA premarket approval, *Proveris* undoubtedly runs against the trend in [*Medtronic* and *Merck*]").

[103] *See* Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1264 (Fed. Cir. 2008) (noting that Proveris argued that Innova's infringement was not "reasonably related" to FDA submissions in part because it was merely for commercial sale).

FDA approval. Viewing the problem within this framework would allow the courts to adequately address the applicability of the FDA safe harbor provision to research tools.

Specifically, it would allow an informed distinction to be drawn between various uses of monoclonal antibodies, as well as between different applications of diagnostic assays (one of the questions posed in the Introduction). Similarly, by addressing the issues with the flexible approach advocated in this article, the courts could properly and directly assess how reasonably-related a use is if it is sold to a third party for FDA-related research versus used in-house.

SYRACUSE SCIENCE & TECHNOLOGY LAW REPORTER

VOLUME 21 FALL 2009 ARTICLE 3, PAGE 57

Virtual Inheritance: Assigning More Virtual Property Rights

Olivia Y. Truong

ABSTRACT

Increasingly, our daily lives revolve around and rely on the Internet and digital world. We will inevitably accumulate some amount of virtual wealth in the form of email accounts, social networking profiles, and even digital replicas (or avatars) of ourselves. As we populate the Internet with traces of our lives, the ugly truth is that none of that virtual wealth really or absolutely belongs to us. This note explores the concept of "virtual inheritance," or the idea of transferring one's virtual property rights—a right to which we should be entitled. By revealing how the right to transfer is frustrated in the virtual game world context, this note will bring to light the growing need for a legal framework that would acknowledge an individual's right to one's virtual property.

TABLE OF CONTENTS

INTRODUCTION……... 58

I. The legal recognition of virtual property……..... 59

II. Current climate of virtual property and its inheritability ……. 66
- *A. Bragg v. Linden Research, Inc*……. 70

III. The interplay and conflicted interests of key virtual players…… 73
- *A. Contractual agreements are problematic*……. 76
- *B. Other implications of virtual inheritance*……. 78

IV. Proposed framework for virtual inheritance……... 79
- *A. Licenses or leases are more suitable*……. 79
- *B. The "brick-and-mortar" equivalence*…….. 80
- *C. As applied for the governance of domain names*…… 82

V. Case Study: Inheritability of email addresses…… 83

CONCLUSION……85

Virtual Inheritance: Assigning More Virtual Property Rights

Olivia Y. Truong*

INTRODUCTION

Traditionally, granting Blackacre "to A and his heirs" has transferred an absolute possessory interest from the property owner to the ascertained individual and subsequently his heirs. Conveying the interest in Blackacre has ordinarily happened as expected provided that the property was either tangible or intellectual. However, if Blackacre existed online and in a virtual game world—that is, if Blackacre were virtual property—then the concept of conveyances and future interests become less clear.

The main objective of this note is to support the legal recognition of virtual property by acknowledging its present value and by realizing its future worth. In particular, this note will focus on one of the bundle of rights that accompany property—the right to transfer—as it applies to a virtual game world context. Further, this note will explore the legal implications of recognizing "virtual inheritance," or the transfer of virtual property rights.

This note is organized in five sections: Part I endorses the legal recognition of virtual property as property and supports that contributing-users should have rights. Part II describes the current climate of virtual property in the virtual game world industry with a focus on the idea of virtual inheritance and why there is a pressing need for a governing framework. Part III discusses the conflicting interests among virtual game developers and users and the legal implications as it relates to virtual inheritance. Part IV purports a framework to govern an

* J.D. candidate, Syracuse University College of Law, expected 2010; Form & Accuracy Editor, *Syracuse Science and Technology Law Reporter*. A special thanks to Professor Jeremy A. Blumenthal for his guidance in writing this note and for his dedication to scholarship. The author would also like to thank J.J. and her family (Anh, Thanh, Calvin) for their unconditional support.

owner's right to transfer as it should apply to virtual property in a virtual game world context. Part V provides a case study with regard to the inheritability of email addresses. This note concludes by maintaining the importance of transferring the present value of virtual property to the future.

I. The legal recognition of virtual property

The virtual world has reached a tipping point from "play" to "reality."[1] Virtual reality is becoming so realistic that users blur the line between virtual fiction and real life. Actions online have prompted users to react in a very real manner. For instance, in October 2008, Tokyo police arrested a woman whose sudden divorce in a virtual world made her so angry that she killed her online husband's digital persona.[2] The woman accessed the man's account by using his identification and password, and deleted his virtual avatar.[3] Although the woman was not plotting any real world retribution or murder, she was jailed on "suspicion of illegally accessing a computer and manipulating electronic data."[4] If convicted, she could face real world penalties of a fine up to $5,000 or imprisonment up to five years.[5] In another incident in August 2008, a U.S. woman was charged with plotting the real-life abduction of a boyfriend she met on a virtual

[1] BENJAMIN TYSON DURANSKE, VIRTUAL LAW: NAVIGATING THE LEGAL LANDSCAPE OF VIRTUAL WORLDS 72 (2008).

[2] *Japanese Woman Arrested for Virtual-World 'Murder,'* FOX NEWS, http://www.foxnews.com/story/0,2933,443767,00.html (last visited Oct. 24, 2008).

[3] *Id.*

[4] *Id.*

[5] *Id.*

game world.[6] Another online episode prompted police to arrest a teenager for "swindling virtual currency worth $360,000 in an interactive role playing game by manipulating another player's portfolio using a stolen ID and password."[7]

People regard their virtual, second lives with as much significance as they do their real lives. Equally, people value their virtual property as much as they do their real and tangible possessions. Virtual properties—such as email addresses, websites, avatars, video game characters, virtual accessories, and any other intangible digital commodities—are more prevalent and abundant today than ever before. Although virtual property is not physical or tangible, proprietors of virtual property consider themselves to be owners of such property.[8] To some extent, "owners" of virtual property place a value on it because they are able to control it and exclude others from it.[9] Additionally, the idea of ownership in virtual property is reinforced because owners can increase the value in it and exchange its worth with other people.[10]

With the continued materialization of virtual property, it is imperative that it be legally recognized as property for three reasons. Firstly, by deeming virtual property as property, it legalizes other areas of virtual law and other legal consequences in the real world.[11] For example, a user cannot be charged with the crime of theft unless the victim had a right to the real

---

[6] *See supra* note 2.

[7] *Id.*

[8] *See* Charles Blazer, *The Five Indicia of Virtual Property*, 5 PIERCE L. REV. 137 (2006).

[9] *Id.*

[10] *Id.*

[11] DURANSKE, *supra* note 1, at 79 (A property law analysis of the virtual world is a "necessary precursor").

or virtual property in question.[12] In another real world situation, a Dutch court convicted two teens of virtual theft.[13] A 15 and 14-year-old coerced a 13-year-old boy into transferring a "virtual amulet and a virtual mask" from an online adventure game to their accounts.[14] Lawyers argued that virtual goods do not really exist, and that transferring them does not conflict with the rules of the game.[15] The Dutch court held otherwise, finding that the victim lost actual control over the virtual goods when the thieves forced the victim to transfer the goods to them.[16] Two boys were sentenced to conditional detention and community service for the virtual theft.[17] Although this situation is set in an international court, the Dutch court underscored an important point that is also raised by Benjamin Duranske, a leading practitioner in the virtual law field.[18] If virtual property is not legally recognized as property, there is "very little point to enforcing contracts created in a virtual world if the subject matter of the contract can't be owned to begin

[12] DURANSKE, *supra* note 1.

[13] Benjamin Duranske, *Netherlands Court Finds Criminal Liability and Sentences Two Youths for Theft of Virtual Goods*, VIRTUALLY BLIND, Oct. 22, 2008, http://virtuallyblind.com/2008/10/22/netherlands-theft-virtual-good/.

[14] *Id.*

[15] *Id.*

[16] VeeJay Burns, *Court Ruling in the RuneScape Case*, MINDBLIZZARD, Oct. 26, 2008, http://blog.mindblizzard.com/2008/10/court-ruling-in-runescape-case_26.html.

[17] *Id.*

[18] About Benjamin Duranske, http://virtuallyblind.com/about-me/ (last visited February 8, 2009) (Benjamin Duranske is one of the leading practitioners on virtual law. He was the editor and primary contributor to *Virtually Blind* from early 2007 to late 2008).

with."[19] As such, it is vital for users and for key developers that virtual property be accepted as property.

Secondly, while property in a virtual world is intangible as well as intellectual, virtual property is unique because it was deliberately designed to behave like traditional property.[20] In effect, virtual property is an asset in digital form.[21] Avatars in virtual game worlds can acquire virtual property such as land, real estate, and personal belongings, just as an individual acquires these assets in the real world. In the course of possessing virtual property, there are two important characteristics, which resemble the way in which real property is acquitted, that should be noted: First, both real and virtual property are unique to the individual or avatar. For virtual property, that particular avatar acquired by creation or through transactions of purchase, of barter, or of exchange. In the real world, property purchased or created would also be exclusive to the individual owner. Consequently, because of the initiative toward acquisition, the individual and avatars should inherently own the real and virtual property, respectively. Second, both real and virtual property are an extension of the individual. Within the virtual world, the virtual property constitutes a user's personal space and virtual imprint; it is an extension of that individual's presence online. Even after a user logs offline, that virtual property holds and retains that individual's virtual existence.

Considering these two natural inclinations, when individuals `acquire virtual possessions, they rely on the value of virtual property to give meaning to their virtual environment—and so

---

[19] DURANSKE, *supra* note 1, at 79.

[20] *See* Bobby Glushko, *Tales of the (Virtual) City: Governing Property Disputes in Virtual Worlds*, 22 BERKELEY TECH. L.J. 507 (2007).

[21] *Id.*

do the virtual world developers.[22] Lastly, virtual property should be recognized legally because without that value, why bother? Beyond the virtual window, the real world also relies on that value. Transactions for virtual property not only happen within the virtual worlds, but also take place in reality and across different online forums. Sales of virtual property did occur on eBay until the company banned the sales to avoid "complex legal issues."[23] Most sales were illegal and inconsistent with developers' contractual agreements.[24] Fact is, however, virtual property is more just a game.

The social and economic importance of virtual property is evident. Legally recognizing virtual property will legitimize it and go further to protect user's property rights. Virtual creations and virtual interactivity exist because of users' investments and contributions. By validating virtual property, it encourages the beneficial growth and technological innovation of the Internet, where user-contributed content has brought the Internet into a vibrant and rich existence.

However, recognizing virtual property may be complicated given the limitations of technology. Virtual game worlds, such as Second Life and Entropia Universe, are a form of "malleable technology," where users contribute to the game.[25] Considering a traditional

---

[22] *See* Kurt Hunt, *This Land Is Not Your Land: Second Life, Copybot, and the Looming Questions of Virtual Property Rights*, 9 TEX. REV. ENT. & SPORTS L. 141 (2007).

[23] *Ebay's Ban on Virtual Property Auctions*, Associated Content, Sept. 12, 2007, http://www.associatedcontent.com/article/372287/ebays_ban_on_virtual_property_auctions.html.

[24] *Id.* at 10.

[25] *See* Lawrence Lessig, *The Law of the Horse: What Cyberlaw Might Teach*, 113 HARV. L. REV. 501 (1999) ("Cyberspace has no nature; it has no particular architecture that cannot be changed. Its architecture is a function of its design [or its code] . . . Enabling *individual* choice

principle in property law—Locke's labor theory[26]—if an individual exerts labor into something unowned, ownership is created and established for the laborer.[27] As applied, because users contribute and add to the virtual world, the property that they labor over should belong to them. However, that concept is problematic in the virtual property context. The individual is exerting his labor into something owned—a space generated by and with tools provided by the game developer. Although designed on an individual's own time and by his own effort, the individual's virtual property lies on the physical server of the game developer.

While contractual agreements currently govern ownership rights, developers continue to muddle the waters with its innovation. Add to the uncertainty of ownership, in September 2008, MindArk[28] began recognizing user-contributed content by drafting wills for virtual property.[29] A representative of MindArk reported that the virtual world pioneer "will begin to draw up wills for their customers to cover the things they own in their virtual computer world."[30] The representative went on to comment that drafting wills is "a natural development."[31]

---

may require collective modification of the architecture of cyberspace, just as enabling *collective* choice may require modification of this architecture.").

[26] JOHN LOCKE, SECOND TREATISE OF GOVERNMENT 19 (C.B. Macpherson ed., Hackett Publishing 1980) (1689) ("Labo[]r put a distinction between them and common: that added something to them more than nature, the common mother of all, had done; and so they became his private right").

[27] *Id.* at 20 ("Common right to everyone until laborer makes it his own").

[28] MindArk, http://www.mindark.com/ (last visited Oct. 3, 2008) (MindArk operates, develops, and markets Entropia Universe).

[29] Benjamin Duranske, *Entropia Creates Virtual Property Wills; Sweden Implements Tax Rules for Virtual Property*, VIRTUALLY BLIND, Sept. 9, 2008, http://virtuallyblind.com/2008/09/09/entropia-wills/.

As a result of MindArk's revolutionary proposition, this note was prompted. It is a natural movement to recognize virtual property as property, albeit some distinct complications inherent to the digital environment on which it exists. There is one undeniable broad notion—the attributes of virtual property can be supported by common-law concepts. For example, the common-law property concept of "relativity of title" is that ownership is not a person's relationship to things, but a person's relationship to others.[32] Virtual environments are hubs for social play and immersion. A user's virtual property rights, as is with real property rights, are a manifestation of one's rights in relation to other virtual residents and even the game developer.

Another property law concept is the "bundle of sticks" that accompanies property rights. The bundle of rights includes the right to possess, to use, to exclude, to occupy, to sell, to dispose, to bequeath, and to transfer.[33] These rights can also be exercised by a user in the virtual context. In the virtual world, a user can possess a virtual home. His avatar can use and occupy it, and at the same time, exclude other avatars from entry.

However, given MindArk's effort, the right to bequeath and to transfer brings to light some unique problems inherent with virtual property. The next section of this note will provide additional background information that lay the groundwork for the legal implications of virtual inheritance.

---

[30] Posting of Emelie Usurper Andersson to http://www.entropiaforum.com/forums/general-discussion/125367-article-about-virtual-wills-entropia.html (Sept. 4, 2008, 12:09 GMT) (where the actual article is in Swedish, but a translated version is posted at Entropia Forum).

[31] *Id.*

[32] *See generally Int'l News Service v. Associated Press*, 248 U.S. 215 (1918); *Johnson v. McIntosh*, 21 U.S. 543 (1823); *Pierson v. Post*, 3 Cai. R. 175 (N.Y.Sup. 1805) (These cases illustrate the traditional concept of "relativity of title").

[33] *See generally id.* (These cases also illustrate the "bundle of rights" that accompanies property).

II. Current climate of virtual property and its inheritability

The current climate of virtual development is brewing into a perfect storm that warrants legislative or judicial attention. Progressive strategies, constructed by key developers of virtual worlds, are revealing new legal issues, particularly dealing with an individual's actual, real world rights to virtual property. Confusion exists partly because individuals are pumping money in and out of these virtual worlds and alternatively because their rights are governed by contractual agreements.

For example, Second Life[34] allows their virtual residents to buy, sell, and trade with other residents using "Linden dollars."[35] The use of actual, converted money blurs the line between contractual provisions that limit a user's rights to a user's right justified by one's own investments and the ownership of the virtual property. Another virtual world, Entropia Universe,[36] not only allows users to convert real world funds into Entropia Universe currency ("PED"), but also allows users to transfer their accumulated PED back into real money.[37] Users are able to develop their virtual avatars and build their virtual lives through this wealth conversion, exchange, and accumulation.

---

[34] Second Life, http://secondlife.com/ (last visited Sept. 18, 2008) (Second Life is a 3-D virtual world created by real-world individuals that establish themselves as virtual residents in this virtual reality).

[35] *Id.* (The Linden Dollar is Second Life's own unit of trade. Linden dollars are actual, converted monies that can be used to pay for goods and services).

[36] Entropia Universe, http://www.entropiauniverse.com/ (last visited Sept. 29, 2008) (The Entropia Universe dubbed itself as the "first virtual universe with a real case economy").

[37] *Id.* (Users can convert their virtual money into real money through Entropia Universe's unique "Real Cash Economy" exchange).

By way of their investments, individuals and users are essentially contributors, creators, and shareholders of the virtual game worlds.[38] By supplying money, time, expertise, and innovation, users transform and contribute to their and others' virtual world experience. Even when users log offline, their virtual impressions impact other's interaction with the virtual world. This attribute of virtual property is significant because if virtual property can still belong to a user upon logging off, should it not also belong to a user who chooses to transfer that virtual property upon his death. Rather than giving ownership to the individual, an individual's property rights exist only to the extent not restricted by Terms of Service agreements signed prior to opening a virtual world account. Generally, those contractual agreements do not allow full ownership. While the game developer has an interest in the scope of ownership, individuals should be able to realize their virtual property in some manner.

Moreover, as virtual property evolved and its exchange progresses as a business, some foreign governments have created taxation schemes for an individual's income from virtual property. In 2006, Entropia Universe reported a turnover of 3.6 billion PED, or $360 million.[39] To "validate this business sector,"[40] the Swedish government implemented and imposed what some have dubbed a "virtual tax."[41] China also plans to impose a personal income tax on profits

[38] *See* John Baldrica, *Mod as Heck: Frameworks For Examining Ownership Rights In User-Contributed Content*, 8 MINN. J. L. SCI. & TECH. 681 (2007).

[39] *See supra* note 36.

[40] Posting of Dan Miller to Economics of Virtual Worlds, http://www.freemmogamer.com/2008/09/project-entropia.html (last visited Dec. 3, 2009).

[41] Joey Seiler, *MindArk Working on Wills for Virtual Property; Swedish Government Implementing Virtual Taxes*, VIRTUAL WORLD NEWS, (Sept. 9, 2008) http://www.virtualworldsnews.com/2008/09/mindark-working.html.

from virtual money.[42] In China, "[s]uccessful online video game players and Internet surfers . . . have found ways to make real money from virtual assets."[43] One reason for a virtual tax is to counter the fast growth and real monetary conversion of virtual currency, which may lead to inflation or illegal laundering of money.[44] The Chinese government, through its new 20 percent virtual tax, mainly targets people who buy virtual currency from gamers and surfers, and sell it to others at a marked-up price.[45] However, some believe that the tax can help better protect the property right of virtual game world users.[46] While foreign governments have imposed virtual taxes, the U.S. Congress has only investigated the idea of taxing such virtual transactions.[47]

Among users of Second Life, the top three nationalities are American, Brazilian, and Japanese.[48] With so many Americans investing in virtual worlds, the United States should address this issue. A senior economist for the U.S. Congressional Joint Economic Committee recognizes that "to a certain degree the law has fallen 'behind'."[49] Ownership, property rights,

---

[42] Posting of Juliet Ye to The Wall Street Journal, China Journal, http://blogs.wsj.com /chinarealtime/2008/10/31/real-taxes-for-real-money-made-by-online-game-players/ (Oct. 31, 2008, 6:17 EST) (The Chinese government will impose a personal income tax of 20% on profits from virtual transactions).

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *See* Adam Reuters, *U.S. Congress launches probe into virtual economies*, FOX NEWS, Oct. 15, 2006, http://secondlife.reuters.com/stories/2006/10/15/us-congress-launchs-probe-into-virtual-economies/.

[48] *See supra* note 2.

[49] Reuters, *supra* note 47.

and all that virtual property entails must be decided.[50] In terms of tax law, certain areas of virtual property management trigger actual consequences. For example, when people "cash out of virtual economies," or transfer their virtual assets into real world money, such a realization is considered income and must be reported to the Internal Revenue Service.[51] While that example illustrates some certainty, other situations are less clear such as the appreciation of virtual assets.[52] For instance, in the real world, if an asset increases in value or produces income, then that income is taxable.[53] However, it is less apparent whether or not "virtual income and capital gains that never leave the virtual economy" is taxable.[54]

Currently, for both property and taxation issues arising from the rapid emergence of the virtual world and its economy, virtual world developers have been resolving such issues through contractual solutions and game architecture. For example, in Second Life's Terms of Service, transferring one's account to another is impermissible.[55] In another virtual world MapleStory,[56] the game developer created its own tax system and built it into each virtual transaction in an effort to curb any "small tremor of inflation."[57] There, the system collects a small tax percentage

[50] Reuters, *supra* note 47.

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] Second Life: Terms of Service, http://secondlife.com/corporate/tos.php (last visited Oct. 17, 2009).

[56] MapleStory, http://www.maplestory.com/ (last visited Oct. 17, 2009).

[57] Game FAQs Review MapleStory, http://www.gamefaqs.com/computer/doswin/review/R97847.html (last visited Oct. 17, 2009).

from a buyer before the in-game money reaches the seller.[58] As a result of contracts and programming, an individual's right to his property is limited. There business decisions ultimately lead to legal issues, as evinced by the following case:

A. Bragg v. Linden Research, Inc.[59]

The Eastern District Court of Pennsylvania was presented with a case that dealt with "the novel questions of what rights and obligations grow out of the relationship between the [developer] of a virtual world and its resident-customers."[60] The court there quickly observed that, "[w]hile the property [at issue] and the world where it is found are 'virtual,' the dispute is real."[61] Although the legal issue itself was procedural in natural, the context under which the claim arose indicates the need for a framework, supplemental to contractual agreements, to govern an individual's rights to virtual property.

In November 2003, Second Life began recognizing virtual property rights by granting "participants' full intellectual property protection for the digital content they create or otherwise owned in Second Life."[62] The plaintiff in this case was fully engaged in his second life.[63] He not only purchased numerous virtual land parcels, but also started his own business.[64] "In his second life, [the plaintiff] digitally crafted 'fireworks' [and sold them] to other avatars for a

---

[58] Wikipedia: Virtual Tax, http://en.wikipedia.org/wiki/Virtual_tax (last visited Oct. 17, 2009).

[59] Bragg v. Linden Research, Inc., 487 F. Supp. 2d 593 (E.D. Pa. 2007).

[60] *Id.* at 595.

[61] *Id.*

[62] *Id.*

[63] *Id.* at 596-97.

[64] *See Bragg*, 487 F. Supp. 2d at 596-97.

profit."[65] At the same time, he also acquired virtual items from other avatars.[66] Further, the plaintiff also paid taxes on his land.[67]

The dispute in this case was triggered in 2006 when the plaintiff purchased an entire region of virtual land for $300.[68] The plaintiff allegedly accessed a land auction site for property and purchased a parcel that had yet been released for auction. By doing so, he acquired that virtual land below Second Life's cost. As a result, the company confiscated the land purchased and froze the plaintiff's account, alleging that the property was improperly acquired through an "exploit."[69] Plaintiff filed this suit alleging conversion, fraud, unjust enrichment and breach of contract.

Although the parties eventually settled outside the court, the dispute illuminated the point that ownership rights are a natural development given decisions made by the company itself. The court mentioned several statements made by Philip Rosedale, the creator of Second Life, with regard to the company's initial announcement to recognize ownership rights. In a press release posted on Second Life's website, Rosedale stated that:

> "We believe our new policy recognizes the fact that persistent world users are making significant contributions to building these worlds and should be able to both own the content they create and share in the value that is created. The

[65] *See Bragg*, 487 F. Supp. 2d at 597.

[66] *Id.*

[67] *Id.* at 596-97, n.7 ("Linden taxes virtual land. In fact, according to Bragg, by June 2004, Linden reported that its 'real estate tax revenue on land sold to the participants exceeded the amount the company was generating in subscriptions.'").

[68] *Id.* at 597.

[69] *Id.*

> preservation of users' property rights is a necessary step toward the emergence of genuinely real online worlds."[70]

In an interview, Rosedale remarked, "Land ownership feels important and tangible. It's a real piece of the future."[71] On another occasion, he acknowledged that "what you have in Second Life is real, and it is yours. It doesn't belong to us. You can make money."[72]

In *Bragg*, Second Life suspended the plaintiff's account for investigation, and then closed the account for violating the Terms of Service, which thereby dissolved his virtual assets.[73] The plaintiff declared that his actual losses were between $4,000 and $6,000 in U.S. dollars. Users are led to believe that they have ownership over their accounts. Because "it's my account," the account holder should have a bundle of rights to the virtual property within that account. Although rights are governed by the contractual agreement to which the user blindly assents, property law should default the rights to the user before contractual agreements direct the rights away.

Private-sector solutions have provided much of the framework for the governance of virtual property thus far. The next section focuses on some of these private business solutions and underscores why they are deficient.

---

[70] *Bragg*, 487 F. Supp. 2d at 596 (citing Press Release, Linden Lab, *Linden Lab Preserves Real World Intellectual Property Rights of Users of its Second Life Online Services* (Nov. 14, 2003)).

[71] *Id.* at 596 (citing Michael Learmonth, *Virtual Real Estate Boom Draws Real Dollars*, USA TODAY, June 3, 2004).

[72] *Id.* (citing Michael Fitzgerald, *How Philip Rosedale Created Second Life*, INC. MAGAZINE, Feb. 1, 2007).

[73] *Id.* at 597 (Linden Lab's usual procedure for closed accounts).

III. The interplay and conflicted interests of key virtual players

In order for virtual reality to exist, there are relationships between a user and the game developer and between a user and other users. These relationships often give rise to conflicts in the virtual world and in the real world. Through their avatars, users "form and break contracts, create works of art, invent new technologies, make money, lose money, buy and develop virtual property, create new brands, defraud each other, defame each other, steal from each other, and attack each other."[74] At the same time, users could purchase virtual land, "make improvements to that land, exclude other [avatars] from entering onto the land, rent the land, or sell the land to other users for a profit."[75] Avatars can virtually create, buy, and sell any digital items fathomable. The interaction between avatars is "limited only by the human imagination."[76]

However, in order to participate, users sign Terms of Service agreements with virtual reality world developers. Of the two relationships, the most problematic is the relationship between a user and the game developers, especially when it comes to the idea of virtual inheritance. A game developer's contractual agreements ultimately govern users' rights to their virtual property. The following are some of the relevant provisions of Second Life's and of Entropia Universe's contractual agreements:

> **Second Life's Terms of Service**[77]
>
> § 3.2—You retain copyright and other intellectual property rights with respect to Content you create in Second Life, *to the extent that you have such rights under*

[74] *See* DURANSKE, *supra* note 1, at 15.

[75] *Bragg*, 487 F.Supp.2d at 596.

[76] *Id.* at 595-96.

[77] Terms of Service, http://secondlife.com/corporate/tos.php (last visited Oct. 22, 2009).

applicable law. By submitting your Content, you automatically grant to Linden Lab:

> (a) a royalty-free, worldwide, fully paid-up, perpetual, irrevocable, non-exclusive *right and license to*
>
> > (i) *use, reproduce and distribute your Content* within the Service as permitted by you through your interactions on the Service, and
> >
> > (ii) use and reproduce (and to authorize third parties to use and reproduce) any of your Content in any or all media for marketing and/or promotional purposes
>
> (b) the perpetual and irrevocable *right to delete* any or all of your Content from Linden Lab's servers and from the Service, and
>
> (c) a royalty-free, fully paid-up, perpetual, irrevocable, non-exclusive *right and license to copy, analyze and use any of your Content as Linden Lab may deem necessary* or desirable for purposes of debugging, testing and/or providing support services in connection with the Service.

§ 3.3—Linden Lab *retains ownership of the account* and related data, regardless of intellectual property rights you may have in content you create or otherwise own.

Entropia Universe's End User License Agreement[78]

§4—Ownership

> The System, including, but not limited to, computer code, text, graphics, audio files, logos, button icons, images, characters, items, concepts, data compilation and software, is the property of MindArk and protected by Swedish and international copyright laws.
>
> *All virtual items are part of the System and MindArk retains all rights, title, and interest* in all parts including, but not limited to Avatars and Virtual Items; these retained rights include, without limitation, patent, copyright, trademark, trade secret and other proprietary rights throughout the world.
>
> *As part of your interactions with the System, you may acquire, create, design, or modify Virtual Items, but you agree that you will not gain any*

[78] Entropia Universe: End User License Agreement, https://account.entropiauniverse.com/legal/eula.xml (last visited Oct. 22, 2009) (emphasis added).

> *ownership interest whatsoever in any Virtual Item, and you hereby assign to MindArk all of your rights, title and interest in any such Virtual Item.*
>
> *You hereby grant MindArk the worldwide, perpetual, irrevocable, royalty-free, right to exercise all intellectual property rights for any content you may upload to the Entropia universe, including, but not limited to, user-to-user communications.*

Ideally, when a user creates a certain virtual property, he should retain the right in that property. He should be able to transfer that virtual property, or his account, in a will. However, here are some problems with that premise: Suppose you build a virtual car using virtual materials and services that you purchased, acquired, and enlisted from other residents (e.g., virtual tires, virtual body frame, and services of a virtual painter). Once you have built that virtual car, you should be entitled to rights of that virtual creation against any other users. Hypothetically, you are the absolute owner because you can exclude other users from your virtual car, sell or trade it with other users, or do what you will to it in the virtual world. However, what happens when you try and place that virtual property or your account which contains that virtual car in your living will? Due to the signed contractual agreements that you accepted, your virtual property ultimately belongs to the developer. And, upon your death, your virtual property no longer exists in your name, but on the developer's server.

Given that Entropia Universe's parent company recently began drafting wills for virtual property,[79] section 7 of its End User License Agreement, which retains ownership of virtual items and materials for the game developer, must be reconciled with who actually owns what is being transferred.

[79] Duranske, *supra* note 29.

A. Contractual agreements are problematic

In February 2009, Facebook changed its terms of service, [80] causing an uproar among many users, who began to question: who actually owns the content shared on the social network site?[81] The former provision stated that any content uploaded would expire when the user closed an account.[82] The updated provision initially read:

> "You hereby grant Facebook an irrevocable, perpetual, non-exclusive, transferable, fully paid, worldwide license (with the right to sublicense) to (a) use, copy, publish, stream, store, retain, publicly perform or display, transmit, scan, reformat, modify, edit, frame, translate, excerpt, adapt, create derivative works and distribute (through multiple tiers), any User Content you (i) Post . . . or (ii) enable a user to Post . . . and (b) to use your name, likeness and image for any purpose."[83]

After three days of pressure from angry users and consumer advocacy groups, Facebook eventually reverted its contract, which now "appear[s] to give [users] perpetual ownership of their contributions to the service."[84] Currently, in early March 2009, Facebook is taking a

---

[80] Facebook, http: //facebook.com (last visited Feb. 18, 2009) (Facebook, a social utility that helps people communicate more efficiently with their friends, family and coworker, is a company that develops technologies to facilitate the sharing of information through the social graph, which creates a digital mapping of a person's real-world social connections.).

[81] Brian Stelter, *Facebook's Users Ask Who Owns Information*, N.Y. TIMES, Feb. 16, 2009, *available at* http://www.nytimes.com/2009/02/17/technology/internet/17facebook.html.

[82] Chris Walters, *Facebook's New Terms Of Service: "We Can Do Anything We Want With Your Content. Forever,"* THE CONSUMERIST, Feb. 15, 2009, *available at* http://consumerist.com/5150175/facebooks-new-terms-of-service-we-can-do-anything-we-want-with-your-content-forever.html.

[83] *Id.*

[84] Brad Stone & Brian Stelter, *Facebook Withdraws Changes in Data Use*, N.Y. TIMES, Feb. 18, 2009, *available at* http://www.nytimes.com/2009/02/19/technology/internet/19facebook.html.

democratic approach by hosting virtual town-hall forums and asking its users to help shape its governance policies.[85]

Ironically, virtual property "is recognized by the black market, denied by providers, and limited only by somewhat suspect contract provisions in potentially unenforceable click-through agreements."[86] If virtual property were legally recognized, these contractual agreements would conflict with any virtual property rights granted, especially the right of conveyance. While some argue that Terms of Service and End User Licensing agreements indirectly provide rights to users, there is a more direct approach: "[T]he law should proactively protect certain rights of virtual world users and game players, via either legislation or interpretation of existing law."[87]

According to Joshua Fairfield, a law professor at Washington and Lee University School of Law, "[c]ontracts cannot, by their very nature, provide for every legal need of large and shifting online communities [but] courts can use basic common law principals to provide online communities with the private property, dignitary and personal protections, and freedom of speech that communities need to thrive."[88] Inevitably, when various parties are involved, each with competing interests, disputes will arise. As the court in *Bragg* recognized, "[w]hile the property and the world where it is found are 'virtual,' the dispute is real."[89] Contractual agreements should not be the only structure by which we resolve these real disputes.

---

[85] Anupreeta Das, *Facebook Lets Users Comment on New Terms of Service*, REUTERS UK, Feb. 27, 2009, *available at* http://uk.reuters.com/article/technologyNews/idUKTRE51P7PE20090227.

[86] DURANSKE, *supra* note 1, at 114.

[87] *Id.* at 25.

[88] *Id.* (citing Joshua Fairfield, *Anti-Social Contracts: The Contractual Governance of Online Communities*, 53 McGill L.J. 427 (2007), *available at* http://ssrn.com/abstract=1002997).

[89] *Bragg*, 487 F.Supp.2d at 595.

B. Other implications of virtual inheritance

As evinced, virtual property rights rest solely with game developers and contractual guidelines. Whether virtual property is governed by propertization or by regulation, there are general, inherent problems with virtual inheritance.

For instance, what, in virtual property, is actually being transferred and conveyed, and ultimately inherited? With respect to copyright laws, the content actually being copyrighted must be specified when concerning virtual creations. Virtual innovations can include text (fiction and code), digital images, characters or avatars, building designs, music, multimedia and three-dimensional environments.[90] Although it is your virtual property, it physically exists on the developer's server. Although your virtual creation, your innovation is only as novel as the developer allows it to be through the architecture, or "code," of the virtual game world because "no genuine 'creation' occurs that is not entirely anticipatable by the game provider based on resources and programming."[91]

However, instead of allowing the conveyance of the code and digital make-up of the virtual property, the value of the virtual property should be transferable because that, to some extent, is a user's investment. With the current trend toward a real monetary equivalence of virtual property, this helps to make transfer easier. Individuals rely on the *value* of virtual property. When an individual chooses to convey that property, he ultimately wants to entrust that value to someone. Notwithstanding the "physical" or "digital" composition of virtual property, individuals should only be able to convey the value. That value should be restricted

[90] Daniel C. Miller, *Determining Ownership in Virtual Worlds*, 22 REV. LITIG. 435, 445 (2003).

[91] DURANSKE, *supra* note 1, at 101.

and allowed to be transferred only to an immediate family member. The next section of this note proposes a framework for virtual inheritance.

IV. Proposed framework for virtual inheritance

Game providers could "either (1) grant ownership of virtual property created in the world to the world's or game's users, who would take possession and ownership of these assets upon receipt in-world, with all that implies, or (2) essentially 'lease' the objects to users as part of the provider's agreement with users of the virtual world or game—that is, retain ownership."[92]

A. Licenses or leases are more suitable

Instead of contractual agreements that take away rights, the more suitable solution is a lease or license. The license itself is the property interest that is conveyed. Individuals and the virtual world sector have relied on the value of virtual property to mean something. Contractual agreements that take away individual's rights should be secondary to an individual's desire to do what he wants with his property. Individuals should be able to transfer that value. Unless the individual has not designated his property according to his desires, contractual agreements that take away rights should be null and void. If an individual waives his rights and does not choose to transfer his property, contractual agreements should be the default. Where an individual has conveyed his virtual property, a court should uphold the individual's rights over contractual agreements.

Because of the nature of virtual property and the competing interest in its value, individuals should only be able to convey that value to an immediate family member. In the

[92] DURANSKE, *supra* note 1, at 101-02.

alternative, individuals should be permitted to convey their virtual property such that it will limit the possible exploitation of the value of virtual property.

B. The "brick-and-mortar" equivalence

The value of virtual property is technically a lease between the user and the game developer to utilize a space on their server. Similarly, a team in the National Football League (NFL) allows individuals to purchase a space in an arena to watch home football games. A season ticket holder purchases the lease for a particular seat and subjects himself to guidelines with regard to his account. Those guidelines, or contractual agreements, govern the transferability of his seat. For example, the following is an excerpt of an NFL team's guidelines[93] with regard to transferring season ticket accounts:

> **Season Ticket Handbook:**
>
> ***Transfer of Seats***
> "It is very important for the Falcons to *protect and reward long-time Season Ticket Holders* by allowing them the chance to upgrade their seat locations rather than allowing Season Ticket Holders to transfer accounts or sell them to third parties. Therefore, *any attempt to sell or otherwise transfer season ticket privileges to third parties will not be recognized by the Falcons and may result in cancellation of all season ticket privileges*."[94]
>
> "*The transfer of an account or seat location to any person or company is not permissible (see exceptions below) whether by request to transfer the account into another name or by an attempt to transfer the seat locations below by sale, gift, transfer by will or trust, property settlement, transfer to creditors or any other means.*"[95]

[93] Atlanta Falcons: Season Ticket Handbook, *available at* http://www.atlantafalcons.com/Venues/Season_Ticket_Holders/Handbook.aspx (last visited Dec. 10, 2009) (emphasis added).

[94] *Id.*

[95] *Id.*

> "Any court order directing distribution of season tickets to a person not listed as the season ticket holder, whether bankruptcy or otherwise, will result in the Falcons exercising its right to immediately withdraw the license represented by the tickets, including any season ticket renewal privileges, upon refund by the Falcons of all amounts paid for games that have not yet been played."[96]
>
> *EXCEPTIONS TO THIS POLICY ARE:*
> - *"Transfers to a Season Ticket Account Holder's immediate family member (spouse, parent, child or sibling).*
> - *Company name changes (due to acquisition or merger) or transfers between company name and company owner."*[97]

Season tickets have both a monetary and a non-monetary value. While the football team limits the monetary transfer of that right, it does not limit the non-monetary conveyance to immediate family members or within a corporation. So long as that value is retained with that season ticketholder's estate or with that company, the value and transfer thereof will be honored by the football team.

In the virtual context, individuals should be allowed to transfer the non-monetary value of their virtual property to their immediate family members. A way to limit exploitation may be to only permit the entire account as a whole be transferred as opposed to singular digital assets. Monetary transfers should be prohibited because of the competing interest of who actually owns the intellectual property between the user and the game developer. Also, another problem with monetary transfers is that not all virtual property is assessed on the same scale or exchange rate.

As with season tickets to sporting events, leagues and teams do not restrict transfers completely. Rather, they limit to whom accounts can be transferred. By doing so, individuals cannot sell their seats to third-party companies that mark-up the cost of tickets in a secondary market. Upon death, seats can be conveyed to family members.

---

[96] *See supra* note 93.

[97] *Id.*

Because real money is being invested in the virtual world, individuals should retain some ownership of their virtual property. Game developers should alter their contractual agreements to reflect that ownership stake. If an individual has made his intention clear in a will, the game developer should honor the execution of the user's wishes. Where an individual has conveyed his virtual property, a court should uphold individual's rights over contractual agreements. If an individual waives his rights and does not choose to transfer his property, contractual agreements should be the default. The bottom line is, however, that an individual should be able to convey his virtual property to family.

The license is essentially the property interest here. The individual may convey the interest to family, who ultimately receives it subject to an expiration date. At such time, family members may choose to renew the agreement, thereby extending their ownership.

C. As applied for the governance of domain names

The Internet Corporation for Assigned Names and Numbers (ICANN) is responsible for managing the assignment of domain names and IP addresses.[98] In November 2008, ICANN modified its policy for the transfer of domain names, effective March 15, 2009.[99] The modified policy provides that a domain name can be transferred if the recipient of the domain name obtains express authorization from the grantor.[100] The registration, or lease, of a domain is the property right conveyed.

---

[98] *See* Internet Corporation for Assigned Names and Numbers (ICANN), http://www.icann.org/ (last visited Feb. 21, 2009).

[99] ICANN: Policy on Transfer of Registration between Registrars, http://www.icann.org/en/transfers/policy-en.htm (last visited Feb. 21, 2009).

[100] *Id.*

Virtual property acquired by individuals in a virtual game world should be transferable under a similar framework. Because virtual game worlds involve not only an individual's time and effort, but also money, virtual property should be owned by the individual as a lease. Should the individual choose the transfer that lease, he should be able to do so. The next section provides a case study of virtual inheritability with regard to email addresses.

V. Case Study: Inheritability of email addresses

Email is a form of virtual property that is unique and personal to an individual. Once an individual dies, how are email accounts treated? By evaluating how email address can be inherited, it will provide guidance on how virtual creations in virtual game worlds may be conveyed or transferred.

In the news, a deceased Marine's parents requested access to their son's Yahoo email account.[101] Initially, Yahoo, Inc. refused to provide the family with access because its internal privacy policy explained that email accounts are terminated when account holders die. The family went to court, where a probate court judge in Oakland County, Michigan granted the family an order compelling Yahoo to turn over the account.[102]

Yahoo's Terms of Service states that e-mail accounts are nontransferable, and rights to e-mail contents or passwords terminate upon death. However, this provision of the agreement was intended to apply to transferring accounts. It was not intended for accessing the contents of the

[101] Ariana Eunjung Cha, *After Death, a Struggle for Their Digital Memories*, THE WASHINGTON POST, Feb. 3, 2005, *available at* http://www.washingtonpost.com/wp-dyn/articles/A58836-2005Feb2.html.

[102] Stefanie Olsen, *Yahoo releases e-mail of deceased Marine*, CNET NEWS, Apr. 21, 2005, http://news.cnet.com/Yahoo-releases-e-mail-of-deceased-Marine/2100-1038_3-5680025.html.

account nor to ownership of the information in the account.[103] While Yahoo owns the right to an account after a user dies, the content of the account should ideally still belong to the estate of the decedent.

By terminating an account upon a user's death, companies like Yahoo are depriving a decedent's "estate and his successors access to potentially significant intellectual property resources."[104] If the deceased had printed out his emails and left them somewhere, the printouts "would be considered his personal property and would have likely become part of his estate."[105] Similarly, if the emails were stored in the hard drive of his personal computer, the physical object, the computer, would ultimately become part of his estate as well.[106]

Personal correspondence may have tremendous historic or economic value—e.g., letters from historical figures have contributed greatly to our understanding of history.[107] The problem in cyberspace is that the ownership of e-information is linked with the ownership of the medium, a server in which the data is stored.[108] Balancing an heir's right to the decedent's estate and an email host's priority of protecting users' privacy must be reconciled.

---

[103] Mark D. Rasch, *A Corporal's Death Starts a Dispute on E-Mail Ownership: Should email accounts perish along with their owners?*, LAW.COM, Mar. 23, 2005, http://www.law.com/jsp/article.jsp?id=1111485911670.

[104] *Id.*

[105] *Id.*

[106] *Id.*

[107] *Id.*

[108] Rasch, *supra* note 103.

In practice, email messages, instant messages, and personal files on a computer or store online are considered private unless the individual publicly circulates that e-information.[109] The problem ultimately is where a decedent did nothing to make his intentions known:

> In theory, a broad durable power of attorney properly executed and delivered to third parties could allow someone to have access to electronic assets, but this does not deal with the problem at Yahoo where an account simply 'disappears' upon death or inactivity. There is no requirement that these e-mail providers give the attorney-in-fact that password, or otherwise keep the account alive. Thus, as a practical matter, access to the IP dies with the owner, absent a court order stating otherwise.[110]

The bottom line is that people should make arrangements that dictate what happens to their property, both real and virtual, in a will to be executed upon death. "So when you create a free e-mail account, whether with an Internet service provider or with a free service, you should also create an 'Internet Living Will[,]' designating who can have access to your electronic assets in the event of death or incapacitation, and the scope of their authority to act on your behalf."[111] Therefore, according to an individual's will, virtual property licenses are transferrable.

CONCLUSION

By the interpretation of existing laws, the virtual world is not an exception its governance. Contract law should not be the only way that we define how the virtual world functions within the confines of our real existence. Through a mixture of contract and property

---

[109] Jennifer Farwell, *Death & Digital Data: What Happens To What You Leave Behind?*, SMART COMPUTING.COM, Sept. 1, 2007, http://www.smartcomputing.com/Editorial/article.asp?article=articles/2007/s1809/09s09/ 09s09.asp&articleid=42187&guid=.

[110] *Id.*

[111] *Id.*

law, licenses or leases are the most suitable way to balance the interest between users and game developers.

There are benefits to permitting virtual inheritability. By doing so, individuals' creations and labor is rewarded. It encourages productive and creative explorations into technology. Moreover, it promotes creativity. Advancements in technology have boosted our generation to a new level. These advancements will continue as long as people are allowed to imagine and explore untouched virtual depths. Recognizing virtual inheritance is another step toward validating people's creations and the value in their designs, thus, encouraging individuals to continue inventing.

Recognizing virtual inheritability will also build upon the existing virtual economy. This new business avenue is growing fast and game developers continue to build upon its growth. By recognizing people's investments, virtual inheritance will drive future growth.

For consumers of virtual property, the lesson here is that it is important to make one's last wishes and intentions known. People should make arrangements that dictate what happens to their property, both real and virtual, in a will to be executed upon death.

It is vital to support the legal recognition of virtual property by acknowledging its present value and by realizing its future worth.

SYRACUSE SCIENCE & TECHNOLOGY LAW REPORTER

VOLUME 21 FALL 2009 ARTICLE 4, PAGE 87

OBVIOUS FALLACY: IMPROVING THE STANDARD OF OBVIOUSNESS FOR CHEMICAL COMPOUNDS TO MORE ACCURATELY REFLECT COMMON PRACTICE IN THE ART

Alison M. Taroli[1]

INTRODUCTION

Patent protection for newly discovered chemical compounds is one of the most important priorities for a successful pharmaceutical company. In order to obtain a patent, a chemical compound must be nonobvious at the time of its invention.[2] As compared with obviousness evaluations in chemical cases, application of the law of obviousness to inventions in the electrical and mechanical sciences is fairly straightforward. Obviousness in the chemical arts has been difficult to determine in light of chemistry's inherent unpredictability. The properties of a chemical compound can be dramatically altered with only slight structural changes. Courts have attempted to address this difficulty by further defining the law of chemical obviousness to include subtests relating to structural similarity and motivation to make the claimed composition. However, these tests have failed at simplifying the obviousness test for chemical compounds,

[1] J.D./M.S. Candidate, Syracuse University College of Law, 2010; Form & Accuracy Editor, Syracuse Science and Technology Law Reporter. The author would like to thank Professor Lisa A. Dolak for her guidance and assistance in writing this note and her family, Mom, Dad, Daniel, and Eric, for all of their unconditional love and support.

[2] 35 U.S.C. § 103(a) (2004) ("A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.").

particularly in light of the significant increase in combinatorial chemistry techniques in the pharmaceutical industry. Due to the enormous costs associated with drug research and discovery, the law of obviousness of chemical compounds needs to be further defined to provide pharmaceutical companies with sufficient notice as to whether their newly created compounds will be refused patent protection due to obviousness in view of the prior art.

BACKGROUND

The patent laws were enacted to prevent publicly available information from being confiscated and monopolized.[3] When a patent is obtained, the inventor receives the right to exclude others, and the public obtains the benefit of the disclosure.[4] Three important requirements to obtain a patent on an invention are utility,[5] novelty,[6] and nonobviousness.[7] The novelty and utility requirements can typically be readily satisfied for chemical compound inventions, as an invention only needs to be minimally useful and comparatively minor structural changes can render an invention novel.[8] Consequently, nonobviousness frequently becomes the critical element in ultimately determining chemical patentability.[9]

---

[3] *See* 60 AM. JUR. 2D *Patents* § 6 (2009).

[4] 60 AM. JUR. 2D *Patents* § 2 (2009).

[5] *See* 35 U.S.C. § 101 (1952).

[6] *See* 35 U.S.C. § 102 (2002).

[7] *See* 35 U.S.C. § 103 (2004).

[8] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 612 (4th ed. 2007).

[9] *Id*.

I. The Law of Obviousness Generally

The law of obviousness is codified in Title 35 of the United States Code ("U.S.C."). Under § 103 (a) of the U.S.C., "patent may not be obtained though the invention is not identically disclosed or described [in the prior art], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[10] The nonobviousness requirement can be described as the "nontriviality" condition; in other words, an invention does not deserve patent protection although it may be new and useful if it embodies only a trivial modification of the prior art. Obviousness is a legal question based on fundamental factual determinations.[11]

In order to understand obviousness, it is crucial to define a person of ordinary skill in the art. The Manual of Patent Examining Procedure describes five factors that can be used to determine the level of ordinary skill in the art: (1) the type of problems encountered in the art, (2) prior art solutions to the problems, (3) rapidity with which innovations are made, (4) sophistication of the technology, and (5) the educational level of active workers in the field.[12] The person of ordinary skill in the art is a hypothetical person and does not necessarily embody the level of skill of the inventor himself.[13]

---

[10] 35 U.S.C. § 103(a) (2008).

[11] *See* Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).

[12] MANUAL OF PATENT EXAMINING PROCEDURE § 2141.03 (8th ed. 2001); *See, e.g., In re* GPAC, Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995); Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986); Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983).

[13] *See* Cool-Fin Elec. Corp. v. Int'l Elec. Research Corp., 491 F.2d 660, 662 n.7 (9th Cir. 1974).

A. Development of the Law of Obviousness

1. The Graham Factors

The Supreme Court in 1966 set forth several factors that can be used to determine obviousness in view of the prior art.[14] In *Graham v. John Deere Co.*, the Court held a patent on a "Clamp for Vibrating Shank Plows," which included a combination of old mechanical elements designed to absorb shock from plow shanks as they moved through rocky soil in order to prevent damage to the plow, as invalid for obviousness.[15] The Court held that the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed invention and the prior art, and objective evidence of nonobviousness should be used to determine nonobviousness.[16] Objective evidence of nonobviousness may include commercial success, long-felt but unresolved needs, and the failure of others.[17] However, the Court emphasized that the obviousness inquiry is clearly fact-specific and an analysis including all of these factors was not determinative.[18]

Although *Graham* provided additional considerations to determine nonobviousness, it did not construct bright-line rules for the nonobviousness requirement. Accordingly, an invention does not need to be completely predicted by prior art to be considered obvious.[19] In fact, the

[14] *See* Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966) (holding that objective evidence of nonobviousness can be used to determine nonobviousness).

[15] *Id.* at 18.

[16] *Id.* at 17.

[17] *Id.*

[18] *Id.*

[19] *In re* O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988) (stating that obviousness does not involve absolute predictability but only a reasonable probability of success).

Federal Circuit in *In re O'Farrell* noted that "[o]bviousness does not require absolute predictability of success."[20] Obviousness only requires a reasonable expectation of success.[21]

2. The Teaching, Suggestion or Motivation Test

In order to examine whether there was a reasonable expectation of success with regard to a particular invention, courts have applied the Teaching, Suggestion, or Motivation test ("TSM test").[22] A teaching, suggestion, or motivation means there was some reason or suggestion to combine known elements in the prior art to form the claimed invention.[23] In *In re Kahn,* the Court of Appeals explained that an analysis of the TSM test involves examining the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole.[24] By looking at these factors together, the court can determine what would have been suggested to those of ordinary skill in the art at the time that the invention was made.[25] Additionally, the teaching, suggestion, or motivation does not need to be found explicitly in the prior art, but it may be inferred by looking at the prior art as a whole.[26]

---

[20] *O'Farrell*, 853 F.2d at 903.

[21] *Id.*

[22] Winner Int'l Royalty Corp. v. Wang, 202 F.3d. 1340, 1348 (Fed. Cir. 2000) (noting that the teaching, suggestion, or motivation test attempts to locate some reason that would have motivated one skilled in the art to modify the prior art to create the new invention). However, the teaching, suggestion, or motivation test was changed in *KSR* (*see infra* note 67).

[23] *Winner Int'l Royalty Corp.*, 202 F.3d. at 1348.

[24] *See In re* Kahn, 441 F.3d 977 (Fed. Cir. 2006).

[25] *Id.* at 986 (holding that the teaching, suggestion, or motivation to modify the prior art may be inferred from viewing the prior art as a whole).

[26] *Id.*

3. Teaching Away

Although an invention merely combines known elements, a patentee may overcome an assertion of obviousness by showing that the prior art teaches away from combining the known elements.[27] In *United States v. Adams*, the Supreme Court held that a patent for a water activated battery, which operated on an open circuit comprising two electrodes, one of magnesium and one of cuprous chloride, was nonobvious even though it simply combined previously known elements in the prior art.[28] The Court emphasized that a person of ordinary skill in the art would have thought that the batteries, which operated on an open circuit and heated in normal use, were not practical. And, water activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium.[29] These accepted principles would have strongly discouraged the person of ordinary skill in the art from attempting to create this particular battery.[30] Therefore, the discovery of a successful means of combining known elements is more likely to be considered nonobvious when the prior art teaches away from their combination.[31]

[27] United States v. Adams, 383 U.S. 39, 51 (1966) (indicating that when the prior art teaches away from combining known elements, the resulting combination is more likely to be nonobvious).

[28] *Id.* at 42, 48.

[29] *Id.* at 51-52.

[30] *Id.* at 52.

[31] *Id.*

4. Unexpected Results

An inventor may also demonstrate that an invention which merely combines known elements in the prior art is nonobvious by providing evidence of "unexpected results."[32] According to *In re Soni*, an inventor may "show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected."[33] Therefore, an invention may be held to be nonobvious if the inventor can show that the invention exhibits properties that would have been unanticipated at the time of invention by a person with ordinary skill in the art.[34] Unexpected results must be established with factual data; a mere contention or conclusory statement that the invention exhibits unanticipated and superior properties is not enough to overcome a finding of obviousness.[35]

II. Obviousness of Chemical Compounds

A. Obviousness Pre-KSR

The above-described principles apply generally to obviousness determinations. However, it is complicated to establish obviousness in the chemical arts due to chemistry's intrinsic unpredictability. In many circumstances, a small and seemingly insignificant change in a chemical structure may generate a compound with remarkably different properties. The Graham factors and the TSM test have proved insufficient at providing a workable formula for

[32] *In re* Soni, 54 F.3d 746, 750 (Fed. Cir. 1995) (holding that evidence of "unexpected results" may provide evidence that an invention is nonobvious).

[33] *Id.*

[34] *Id.*

[35] *Id.* at 752.

determining chemical obviousness. Accordingly, courts have attempted to normalize the obviousness standard for chemical compounds by further delineating the requirements. Some of the earliest precedent regarding the obviousness of chemical compounds derives from two early seminal cases: *In re Hass* and *Application of Henze*.[36] The resulting principle of law derived from these two cases is conventionally known as the Hass-Henze Doctrine.[37]

1. The Hass-Henze Doctrine

In re Hass involved an appeal to the Court of Customs and Patent Appeals, predicated on the Board of Patent Appeals' rejection of Hass' patent application.[38] In his patent application, Hass claimed a genus of compounds which included a homologue,[39] 2–nitro–2–pentene, of a compound previously disclosed in the prior art.[40] The Board rejected Hass' claims because there was no critical difference between the properties of the prior art compound and Hass' claimed homologue.[41] Hass argued that it was not necessary to establish any material difference in the properties of the claimed homologue and the prior art compound because the claimed homologue

[36] *In re* Hass, 141 F.2d 122 (C.C.P.A. 1944); *Application of* Henze, 181 F.2d 196 (C.C.P.A. 1950).

[37] *See* Helmuth C. Wegner, *Prima Facie Obviousness of Chemical Compounds*, 6 AIPLA Q. J. 271 (1978) (discussing the evolution of the Hass-Henze doctrine, which was named after *In re* Hass and the *Application of* Henze).

[38] *Hass*, 141 F.2d at 122.

[39] "The term homologue is used to describe a compound belonging to a series of compounds differing from each other by a repeating unit, such as a methylene group, a peptide residue, etc." International Union of Pure and Applied Chemists, *Glossary of Terms Used in Medicinal Chemistry* (1998), *available at* http://www.chem.qmul.ac.uk/iupac/medchem/ah.html#a9 (last visited Jan. 15, 2009).

[40] *Hass*, 141 F.2d at 122-23 (holding that novelty alone does not cause a chemical compound to be patentable over the prior art).

[41] *Id.* at 123.

was novel.[42] The court disagreed with Hass' argument because novelty alone, without non-obviousness, does not render a compound patentable over the prior art.[43] A person skilled in the art would have been motivated to make the claimed homologue since:

> It is well understood by chemists that the members of a homologous series of chemical compounds possess the same principal characteristics; that generally the chemical and physical properties of the individual members vary gradually from member to member; and that knowledge of the properties and chemical behavior of one of the members of the series suggests to the chemist the properties and chemical behavior of the other members of the series.[44]

Consequently, the decision of the board was accordingly affirmed.[45]

A few years later, the Court of Customs and Patent Appeals decided the *Henze* case on similar grounds. The Board of Patent Appeals held that Henze's claimed compound, 5–isopropoxymethyl–5–phenylhydrantoin, was obvious in view of prior art containing the homologue, 5–ethoxymethyl–5–phenylhydratoin.[46] The prior art stated that 5–ethoxymethyl–5–phenylhydratoin caused convulsions at moderate doses, and the range between an effectual and lethal dose was too narrow for 5–ethoxymethyl–5–phenylhydratoin to be commercially viable.[47] Conversely, the compound 5–isopropoxymethyl–5–phenylhydrantoin was shown to have been

---

[42] *Hass*, 141 F.2d at 123.

[43] *Id.* at 125.

[44] *Id.* (*citing* Holeman & Walker, Textbook of Organic Chemistry, 5th ed., 1920. 41-42; Paul Karrer, Organic Chemistry, 1938, 23).

[45] *Id.* at 126.

[46] *Henze*, 181 F.2d at 198 (holding that an invention must show that a prior art did not have the same properties as the claimed compound).

[47] *Id.* at 200.

successful as an anticonvulsant with low toxicity.[48] Henze's 5–isopropoxymethyl–5–phenylhydrantoin was rejected as obvious in view of the prior art containing 5–ethoxymethyl–5–phenylhydratoin, even though the prior art made no mention of 5–ethoxymethyl–5–phenylhydratoin's anticonvulsant properties at any level other at moderate levels.[49]

The court held that Henze failed to show that 5–isopropoxymethyl–5–phenylhydrantoin possessed unexpected and advantageous properties not found in the prior art compound 5–ethoxymethyl–5–phenylhydratoin.[50] Henze attempted to assert that it would be sufficient to prove that 5–isopropoxymethyl–5–phenylhydrantoin had properties which were not known to be properties possessed by 5–ethoxymethyl–5–phenylhydratoin.[51] The court rejected this rationale, stating that Henze made no showing that 5–ethoxymethyl–5–phenylhydratoin would not exhibit similar anticonvulsant properties under the same dosage conditions.[52] It was necessary that Henze prove that the prior art compound does not exhibit the same properties of the claimed compound under the same conditions.[53] Again, the assumption underlying this decision is that a chemist skilled in the art would know that homologues typically possess similar properties, and the applicant has the burden of showing that a homologue possesses unexpected properties which make it patentable over the prior art.[54] Essentially, the *Hass-Henze Doctrine* indicates that if an

[48] *Henze*, 181 F.2d at 200.

[49] *Id.*

[50] *Id.* at 201.

[51] *Id.* at 200.

[52] *Id.* at 202.

[53] *Henze*, 181 F.2d at 202.

[54] *Id.* at 201.

examiner finds a compound in the prior art that is close enough to the claimed compound such that it would motivate a person skilled in the art to make the claimed compound (e.g., a homologue), then the claimed compound is assumed to be obvious unless evidence is provided which shows that the claimed compound possessed unexpected properties.[55]

2. Structural Similarity

The *Hass-Henze Doctrine* was considered good law until *Henze* was explicitly overruled in *Application of Stemniski*. In *Stemniski*, the Court held that an inventor does not need to prove that a prior art homologue to the claimed compound with no disclosed utility possesses properties that are materially different from the claimed compound at issue in order to render the claimed compound patentable over the prior art.[56] Although this portion of the *Henze* decision was overruled, courts continued to use a "structural similarity" test to address the issue of obviousness as shown in *In re Dillon*.[57] In this case, the Court of Appeals held that obviousness could be shown by "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions."[58] An obviousness rejection based on structural similarity and function means that there was sufficient motivation for a person of ordinary skill in the art to create the

[55] Harold C. Wegner, POST-KSR CHEMICAL OBVIOUSNESS IN LIGHT OF PFIZER V. APOTEX 8 (2007), *available at* http://www.patenthawk.com/blog_docs/070613_PostKSRChemical Obviousness.pdf (last visited Jan. 14, 2009).

[56] *Application of* Stemniski, 444 F.2d 581, 587 (C.C.P.A. 1971).

[57] *In re* Dillon, 919 F.2d 688 (Fed. Cir. 1990) (noting that a compound may be rejected as obvious in view of the prior art if the claimed compound is structurally similar to the prior art compound and there was motivation to modify the prior art to achieve the claimed compound).

[58] *Id.* at 692.

new compound with the expectation that the new compound would exhibit properties similar to that of a prior art compound because of their structurally similarity.[59]

3. Unexpected Properties

Courts also continued to recognize that obviousness based on structural similarity between a new compound and a prior art compound may be overcome by a showing that the new compound exhibited unexpected properties.[60] In *Application of Papesch*, the inventor claimed a family of compounds which included the compound 2,4,6-triethylpyrazolo(4,3-d)-4,5,6,7-tetrahydropyrimidine-5,7-dione.[61] It was undisputed that this compound was obvious due to structural similarity in light of a prior art compound 2,4,6-trimethylpyrazolo(4,3-d)-4,5,6,7-tetrahydropyrimidine-5,7-dione, since these two compounds differ only in that the prior art compound has three methyl groups where the claimed compound has three ethyl groups.[62] However, the inventor provided test results that demonstrated that the claimed triethyl compound was an active anti-inflammatory agent, whereas the prior art trimethyl compound did not exhibit any anti-inflammatory properties.[63] A close similarity in structure alone does not render a compound obvious.[64] The Court held that the properties of compounds may and should be taken

[59] *Dillon*, 919 F.2d at 692

[60] *Application of* Papesch, 315 F.2d 381 (C.C.P.A. 1963) (stating that a compound may not be held obvious if the inventor can provide evidence that the claimed compound possessed unexpected properties).

[61] *Id.*

[62] *Id.*

[63] *Id.* at 383.

[64] *Id.* at 391.

into account when analyzing obviousness.[65] A compound's structure and its physical, chemical, and biological properties cannot be separated; thus, when proving obviousness, a chemical compound must be considered as a whole.[66]

B. Flexible Teaching, Suggestion, or Motivation Test in *KSR*

In 2007, the Supreme Court made a decision that would significantly affect the obviousness standard for all inventions in *KSR Int'l Co. v. Teleflex, Inc.* *KSR* concerned a patent for an "Adjustable Pedal Assembly with Electric Throttle Control" which was licensed to Teleflex.[67] The claimed invention included an electronic sensor placed on the pivot point of an adjustable accelerator pedal.[68] The sensor detected the position of the pedal and sent this information to a computer which controlled the amount of fuel injected into the engine.[69] Teleflex claimed that KSR infringed the patent when KSR developed an adjustable mechanical pedal with a modular sensor for Ford Motor Company.[70] KSR argued that the Teleflex patent was obvious in light of the relevant prior art.[71] The District Court granted summary judgment for KSR because there was little difference between the prior art and the claimed invention.[72]

---

[65] *Papesch*, 315 F.2d at 391.

[66] *Id.*

[67] KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 399 (2007) (holding that the "teaching, suggestion, or motivation" (TSM) test should be flexibly applied, not as "rigid and mandatory formulas").

[68] *Id.* at 399.

[69] *Id.* at 398.

[70] *Id.* at 399.

[71] *Id.*

[72] *KSR*, 550 U.S. at 399-400.

Additionally, the District Court found that the relevant prior art satisfied the Teaching Suggestion or Motivation (TSM) test, and the claimed invention would have been obvious to a person of ordinary skill in the art.[73] The Court of Appeals reversed the district court's decision, stating that the district court did not apply the TSM test strictly enough.[74] The Court of appeals noted that "the District Court's recourse to the nature of the problem to be solved was insufficient because, unless the prior art references addressed the precise problem that the patentee was trying to solve, the problem would not motivate an inventor to look at those references."[75]

The Supreme Court reversed the decision of the Court of Appeals, agreeing with the District Court that the claimed invention would have been obvious to one of ordinary skill in the art.[76] The Supreme Court stated that the Court of Appeals applied the TSM test too rigidly, and criticized the Court of Appeals for indicating the District Court had not applied the TSM test strictly enough.[77] The Supreme Court disapproved of the Court of Appeal's assertion that the prior art must necessarily include a discussion of the exact problem the invention was created to address.[78] The Court of Appeals thought the District Court incorrectly stated that the nature of the problem to be solved satisfied the TSM test.[79] The Court of Appeals indicated that unless the

[73] *KSR*, 550 U.S. at 399-400.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *Id.* at 415.

[78] *KSR*, 550 U.S. at 420.

[79] *Id.* at 400.

prior art references addressed the specific problem that the inventor was attempting to solve, the inventor would not be motivated to consider those references.[80] The Supreme Court disagreed, stating "[w]e begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here."[81]

In deciding the *KSR* case, the Supreme Court did not substantially change the TSM test. In fact, the Supreme Court commended the introduction of the TSM test into the obviousness inquiry. The Supreme Court noted, "[w]hen it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight."[82] The Supreme Court repeatedly cautioned against the use of a rigid, pedantic application of the TSM test that the Court of Appeals recommended.[83] The Supreme Court noted:

> Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way.[84]

[80] *KSR*, 550 U.S. at 400.

[81] *Id.* at 415.

[82] *Id.* at 418.

[83] *Id.* at 419.

[84] *Id.*

C. Obviousness of Chemical Compounds Post-*KSR*

As a result of *KSR*, determining the obviousness of chemical compounds became increasingly uncertain. It has been speculated that the flexible TSM test supported by the Court in *KSR* would strengthen the ability of generic drug companies to challenge the validity of some pharmaceutical patents.[85] Although many pharmaceutical patents held by major drug companies involve the invention of innovative new drug compounds, many patents simply cover the homologues, salts, metabolites, or new formulas of prior art compounds including time-release capsules, new combinations of old drugs, and larger doses which can be taken less frequently.[86] These patents are a critical part of the innovation companies' strategy for prohibiting generic drug companies from making minor changes to the innovative new patented drugs and claiming them as their own.[87] It has been argued that *KSR*'s flexible TSM test will easily allow generic drug companies to prove that the homologues, salts, metabolites, and new formulas would have been obvious at the time they were made.[88]

In addition to the problem of easing the way for generic drug companies to prove that patented compounds were obvious, it has been argued that *KSR* essentially changed the long-standing rigid approach of evaluating the obviousness of chemical compounds to a new flexible approach inconsistent with the prior case law. Under the so-called "old rigid approach," patent examiners would be required to find structural similarity between the claimed compound and a

[85] Rebecca Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 377 (2008).

[86] *Id.*

[87] *Id.*

[88] *Id.*

prior art compound.[89] This approach frequently allowed claimed compounds which are not structurally similar to the prior art to automatically be considered nonobvious, even if there may have been some motivation in the prior art to make the claimed compound.[90] For example, in the case of *In re Deuel*, the Court of Appeals indicated that a DNA sequence encoding a polypeptide was nonobvious over prior art which disclosed a partial amino acid sequence.[91] Even though the prior art provided sufficient motivation for a person skilled in the art to clone the DNA sequence, the partial amino acid sequence was not "structurally similar" to the claimed DNA sequence.[92] Ultimately, the court held that the DNA sequence was nonobvious.[93] In the absence of a rigid formula of structural similarity, the Court of Appeals would have been able to find the DNA sequence obvious since there was explicit motivation to make the partial amino acid sequence in the prior art. Therefore, it has been argued that the flexible TSM formula articulated in *KSR* is a deviation from prior precedent.

On the other hand, it has been suggested that the *KSR* decision did not substantially change the obviousness inquiry with regard to chemical compounds.[94] It is contended that by

---

[89] Eisenberg, *supra* note 85.

[90] *Id.*

[91] *In re* Deuel, 51 F.3d 1552, 1556 (Fed. Cir. 1995) (holding that motivation to combine the prior art does not render a compound obvious without structural similarity. If the case had been decided using the flexible teaching, suggestion, or motivation test in *KSR*, the court may have reached a different result given that the structural similarity test need not be rigidly applied).

[92] *Id.* at 1557.

[93] *Id.* at 1559.

[94] *See generally* Jonathan M. Spenner, *Obvious-to-Try: Obviousness of Chemical Enantiomers in View of the Pre- and Post-KSR Analysis*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 475 (2008) (arguing that the *KSR* decision may have been a mere anomaly).

rejecting the Court of Appeals' rigid application of the TSM test, the Supreme Court was simply instructing the Court of Appeals to follow its own precedent.[95] Prior to *KSR*, a flexible TSM test was employed to determine the obviousness of chemical compounds.[96] For example, in the case of *Forest Labs., Inc. v. Ivax Pharms., Inc.*, the Court of Appeals held that a claimed enantiomer[97] was nonobvious over the disclosure of the racemic mixture[98] found in the prior art.[99] The Court held that an inventor would not have been motivated to attempt a difficult racemate separation rather than simply try to discover a new compound and the claimed enantiomer was nonobvious.[100] Consequently, the Court failed to make the rigid assumption that enantiomers which were separated from the racemic mixture were obvious over the prior art.[101]

D. *Eisai v. Dr. Reddy's*: Active Site Substitution is "Per Se" Nonobvious

There were clearly conflicting opinions regarding the affects of *KSR* on the obviousness in pharmaceutical cases. In 2008, however, the Court of Appeals had a chance to directly

[95] Spenner, *supra* note 94, at 514.

[96] *Id.*

[97] Enantiomers are molecules having "the same conductivity but differ[ing] in the arrangement of atoms in space . . . that are nonsuperposable mirror images of each other." ERIC V. ANSLYN & DENNIS A. DOUGHERTY, MODERN PHYSICAL ORGANIC CHEMISTRY 299 (John Murdzek ed., University Science 2006).

[98] A racemic mixture is "a 50:50 mixture of enantiomers." ANSLYN & DOUGHERTY, *supra* note 97, at 300.

[99] *See* Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263, 1265-66 (Fed. Cir. 2007) (noting that enantiomers separated from a racemic mixture known in the art are not necessarily obvious).

[100] *Id.* at 1267.

[101] *Id.*

address this question in *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*[102] Eisai had a patent ("the '552 Patent") on rabeprazole, the active ingredient in Aciphex, shown to be an effective drug for treating ulcers.[103] In order to be able to manufacture a generic version of Aciphex before the end of the patent term, Dr. Reddy's Laboratories ("Dr. Reddy's") and Teva Pharmaceuticals ("Teva") filed Abbreviated New Drug Applications ("ANDA") under the Hatch-Waxman Act.[104] As a result, Eisai filed suit against Dr. Reddy's and Teva for patent infringement since the filing of an ANDA is a legally recognized form of patent infringement.[105] At the trial court, Dr. Reddy's and Teva were found to infringe the '522 Patent, and they appealed the court's judgment.[106] Specifically, Teva asserted that the '552 Patent was invalid for obviousness over a European patent and a United States patent ("the '431 Patent") claiming, as well as an article describing, the ulcer-treating compound lansoprazole.[107]

The chemical formulas of lansoprazole (R-OCH_2CF_3) and rabeprazole (R-$OCH_2CH_2CH_2OCH_3$), where the R-core structure is identical in both molecules, differ only in one substituent group, the trifluoroethoxy substituent (-OCH_2CF_3) for lansoprazole compared to the methoxypropoxy substituent (-$OCH_2CH_2CH_2OCH_3$) for rabeprazole.[108] Lansoprazole was

---

[102] *See* Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1362 (Fed. Cir. 2008) (holding that the claimed compound was nonobvious in view of the prior art because the claimed compound was modified at the particular substituent which activated the prior art compound).

[103] *Id.* at 1356.

[104] *Id.*

[105] *Id.* (*citing* Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1344 (Fed. Cir. 2004)).

[106] *Id.* at 1356.

[107] *Eisai*, 533 F.3d at 1356-57.

[108] *Id.* at 1357.

known to possess qualities, including a low molecular weight and lipophilicity, which a person skilled in the art of drug discovery would recognize as positive characteristics for a potential drug candidate.[109] Additionally, lansoprazole was determined to be twenty times more effective than another compound of similar structure, omeprazole, in treating ulcers.[110]

Clearly concerned about the affect of *KSR* on the determination of obviousness of chemical compounds, the Court explained:

> The Supreme Court's analysis in *KSR* thus relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. Third, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions." In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc*., 520 F.3d 1358, 1364 (Fed. Cir. 2008), this court further explained that this "easily traversed, small and finite number of alternatives . . . might support an inference of obviousness." To the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these "identified, predictable solutions" may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.[111]

The Court noted that the *KSR* decision did not significantly change the obviousness inquiry with respect to chemical compounds.[112]

The Court began its obvious inquiry by identifying lansoprazole as the lead compound

---

[109] *Eisai*, 533 F.3d at 1358.

[110] *Id.*

[111] *Id.* at 1359.

[112] *Id.* at 1358.

since the data presented indicated that lansoprazole would make a good starting candidate for anti-ulcer drugs.[113] The Court then attempted to discover some motivation in the prior art for a person skilled in the art to modify lansoprazole to achieve rabeprazole.[114] The prior art European patent containing lansoprazole indicated that lansoprazole's fluorinated substituent gave the compound its increased lipophilicity, which made it a particularly favorable drug candidate.[115] Additionally, Teva's expert witness at trial provided testimony that fluorinated-substituted groups increase lipophilicity.[116] The Court pointed out that lansoprazole's advantageous property, namely its increased lipophilicity, could be attributed to the fluorinated substituent.[117] Consequently, the Court reasoned that a person skilled in the chemical arts would not have considered the elimination or alteration of the same substituent group which gave lansoprazole its beneficial properties to be an identifiable, predictable solution.[118] Although lansoprazole and rabeprazole were structurally similar, the trial court's determination of nonobviousness was affirmed on appeal due to the lack of motivation for a person skilled in the art to modify lansoprazole at the activating substituent group.[119]

III. Compounds Modified at the Active Site Should Be Considered "Ad Hoc"

While it is certainly debatable whether the Court of Appeals in *Eisai* reached the correct

[113] *Eisai*, 533 F.3d at 1358.

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] *Id.*

[118] *Eisai*, 533 F.3d at 1358.

[119] *Id.*

conclusion regarding the obviousness of rabeprazole in view of lansoprazole, its reasoning for the ultimate conclusion of nonobviousness is troublesome. The Court indicated that there was no evidence in the record that would motivate a person skilled in the chemical arts to modify the fluorinated substituent group of lansoprazole when that exact group gave the compound its superior properties in comparison to other compounds with the same core structure. Essentially, the argument suggested that chemists skilled in the art, after realizing the effectiveness of a compound following the successful addition of a particular substituent group in a given location, would not further attempt to modify that compound at the same location to improve its efficacy. The logical conclusion which flows from that argument is that a novel compound which is known to possess favorable properties as a drug candidate for a specific human condition will never be obvious in view of a structurally similar prior art compound used for treating that same condition if the novel compound was synthesized solely by altering the activating substituent site. In other words, altering a compound at the location of the particular activating substituent can never be obvious. This represents a fundamental misconception of the drug discovery process. The danger underlying the *Eisai* decision is not the ultimate conclusion of nonobviousness but rather the reasoning behind that decision.

Although chemists regularly synthesize a drug candidate compound with a core structure not previously known to possess therapeutic properties, they will often begin with a core structure which is known to successfully treat a given condition and then subsequently alter the substituent groups.[120] By altering the substituent groups of a compound selected for

[120] *See* ALFRED BURGER, A GUIDE TO THE CHEMICAL BASIS OF DRUG DESIGN, 15 (Wiley-Interscience, Inc. 1983) ("The pattern of accidental or semiplanned drug discovery followed by systematic variation of the 'lead' has been repeated time and again."); 1 C.J. CAVALLITO, MEDICINAL CHEMISTRY 233 (Alfred Burger ed., Wiley-Interscience, Inc. 1957) ("New drug discovery may be considered broadly in terms of two kinds of investigational activities,

experimentation due to some desirable properties, chemists strive to increase the efficacy and decrease the toxicity of the compound.[121] Even if the addition of a particular substituent group increased the therapeutic properties of the compound, chemists will frequently replace this group with other substituent groups which can be reasonably expected to possess the similar or increased advantageous properties at the exact same location. In order to determine what types of substituent groups would be expected to possess the same advantageous properties, chemists will look at structure-activity relationships.[122] Chemists may substitute substituent groups possessing many of the same properties, such as molecular weight, polarity, stereochemical arrangement, and reactivity, since similar substituent groups would likely behave with comparable biological activity.[123] Chemists skilled in the art thoughtfully select particular substituent groups expected to produce a similar or enhanced resulting efficacy to substitute at

---

'exploration' and 'exploitation' of leads . . . the latter [involves] the assessment, improvement, and extension of the lead. It is largely in the latter area that rational approaches to drug design have been productive."); *Id*. at 236 ("In molecules with a variety of potential bonding interacting moieties it is useful, when possible, to eliminate individual bonding components sequentially and observe the effects on activity.").

[121] BURGER, *supra* note 120, at 86 ("The purpose of molecular modification is usually to seek subtle changes in the compound that should not alter some properties but change others in order to improve potency, selectivity, duration of action, and reduce toxicity").

[122] *See generally* G. A. Patani & E. J. LaVoie, *Bioisosterism: A Rational Approach in Drug Design*, 96 CHEM. REV. 3147-76 (1996).

[123] BURGER, *supra* note 120, at 86 ("Bioisosteric replacement is the principal guide followed by medicinal chemists in developing analogs of a 'lead' compound . . . [t]he parameters being changed are molecular size, steric shape (bond angles, hybridization), electron distribution, lipid solubility (= hydrophobicity), water solubility, the pKa, the chemical reactivity to cell components and metabolizing enzymes, and the capacity to undergo hydrogen bonding (receptor interactions). [If similar properties predominate], the overall properties of the two compounds may be adequately similar.").

the activating site.[124]

Many examples illustrate this strategy, including research performed on paclitaxel.[125] In its naturally-occurring form, paclitaxel can be used as an anticancer drug.[126] Even after years of its successful use in chemotherapy treatments, researchers continued to modify the peripheral substituent groups which gave paclitaxel its advantageous properties in an effort to improve its efficacy and decrease its toxicity.[127] Although paclitaxel was already known to work for its intended purpose, researchers continued to attempt to improve its effectiveness by modifying its substituent groups.[128]

Another example which illustrates how chemists modify substituent groups on a core molecule to achieve new or enhanced properties involves a group of statins, which are cholesterol-lowering drugs.[129] One of these statins, Mevacor, is a naturally occurring compound which can be isolated from the bacterium *Aspergillius terreus*.[130] Researchers attached one

---

[124] *See* 1 ALFRED BURGER, MEDICINAL CHEMISTRY 72-73 (Alfred Burger ed., Wiley-Interscience, Inc. 1957) ("The search for structural analogs for 'lead' compounds . . . can be rationalized by gradually substituting one atom or group of atoms in the parents compound for another with a similar electronic and steric configuration.").

[125] *See generally* W.S. Fang & X.T. Liang, *Recent Progress in Structure Activity Relationship and Mechanistic Studies of Taxol Analogues*, 5 MINI REVIEWS IN MEDICINAL CHEMISTRY 1 (2005).

[126] *Id.*

[127] *Id.*

[128] This is not to suggest that any substituent group substituted at an activating site would necessarily be obvious to one skilled in the art.

[129] Rebecca M. Wilson & Samuel J. Danishefsky, *Small Molecule Natural Products in the Discovery of Therapeutic Agents: The Synthesis Connection*, 71 J. ORG. CHEM. 8329, 8332 (2006).

[130] *Id.*

additional methyl group to Mevacor, which produced the new separately patentable molecule Zocor.[131] Another statin, compactin, is also a naturally occurring compound isolated from the bacterium *Penicillium brevicompactin*.[132] By adding a hydroxyl group to compactin and opening the ring on the core, chemists synthesized the new compound Pravachol, which was subsequently patented by Bristol-Myers Squib.[133] In both of these situations, the two pairs of molecules differed from each other by one substituent group while the core remained the same.

In addition to these specific examples, it is crucial to note that it is common practice for chemists to begin with a known compound and modify the substituent groups when synthesizing new compounds. For example, researchers at Hoffman-La Roche, Inc. fabricated a collection of forty-five benzodiazepines.[134] In order to create this collection, the researchers maintained the core benzodiazepine structure and varied the substituent groups.[135] Then, the newly created compounds were tested for acute toxicities and screened for sedative, muscle-relaxant, taming, and anticonvulsant effects.[136] Two patented drugs resulted from such molecular modification programs focused on benzodiazepines: flurazapem and nitrazepam, both used to treat insomnia.[137] This case presents a clear model of the general practice in the chemical arts of

---

[131] Wilson & Danishefsky, *supra* note 129.

[132] *Id.*

[133] *Id. See generally* Bristol-Myers Squib, *Pravachol*, www.pravachol.com (last visited Feb. 28, 2009).

[134] *See* L. H. Sternbach, et al., *Quinazolines and 1,4-Benzodiazepines. XXV. Structure-Activity Relationships of Aminoalkyl-Substituted 1,4-Benzodiazepin-2-ones*, 8 J. MED. CHEM. 815 (1965).

[135] *Id.*

[136] *Id.* at 819.

[137] BURGER, *supra* note 120, at 133.

modifying substituent groups on the core of a compound in order to synthesize a new compound.

One of the best classic examples of the use of molecular modification of known compounds to arrive at potentially useful therapeutic agents involves the sulfanilamides.[138] The antihyperglycemic and diuretic properties of known sulfanilamides prompted investigators to create and test over two thousand analogs.[139] One product of the research was the discovery of acetazolamide, which has been proven clinically useful for treating glaucoma.[140] Therefore, since the obviousness determination would depend on the particular substituent substitution made as shown in the previous examples, it is clear that an ad hoc analysis of a claimed compound in view of the prior art is necessary to more accurately determine the obviousness standard for chemical compounds. In sum, the emphasis should be placed on what substitution was made, not the location of such substitution on the compound.

IV. Proposed Two-Part Test for Obviousness of Chemical Compounds

In order to improve the standard of obviousness for chemical compounds to more accurately reflect synthesis techniques in the art, the following two-part test should be employed: (1) was the particular substitution obvious to a person skilled in the art?; and (2) if so, did the compound exhibit unexpected results?

A. Whether the Particular Substitution Was Obvious to One Skilled in the Art

I propose that a factual inquiry into what specific substitution was made and the reasoning for that specific substitution at the activating site would be required to ultimately determine if a novel compound is truly nonobvious. For example, a substitution involving two

---

[138] BURGER, *supra* note 120, at 80.

[139] *Id.*

[140] *Id.*

substituents with similar polarity and molecular weight would more likely be held obvious compared to the substitution of a strong polar substituent for a nonpolar substituent. There is no evidence that the *Eisai* court even considered whether lansprazole's trifluoroethoxy substituent (-OCH_2CF_3) and rabeprazole's methoxypropoxy substituent (-$OCH_2CH_2CH_2OCH_3$) would be expected to possess similar properties and, consequently, cause similar or enhanced antiulcer capabilities.[141] Following this type of inquiry, the *Eisai* court would have been better equipped to determine rabeprazole's potential obviousness.

B. Whether There Were Unexpected Results

Even if a particular substitution may have been considered obvious to one of ordinary skill in the art, an appropriate standard for determining the obviousness of chemical compounds must include a consideration of unexpected results. The doctrine of unexpected results has long been a part of the obviousness inquiry. In *In re May*, the invention encompassed the acid addition salts of certain levo and alpha-levo isomers of N-methyl benzomorphan.[142] May attempted to rebut the presumption of obviousness by showing that claimed compounds possessed pain-relieving properties similar to morphine, but they did not have the adverse side effects of morphine, for example, addictiveness.[143] The court determined that the nonaddictive property of the N-methyl benzomorphans would have been totally unexpected to a person skilled in the art.[144] Due to this unexpected property, the court held that the N-methyl benzomorphans

---

[141] *See generally Eisai*, 533 F.3d 1353.

[142] *In re* May, 574 F.2d 1082, 1084 (C.C.P.A. 1978) (stating that evidence of unexpected properties may refute a determination of obviousness).

[143] *Id.*

[144] *Id.* at 1092.

would not have been obvious to one skilled in the art.[145]

Accordingly, the standard for determining obviousness of chemical compounds should also allow for a compound which was synthesized by obvious substitutions to a prior art compound to be patented when there is a showing of unexpected results. Pharmaceutical companies should not be barred from patenting a compound with clearly new or significantly enhanced therapeutic properties simply because an obvious substitution was made to the prior art compound.[146]

C. Proposed Two-Part Test Would Lead to Increased Efficiency

By employing a test of chemical obviousness which allows a fact-specific inquiry into the particular substitution and reasoning, the standard of obviousness for a novel chemical compound would become more practicable. Chemists skilled in the art are capable of predicting, within the limits of chemistry's uncertainty, whether certain substituent groups substituted on a core molecule could reasonably lead to expected results. This would result in a more efficient allocation of monetary resources, because chemists would spend more time and money pursuing the development of compounds which are less likely to be held obvious. The expansion of drug development involving compounds, which would be nonobvious under my proposed standard, would potentially lead to the discovery of truly innovative, not merely trivially different, drugs.

Additionally, a more clearly defined obviousness standard for chemical compounds would allow pharmaceutical companies to pursue the most economically viable, potential drug candidates. In 2004, United States pharmaceutical companies alone spent approximately $98

---

[145] *May*, 574 F.2d at 1093.

[146] ALFRED BURGER, MEDICINAL CHEMISTRY 64 (Alfred Burger ed., Wiley-Interscience, Inc. 1957) ("An added bonus of molecular modification may be the discovery of an unrelated pharmacological side effect that could be of interest in another context.").

billion on drug research and development; this represents approximately 0.85 percent of the United States gross domestic product (GDP).[147] This enormous amount of money spent on drug research should be spent striving to attack new and unsolved problems in medicinal chemistry rather than making minimal changes to compounds which have already been shown to work for a specified purpose. The Constitution of the United States gives Congress the 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."[148] The most important word in this clause is progress. By more efficiently allocating the money spent on pursuing drug research, the United States could be at the forefront of progressive drug exploration, targeting key diseases like cancer, AIDS, autism, and many others.

In addition, the widespread use of combinatorial chemistry[149] significantly increases the discovery rate of new chemical compounds that can be reasonably synthesized and tested for pharmacological activity. Combinatorial chemistry is relatively new methodology developed by chemists to decrease the time and monetary costs required to produce effective new drug compounds. Chemists use combinatorial chemistry to generate a library of molecules that can be examined resourcefully at the same time. Through creating increasingly diverse chemical

---

[147] Samuel C. Silverstein, M.D., *What does economic research tell us about the economic benefits of investments in medical and health research and training?* 2 (2005), *available at* http://www.asbmb.org/uploadedFiles/Advocacy/Economic%20Benefits%20of%20Research%20Investments%20(Silverstein,%20SC).pdf (last visited Jan. 16, 2009).

[148] U.S. CONST. art 1, § 8, cl. 8.

[149] For a detailed description of combinatorial chemistry techniques, *see* E. V. Gordeeva et al., *COMPASS program – An Original Semi-Empirical Approach to Computer-Assisted Synthesis*, 48 TETRAHEDRON 3789 (1992); X. D. Xiang et al., *A Combinatorial Approach to Materials Discovery*, 268 SCIENCE 1738 (1995); Miklos Feher & Jonathan M. Schmidt, *Property Distribution: Differences Between Drugs, Natural Products, and Molecules from Combinatorial Chemistry*, 43 J. CHEM. INF. COMPUT. SCI. 218 (2003).

compound libraries, pharmaceutical companies can enhance the probability of identifying novel compounds with important medicinal and economic value. With these techniques, the patent office and the courts should anticipate an increase in the number of chemical compound patents whose ultimate patentability will depend on the nonobviousness requirement. Therefore, a more well-defined and accurate obviousness standard for chemical compounds based on actual practice in the art will decrease the burden placed on patent examiners and the court system who are frequently left to toil with a vague and impracticable chemical obviousness standard.

CONCLUSION

The law of obviousness has been constantly evolving since its statutory enactment in 1952. While this law has been an effective tool in eliminating trivial improvements on inventions in the electrical and mechanical sciences, the law of obviousness has failed to provide the chemical arts with a clear standard to determine whether chemical compounds will be held obvious in view of the prior art.

The current standard for assessing the obviousness of a chemical compound has two parts: (1) identification of a prior art compound with a structure similar to the claimed compound and (2) motivation for a person skilled in the art to modify the prior art compound to achieve the claimed compound. *KSR*, which struck down the rigid TSM test employed by the Court of Appeals, raised questions as to whether it would be essentially the same or easier for generic drug companies to show that patented chemical compounds would have been obvious at the time of their discovery. When the Court of Appeals had the chance to specifically address this issue in the *Eisai* case, the court failed to more clearly delineate the obviousness standard for chemical compounds. Additionally, the Court's reasoning for holding the claimed compound in *Eisai* to be nonobvious is inconsistent with generally accepted drug discovery principles. An

inquiry into the motivation for making a substituent substation on the core of a molecule known to have therapeutic properties must necessarily include an investigation of the particular substitution made and the reason for that substitution, not merely an analysis of the location of that substitution on the compound's core.

Chemistry is an intrinsically volatile art; consequently, an unambiguous obviousness standard has been difficult to outline. The *Eisai* court's decision has set the stage for trivial substitutions to known compounds to be held nonobvious. Due to the enormous amount of money spent on pharmaceutical research and development in the United States, the development of a more well-defined obviousness standard is necessary to allow pharmaceutical companies to put the most time and money into economically practical areas to promote the progress of the human society.

SYRACUSE SCIENCE & TECHNOLOGY
LAW REPORTER

VOLUME 21 FALL 2009 ARTICLE 5, PAGE 118

The Stem Cell Dilemma: Beacons of Hope or Harbingers of Doom?

By: Leo Furcht, M.D. and William Hoffman

Citation: LEO FURCHT & WILLIAM HOFFMAN, THE STEM CELL DILEMMA: BEACONS OF HOPE OR HARBINGERS OF DOOM? (Arcade Publishing 2008).

Reviewed by: Heather Giglio[1]

Relevant Legal and Academic Areas: Bioethics, Biotechnology

Summary: People are intrigued by all the possibilities and hope that stem cell research has to offer. In a time where we are so technologically advanced and interested in finding cures for so many debilitating and potentially life-threatening diseases, stem cell research makes scientists hopeful that these cures will be more than just a possibility and instead a reality. Law-makers and the government as a whole are involved, as well, and need to determine whether to make such research legal and how much money to delegate to such experimentation. Society has also taken interest in this controversial topic and has been very vocal. The authors set out to discuss both sides of this controversy, highlighting the potential hopes and dangers. The authors contend that whether this knowledge and technology is used for good or evil is up to society.

Chapter One: Agents of Hope

- **Chapter Summary:** The authors discuss the hopeful possibilities that stem cells have in curing heart disease, diabetes and other autoimmune diseases, spinal cord injury, and nervous system diseases.
- **Chapter Discussion:** The umbilical cord is a symbol of hope in the world of science. It contains cells with the ability to regenerate and possibly put an end to a vast number of diseases.[2] No one is more aware of this than the Nash family. Molly Nash suffered from a genetic disease that caused a failure of bone marrow and developed leukemia by the age

[1] J.D. Candidate, Syracuse University College of Law, 2010; Associate Editor, *Syracuse Science and Technology Law Reporter*.

[2] LEO FURCHT AND WILLIAM HOFFMAN, THE STEM CELL DILEMMA: BEACONS OF HOPE OR HARBINGERS OF DOOM? 2 (2008) [hereinafter Furcht].

of six. Molly's blood needed to be replaced with healthy blood and this healthy blood needed to be a perfect match. Such blood could come only from a sibling, whose umbilical cord would harbor the necessary stem cells. Molly's parents conceived a baby through in vitro fertilization to ensure that the baby would not have the same genetic disease as Molly and essentially created "the world's first designer baby."[3] The stem cells from his umbilical cord rehabilitated Molly's entire blood system. Such is an example of only one of many possibilities stem cells offer the world of medicine.

Stem cells also offer profound and much needed possibilities for cardiology.[4] Diabetes is another area of interest, especially as obesity becomes a more common occurrence in today's world.[5] Stem cell research is the avenue that would most likely lead to finding a renewable source of insulin-producing cells.[6] A diabetic needs insulin to live. Parents supporting stem cell research in the area of diabetes wrote, "Eight times a day and sometimes more, and once or maybe twice each and every night, we poke our daughter's soft fingers to find out if she needs insulin or a cookie for 'lows.'"[7] Stem cell research, and an eventual cure for diabetes, would completely alter the lives of such parents for the better.

[3] Furcht, *supra* note 2, at 3.

[4] *Id.* at 11.

[5] *Id.* at 16.

[6] *Id.* at 19.

[7] *Id.* at 18.

In 2006, television viewers were able to see paralyzed rats moving their limbs.[8] That movement was a result of being implanted with rat embryonic stem cells. The researcher responsible for this, Douglas Kerr, believes that the stem cells went to the most severely damaged spots of the rats' spinal cord and rescued dying neurons, thereby reforming sufficient connections affording movement in the rats.[9] If aiding paralysis is possible in rats, perhaps it is possible in humans, as well. Stem cell research could potentially benefit those suffering from multiple sclerosis.[10]

Another disease in desperate need of a cure is Alzheimer's. Statistics project that by 2050, the rate of Alzheimer's will increase by nearly 300 percent.[11] Stem cells offer the possibility of being regenerators of brain tissue, which could replace lost brain cells. While hopeful, there is still some serious doubt in this area. "Expecting transplanted neurons to weave themselves into the fraying circuits seems about as likely as a skein of yarn inserting itself into a damaged tapestry and recreating the original."[12] Additionally, there's no guarantee that embryonic stem cells will affect the desired cells. Instead of

[8] Furcht, *supra* note 2, at 22.

[9] *Id.* at 23.

[10] *Id.* at 25.

[11] *Id.* at 26.

[12] *Id.* at 27. (citing Sharon Begley, *Harnessing Stem Cells to Battle Alzheimer's Is at Least Worth a Try*, WALL ST. J., July 2, 2004 at B1).

becoming brain cells, stem cells could form bone.[13] Such doubt deters using stem cells for cures since the patient could be exposed to unnecessary risk.

With all of this hope, there are also serious risks to consider. Among these risks is the possibility of developing tumors after an embryonic stem cell transplant. This opens the door to a host of questions: Would you accept the risk of a possible tumor? Would you accept it for your child? Would the FDA accept it?[14] Despite how these questions may be answered, it is undeniable that stem cell research does offer a lot of knowledge about human disease.[15]

Chapter Two: Architects of Development

- **Chapter Summary:** The authors provide a brief overview of stem cells generally, as well as regenerative science.
- **Chapter Discussion:** The stem cell is the "architect and engineer of all complex organisms."[16] They maintain continual self-renewal, self-differentiation, and self-destruction.[17] Their "duality of purpose" marks their ability to reproduce themselves and create new tissues.[18] These stem cells are of one of two categories: adult stem cells and

[13] Furcht, *supra* note 2, at 28.

[14] *Id.* at 32-3.

[15] *Id.* at 33.

[16] *Id.* at 36.

[17] *Id.*

[18] Furcht, *supra* note 2, at 36.

embryonic stem cells.[19] Adult stem cells have a more limited potential for regeneration. Some, however, are more versatile and known as multipotent, meaning they can regenerate tissue other than that in which they originate.[20] They typically come from bone marrow, umbilical cord blood, and less often from circulating blood.[21] The embryonic stem cell is pluripotent because it builds entire bodies.[22] They come from embryos that are created but never used.[23]

Chapter Three: Challengers of Ethics

- **Chapter Summary:** This chapter focuses on the ethical concerns regarding stem cells. It seeks to show the divide that exists among different sects of society.
- **Chapter Discussion:** There is much uncertainty about stem cells and their possible uses. What is right and what is wrong? Who decides this? Where is the ethical line and who draws it? The term "stem cell" has become very controversial in and of itself and is a hot button issue. This is due in part to the debate of the moral standing of an embryo[24] and also because of language. Words like "stem cells" and "cloning" have the power to enrage the public. Avoiding these words, however, will likely to appeal to more people.[25]

[19] Furcht, *supra* note 2, at 38.

[20] *Id*. at 39.

[21] *Id*.

[22] *Id*.

[23] *Id*. at 40.

[24] Furcht, *supra* note 2, at 79.

[25] *Id.* at 78.

"Preserving the nation's shared values while reining in its deepest moral divides was the challenge,"[26] write the authors in reference to President Bush's take on stem cell research. "President George W. Bush announced that (he was going to restrict) federal funding for embryonic stem research to existing stem cell lines".[27] This seemed to placate those who want to further medical research and the pro-life community.[28] Despite a seemingly agreeable decision regarding stem cells, controversy still abounds.

"Cloning" is a word that often comes up when discussing stem cells. This term ignites fear in the public, and it is necessary to make the distinction between reproductive cloning and therapeutic cloning. "The goal of reproductive cloning is to create a new organism, the goal of therapeutic cloning is to create stem cells to treat or cure a patient with a disease."[29] They are entirely different.

"Designer [b]abies" are also a source of fear.[30] For families like the Nashes, guaranteeing the birth of a healthy child was necessary to save their sick daughter.[31] Critics vehemently oppose exactly what the Nashes did, known as preimplantation

[26] Furcht, *supra* note 2, at 81.

[27] *Id.* at 80.

[28] *Id.* at 81.

[29] *Id.* at 86.

[30] *Id*. at 88.

[31] *See* Furcht, *supra* note 2, at xxiii.

genetic diagnosis, calling it the "ultimate shopping experience" and "morally wrong."[32] These opponents believe it is morally objectionable to predetermine the traits of unborn children and to create embryos that the parents know will be discarded.[33] David Fleming, a physician who teaches medical ethics, addresses this issue: "If we create another human life in order to kill it and use it to heal somebody else, it is slavery. We fought a civil war to prevent this."[34]

There is also the issue of using surplus embryos. There are those who argue that this is just another way to participate in research.[35] It has been argued that people are always donating kidneys or portions of their livers for research.[36] What makes these surplus eggs, of which the parents have no use, any different?[37] On the other hand, there is a growing concern that these donated eggs may end up in the wrong hands and used for research cloning. It is undeniable, clear regulations on egg donation are needed.[38]

[32] Furcht, *supra* note 2, at 91.

[33] *Id.*

[34] *Id.* at 82.

[35] *Id.* at 97.

[36] *Id.*

[37] Furcht, *supra* note 2, at 97.

[38] *Id.* at 96.

Society may never reach a common ground on stem cell research. There will always be those that disagree about when life begins.[39] In the United States, publicly funded research at the federal level is restricted to approved stem cells,[40] and yet the FDA has no ban on reproductive cloning in federal law.[41] Despite all of these differences, as long as death remains to be seen as "public enemy number 1,"[42] stem cell research will continue to be present in our world.

Chapter Four: Barometers of Politics

- **Chapter Summary:** The stem cell controversy extends to politics and the law. This chapter highlights some of the important issues that must be addressed by the country's legislators and politicians.
- **Chapter Discussion:** There is no neat division of those for and against embryonic stem cell research in our two party Democratic system. This issue potentially divides traditional constituencies and alignment.[43] It is a marriage of moral and economic issues, as well as a heavy component of life and death.[44] And the issue shows no sign of

[39] Furcht, *supra* note 2, at 102.

[40] *Id.* at 111.

[41] *Id.* at 113.

[42] *Id.* at 105.

[43] *Id.* at 116.

[44] Furcht, *supra* note 2, at 116.

disappearing. The next step in stem cell research is essentially for legislators and politicians to decide.[45]

Of particular interest is stem cells and how they relate to the law. One crucial question to confront is how the law will deal with human embryos created outside of the body.[46] Will they be afforded the full protection of the law just like any citizen? How, if at all, will constitutional rights to privacy, equality, and free expression come into play? Should the research be funded by the government? Should the embryos be able to be donated? Should the donors receive payment for such a donation? Who, if anyone, should be held liable if stem cells used prove to be ineffective or detrimental?[47] Such questions are currently unanswered and there is no promise of definitive answers in the near future.

Another controversial issue, which has been addressed in the past by the Supreme Court, is whether human life is patentable. In *Diamond v. Chakrabarty*, the Supreme Court held that "anything under the sun made by the hand of man" could be patented.[48] However, the passing of the Thirteenth Amendment of the U.S. Constitution dictated that one human being could not hold a property right in another human being. A patent is a

[45] Furcht, *supra* note 2, at 126.

[46] *Id.* at 135.

[47] *Id.* at 135-36.

[48] *Id.* at 138.

property right.[49] So is human life patentable? It is clear that all of these questions need resolving, which will be a difficult task on moral and legal grounds.

Chapter Five: Objects of Competition

- **Chapter Summary:** This chapter raises the issue of whether such a controversy should essentially stifle scientific research and technology.
- **Chapter Discussion:** Stem cell research is full of ethical, cultural, and religious diversity. It is also a field that the government and research universities are looking to seize for their own competitive edge.[50] But is the United States a competitor? President Bush made it glaringly clear that the United State would not be competing with the rest of the world.[51] He called for legislation that outlawed human cloning in all forms.[52] He also vetoed the Stem Cell Research Enhancement Act of 2005, HR 810, that would have made more funding available for such research and would have relaxed restrictions.[53] He also vetoed similar legislation passed by Congress.[54] The United States thus was not a contender in the stem cell race. Not only was the country out of the stem cell race but also out of the greater race of science. Such is unexpected of a country that has amassed

[49] Furcht, *supra* note 2, at 139.

[50] *Id.* at 146-47.

[51] *Id.* at 150.

[52] *Id.*

[53] *Id.*

[54] Furcht, *supra* note 2, at 150.

numerous Nobel Awards and spends upward of $100 billion in research and development expenditures.[55]

Chapter Six: Harbingers of Destruction

- **Chapter Summary:** The authors end their book offering a glimpse into the potential dangers that could face the world as a result of growing research and understanding of stem cells.
- **Chapter Discussion:** There is obvious opposition to stem cell research. In addition to this opposition is fear. Will stem cells have any consequences in global pandemics and biowarfare? Can stem cells be used for evil and turn into biological weapons capable of killing?[56] Bioterrorism is now, more than ever, a reality that confronts today's world. A chance of survival depends upon the health of human immune systems. Stem cell research, biotechnology, and nanotechnology have all shed light on the complexity of the immune system. We currently face a time where it is of utmost importance to understand the immune system and these technologies.[57] Perhaps designer babies should not be feared, but instead the engineering of biology for annihilation.[58] With a rapidly growing understanding of science and biotechnology,[59] it becomes a real possibility that people

[55] Furcht, *supra* note 2, at 150-51.

[56] *Id.* at 196.

[57] *Id.* at 198.

[58] *Id.* at 224.

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

with evil intentions harbor this knowledge and can be potentially capable of destruction.[60] The authors note that "stem cells are the opening act and may close the final act."[61] While this is an undeniably terrifying idea, does it mean that such research should entirely come to a halt? Many would answer that "No, it should not." The "intrinsic content of science" is not what causes danger; it is human choice.[62] People with ill intent should not be responsible for the suppression of research that holds a lot of promise for many people. It is up to us to decide whether stem cells will be used for good or evil.[63]

[60] Furcht, *supra* note 2, at 227.

[61] *Id.* at 225.

[62] *Id.* at 228.

[63] *Id.* at 232.

SYRACUSE SCIENCE & TECHNOLOGY
LAW REPORTER

VOLUME 21 FALL 2009 ARTICLE 6, PAGE 130

Against Intellectual Monopoly

By: Michele Boldrin & David K. Levine

Citation: Michele Boldrin & David K. Levine, Against Intellectual Monopoly (Cambridge University Press, 2008).

Reviewed by: Susan C. Azzarelli[1]

Relevant Legal and Academic Areas: Intellectual Property; Copyright; Patents; Economics

Summary: This book asks whether patents and copyrights are essential to creation and innovation based on recent controversies in intellectual property. The authors found that a teenager being sued for "pirated" music and the inability of patients in Africa to pay for AIDS medication show that patents and copyrights are not needed. They illustrate that "intellectual monopoly" hinders the competitive free market and the authors agree that patents and copyrights as they exist today should be eliminated.[2]

About the Authors:

Michele Boldrin is a Joseph G. Hoyt Distinguished Professor of Economics in Arts and Sciences at Washington University in St. Louis, a Fellow of the Econometric Society, and a research fellow at economic policy centers in England and Spain. Boldrin's research interests include innovation and business cycles, public policy, institutions and social norms. He has been published in many leading economic journals and has co-authored or co-edited four books.[3]

David K. Levine is a John H. Biggs Distinguished Professor of Economics in Arts and Sciences at Washington University in St. Louis, a Fellow in the Econometric Society, research associate of the National Bureaus for Economic Research, President of the Society for Economic Dynamics, and co-editor of two journals. Levine's research interests include the study of intellectual property and endogenous growth in dynamic general equilibrium models and he has been published in many leading economics journals.[4]

---

[1] Syracuse University College of Law, Juris Doctorate Candidate 2010, Syracuse Science & Technology Law Reporter Executive Editor 2009-2010.

[2] MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY (Cambridge University Press, 2008).

[3] *Id.*

[4] *Id.*

Chapter One: Introduction

- **Summary**: The authors introduce the ideas of their book by using 16th century inventor James Watt as an example of the ills of the copyright and patent systems. This example leads the authors to their ultimate question: are the patent and copyright systems a "necessary evil we must put up with to enjoy the fruits of invention and creativity," or are they simply "unnecessary evils, relics of an earlier time when governments routinely granted monopolies?"[5] The authors state "both sides agree that 'intellectual property' law needs to strike a balance" between the freedom to use existing ideas and the incentive to create.[6] However, they find patents and copyrights are an unnecessary evil, because property rights can be protected without intellectual property.[7]

- **Discussion**: The chapter begins with the details of James Watt and his patent on the Newcomen steam engine. After securing a patent, and successfully extending it, Watt spent a great "portion of his energy defending the patent from rival inventors with the full force of the legal system."[8] After his patents expired, there was an increase in production, as well as efficiency of engines because the Watt patent had blocked the key innovation necessary to build a better engine.[9] Watt had effectively hindered his own ability to innovate and develop a new engine.[10]

---

[5] Boldrin, *supra* note 2, at 3.

[6] *Id*. at 6.

[7] *Id*. at 7.

[8] *Id*. at 1.

[9] *Id.* at 2.

[10] Boldrin, *supra* note 2, at 2.

The authors are generally concerned with the use of the patent and copyright systems as a means of suppressing competition, and stress when "monopoly over ideas is absent, competition is fierce."[11] They found that the monopoly over useful inventions creates intellectual inefficiency because it also blocks the development of other potentially useful inventions.[12] The intellectual monopoly created by copyrights and patent creates a "double-edged sword," with monopolies creating a greater reward for innovators, however, at a higher cost for creation.[13] They find it to be an unnecessary evil because the cost cannot outweigh the social benefit.

Chapter Two: Creation under Competition

- **Summary**: Based on the idea that intellectual monopoly (copyrights and patents) are unnecessary, this chapter illustrates examples of industries and innovations that thrived without intellectual property protection. This includes the software industry, copyrightables (such as books, news and movies), and even the pornography industry.

- **Discussion**: The chapter begins with a look into the software industry, which began with virtually no intellectual property protection for their innovations. Prior to 1981, when the Supreme Court decided *Diamond v. Diehr*, it was not possible to patent software at all.[14] According to Bill Gates, "if people had understood how patents would be granted when most of today's ideas were invented, and had taken out patents, the industry would be at a complete

[11] Boldrin, *supra* note 2, at 10.

[12] *Id.* at 4.

[13] *Id*. at 10-11.

[14] *Id.* at 16.

standstill."[15] The history of the industry would have been much different if innovators had managed to patent and protect things like web browsers.

Innovation and creation can thrive in a competition, something evidenced by open-source software. The software is released under licenses which are a voluntary commitment to operate under free competition, or "copyleft."[16] This technology is commonly used by web browsers. It makes available underlying source code, which enables those who want to freely contribute to add to the code.[17] This allows individuals to benefit from the sharing of the others' innovations, and further those innovations with their own additions. There are also modifications to open-source software which have become profitable systems, despite "pirating" by other programmers. The leading systems are still thriving and the most profitable.[18] This shows that creativity and competition can thrive without intellectual monopoly.

The chapter also considers the competition in the literary, news, music and pornography industries. In fiction and literature, the lack of copyright protection in the 1800s permitted "pirating" of copies of English works by U.S. publishers and was ultimately more profitable for the authors.[19] Currently there is more competition in the right to have the "authorized" copy, as was evidenced by the 9-11 Commission Report. The Report generated revenue even though there were many editions available; the authorized edition was the best seller.[20] In the news

---

[15] Boldrin, *supra* note 2, at 16.

[16] *Id.* at 18.

[17] *Id*. at 20.

[18] *Id.* at 22.

[19] *Id.* at 23.

[20] Boldrin, *supra* note 2, at 24-25.

industry, "copyright protects specific words" not the news itself.[21] News trickles down from wire services to local news papers, replicators who cannot have reporters all over the world, but the competition lies in getting the news the fastest. This chapter also uses the pornography industry as model for what the movie industry would look like without copyright protection. While the production and distribution are the same, because there is a lack of protection, the industry has been among the first to exploit new technology and have become one of the most profitable online industries.[22] While monopolies of the industry, like Playboy, are losing market share, small-scale producers are thriving competitively because they are quickly adapting and putting out more diversified products at lower prices.[23]

Chapter Three: Innovation under Competition

- **Summary**: The chapter explores the idea that patents actually tame the innovative force. The authors follow the idea that intellectual property comes into an industry when the innovation has slowed; intellectual property has little role in the early stages of new inventions. The chapter illustrates this through the history of patents, as well as through examples in agriculture, design and sports.

- **Discussion**: In 1623, English Parliament pioneered patent law with the Statute of Monopolies by taking the monopoly power away from the monarchy and strengthening private

[21] Boldrin, *supra* note 2, at 27.

[22] *Id.* at 36-37.

[23] *Id*. at 37-38.

property rights and economic incentive.[24] The statute did not "replace intellectual competition with intellectual monopoly" but made a broad government monopoly into a private monopoly.[25]

France, Germany, Italy and Spain had fairly comprehensive intellectual property laws by the twentieth century, but the United States entered the patent picture in 1790 with the Patent Act. Following the first patent, which was granted for a formula used in soap-making, a new business, industries and inventions have been added and the length of patents continue to grow as courts increasingly favor the patent holder.[26] However, evidence shows patents come after an industry has matured and not because of patent protection.[27]

In the agriculture industry, where innovation centers on plants and animals, incentives to copy and reproduce seeds emerged early on, but changed as the industry grew more powerful.[28] In 1930, the Plant Patent Act was enacted, which allowed patent protection for asexually reproduced plants.[29] The Patent Protection Act was extended in the 70s and again in the late 80s to include products of biotechnology.[30] The extension of patent protection was supposed to benefit the corn production; however, levels of corn production fell following the extension.[31]

---

[24] Boldrin, *supra* note 2, at 44.

[25] *Id.*

[26] *Id*. at 45.

[27] *Id*. at 46.

[28] *Id*. at 53.

[29] Boldrin, *supra* note 2, at 53-54.

[30] *Id*. at 54.

[31] *Id.* at 55.

Design patents exist, but, there is still great deal of imitation, even though these patents are "carefully and scrupulously described" in filed patent applications.[32] For example, in fashion design, a newly accepted area entitled to patent and copyright protection, the real innovators are still on top, despite imitation, because their designs get to the wealthiest customers first.[33]

Also, in sports, there is nothing to prohibit professional sports teams from patenting a coach's new play; however, no league has ever done this because "the competitive provision of innovation serves the social purpose."[34]

Chapter Four: The Evil of Intellectual Monopoly

- **Summary**: This chapter focuses on the "intellectual monopoly" of ineffective and costly patents. Monopolies work to move the wealth to the monopolists, most easily accomplished by blocking and stifling innovation, productivity growth. This has led to what the authors call "IP-inefficiency" because monopolists will do everything necessary to retain their profits.

- **Discussion**: Since the late 90s there have been dramatic increases in patents, going up 50% between 1997 and 2000, partly because patents are protecting existing patents.[35] Defensive patents help the monopolies because the threat of a lawsuit is an incentive to pay licensing fees that are cheaper than going to court, even though the patent is not innovative or producing anything beneficial for consumers. These patents also keep out potential new innovators who

[32] Boldrin, *supra* note 2, at 59.

[33] *Id.*

[34] *Id*. at 61.

[35] *Id*. at 72-73.

cannot afford to enter the market and compete. According to the authors, "this is IP-inefficiency at work."[36]

Patents are being used as legal and bargaining tools rather than for actual innovation. The aim is blocking competition; preventing others from producing the same product of better quality, or at a lower price.[37] In the agricultural sector, this has led to acts protecting seed varieties, whose patents are held by U.S. corporations, forcing poor farmers in less developed countries to pay licenses in order to earn a livelihood.[38] Thus, foreign farmers are also supporting U.S. non-farmers.

IP-inefficiency also includes "submarine patents" which is "the filing of a useless patent on a broad idea that might, one day, be useful."[39] This allows the holder to wait until someone else develops the idea, at which time they can charge licensing fees to the actual innovator, who because of fees may not be able to cover his costs of innovations. Because of IP-inefficiency, "patenting is found to be a substitute for research and development, leading to a reduction of innovation."[40]

Chapter Five: The Devil in Disney

- **Summary**: Copyrights can seem less threatening than patents because they are much narrower, and may allow the productions of similar but different works since they only cover the

[36] Boldrin, *supra* note 2, at 75.

[37] *Id.* at 77.

[38] *Id.* at 80.

[39] *Id.* at 84.

[40] *Id*. at 83.

expression of an idea and not an idea itself. However, they are as inefficient because of the extensions on the "limited times" allowed and are economically insufficient.

- **Discussion**: The Sonny Bono/Mickey Mouse Act of 1998 increased the protective time of copyrights on literary work from 50 years beyond the death of the author to 75 years beyond the author's death.[41] However, it has not led to great production of literature[42] proving the point that there is not economic significance in copyrights because there is little benefit to the author. This legislation is more focused on the continued earning of large companies who hold royalties after the author, musician or artist is gone.

Copyright keeps literary and musical works unavailable because large corporations, like Disney, want to keep a few titles protected. To do so the protection has to be extended to all works, essentially holding any protected work hostage because licensing fees are too expensive.[43] The copyright system is also an issue in the music industry. Although the RIAA believes piracy is detrimental to the industry, copyrights are equally as detrimental. Copyrights in music are "not about the incentive to create, innovate, or improve" but are about using payola to get radio air time and keeping monopoly profits high although the actual cost to produce music is low.[44] The benefits of the copyright seem to be much smaller than the means needed to acquire them.

---

[41] Boldrin, *supra* note 2, at 99.

[42] *Id*.

[43] *Id*. at 104-05.

[44] *Id.* at 105-07.

Chapter Six: How Competition Works

- **Summary**: Property rights provide incentive to produce, accumulate and trade, but intellectual property creates a monopoly where the holders of intellectual property rights are able to tell individuals what they can do with the holders' property rights. This reduces competition in the market place of ideas.

- **Discussion**: Even without intellectual monopoly, competition would be beneficial for innovators because although the consumer of their idea may be able to copy and reproduce the idea, the idea originally need to be purchased from the innovator.[45] Although the amount collected may be smaller, it is the competitive value of the innovation. Patents and copyrights become unnecessary because it gives a "right to tell other people what they cannot do with the copies they have lawfully purchased."[46]

The idea holds that if people were given ordinary property rights instead of the additional property rights of the intellectual monopoly there would be more ideas and innovation. "Because copies of an idea are always limited . . . they always command a positive price."[47] In this sense it is beneficial to be first, as the authors note "it takes time and money to reverse engineer a product,"[48] but also because it leads to imitation which is socially beneficial when done in respect of the original property rights. Competition in the market of ideas also encourages collaboration because those sharing information may also benefit from those who use

[45] Boldrin, *supra* note 2, at 127.

[46] *Id.* at 128.

[47] *Id*. at 132.

[48] *Id*. at 139.

their knowledge. Therefore, in essence "competitive innovation . . . is the source of all progress.[49]

Chapter Seven: Defenses of Intellectual Monopoly

- **Summary**: Although arguments that favor intellectual monopoly may be logical, they generally do not follow common sense. Things that stand out in these arguments are that things are never equal (monopoly may have more profit, but raises production cost), monopoly is not widely viewed as a friend of innovation, and if it is good it must increase innovation over the competitive system.[50] This chapter considers theories behind the "obvious" and "logical" reasons for arguments in favor of intellectual monopoly.

- **Discussion**: "There is good property—property of land and cars—which leads to competition. And there is bad property—property of ideas—that leads to monopoly."[51] The authors favor the view of owning a copy of an idea, but not the idea itself. They find that, if they were really public goods, it would be something that everyone could make use of without interfering with one another.[52]

Copies are what actually have economic value, and it is those copies that should have all property rights including the owner's legal right to sell them.[53] However, some economists have argued that intellectual monopoly may be the only way to adequately compensate innovators and

[49] Boldrin, *supra* note 2, at 139.

[50] *Id.* at 150-51.

[51] *Id.* at 152.

[52] *Id.* at 154.

[53] *Id*. at 157.

without those protections there is no incentive to create. But this is refuted by the competition theory previously presented, which leads to innovation instead of restricting it.

Another argument for patents is that you must reveal the secret to acquire the patent. However, ideas are generally hard to communicate and resources are limited so the innovative creation will most likely have to be purchased before the secret is revealed.[54] But generally, because the secrets are protected for such a long period of time, the innovation period for imitators will not benefit when secrets are revealed.

The chapter also looks at the Schumpeterian view that monopolies are the highest form of capitalist achievement. This argument holds that "only the monopolists who innovate as fast or faster than potential competitors remain viable,"[55] so there should be a great deal of innovation where there is monopoly. However, because licensing allows monopolies to keep competitors at bay and remain viable although they are not innovating the argument is not persuasive.

Chapter Eight: Does Intellectual Monopoly Increase Innovation?

- **Summary**: This chapter considers whether intellectual monopoly actually leads to a higher rate of innovation. In response, the authors provide evidence that intellectual monopoly cannot lead to a higher rate of innovation than normal property rights for ideas in a competitive market.

- **Discussion**: Although more innovations occur cumulatively and simultaneously with other innovations, intellectual monopoly gives all rewards to those who manage to grab the patent and monopoly first.[56] The introduction of copyrights for classical music in the 1700s is an

[54] Boldrin, *supra* note 2, at 152.

[55] *Id*. at 170.

[56] *Id.* at 208.

example to illustrate intellectual monopoly does not increase innovation. They note that although the amount of composer declined in general, they "declined considerably faster in the United Kingdom after the introduction of copyright"[57] than in other European countries at that time.

The authors also note that it may be difficult to gauge the level of innovation actually going in a country. Measuring the number of patents can be meaningless because not all countries have patent law and the laws may change,[58] as well as the increase of patents that may not actually be for anything innovative. "Patents create a market in patents and in the legal and technical services required to trade and enforce them"[59] which may also make them an inaccurate factor of innovation levels.

There seems to be more beneficial results in a competitive market of ideas. In software development, Silicon Valley required continuous and competitive innovation, which also led to cooperation among firms.[60] With higher cooperation and the sharing of knowledge, there can be greater innovation because innovators can build on other ideas. Cooperation could also diminish the rush to acquire broad protection to avoid "simultaneous discovery," where a fellow inventor develops the same idea.[61]

---

[57] Boldrin, *supra* note 2, at 188.

[58] *Id.* at 190.

[59] *Id*. at 192.

[60] *Id.* at 200.

[61] *Id*. at 202.

Chapter Nine: The Pharmaceutical Industry

- **Summary**: The pharmaceutical industry is often used as the best example of the need for patents. Although the industry seems to fit the competitive model, with innovation as the main competitive edge and large fixed costs, pharmaceutical patents are still only good for monopolists and not society.

- **Discussion**: The U.S. has always allowed the patenting of drugs, both for the process to produce and for the chemical formula.[62] However until recently, many European countries only allowed the patenting of the process to make a new drug. "There is negative social value in patenting a specific product, as this would exclude all others from producing it, even though different processes."[63] Even though the European Union has similar laws similar to the US today, if the monopolies were really necessary the previous differences would have has a large "impact on the national pharmaceutical industries,"[64] and this is not the case.

Prior to pharmaceuticals, the major form of patent protection was for chemical production of paints and dyes, which were generally held in German and French corporations, slowing any growth in the industry in the U.S. until after the world wars when the patents and plants were confiscated.[65] Today, because there have been so many mergers among large pharmaceutical companies, they have become accustomed to operating like a monopoly, and the

[62] Boldrin, *supra* note 2, at 215.

[63] *Id.* at 216.

[64] *Id.* at 218.

[65] *Id.* at 219-21.

patents are not helpful to innovation. They produce "too much expense of the wrong kind"[66] without producing enough social good.

Chapter Ten: The Bad, the Good, and the Ugly

- **Summary**: In their closing chapter, the authors look at the different proposals for the system of intellectual property.

- **Discussion**: "A realistic view of intellectual monopoly is that it is a disease rather than a cure," and "cutting it all out at once might not be a good idea."[67] There are many ideas and proposals which would strengthen intellectual monopoly and produce an intellectual property system that would be worse than the current state. Some of the ideas which should be rejected include: extending patents to include sports moves, news clips or press releases; extending the level of protection to databases; extending protection of scientific research; extending European patents to match the U.S.; imposing legal restrictions on the design of computers; and allowing patenting of any plant variety outside the U.S.[68]

The worst possibility, leading to more stalled innovation and monopoly control, would be to "Stay the Course" or "Do Nothing."[69] Instead, gradual reform is necessary,[70] with the ultimate goal to be the elimination of the patent and copyright system. Important improvements would prevent losing more public domain by allowing patents to be freely available and challenged

[66] Boldrin, *supra* note 2, at 238.

[67] *Id*. at 244.

[68] *Id*. at 246-47.

[69] *Id.* at 264.

[70] *Id.* at 245.

before they are granted.[71] Deregulation should be encouraged, leading to the eventual abolition of the system as a whole, because the markets can function, and function well, without intellectual monopoly.

[71] Boldrin, *supra* note 2, at 248-49.