



WAKE FOREST
JOURNAL OF BUSINESS AND
INTELLECTUAL PROPERTY LAW

VOLUME 11

2010 - 2011

NUMBER 2

**INTELLECTUAL PROPERTY: FUELING THE HEALTH
CARE REFORM ENGINE**

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INTRODUCTION

Among its many notable accomplishments, the 111th United States Congress likely will be remembered most for its groundbreaking, albeit controversial, passage of comprehensive health care reform legislation in the form of the Patient Protection and Affordable Care Act (the “Affordable Care Act”).¹ Signed into law on March 23, 2010, the Affordable Care Act aims to expand health care coverage for the nearly 50.7 million Americans who are currently without health insurance.²

While the Affordable Care Act may be viewed as the defining moment in the decades-long health care reform movement, significant health care reform in the United States was already underway more than a year earlier. On February 17, 2009, President Barack Obama signed into law the American Recovery and Reinvestment Act of 2009 (the “Recovery Act”).³ Included within the Recovery Act are

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¹ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111–152, 124 Stat. 1029.

² *Id.*; CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2009, at 24 (2010), *available at* <http://www.census.gov/prod/2010pubs/p60-238.pdf>.

³ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

provisions known as the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”),⁴ which appropriates billions of dollars in incentives for the adoption and implementation of electronic health record (“EHR”) technology.⁵

In recent years, health policy studies have espoused the many benefits of health information technology (“HIT”), asserting that HIT “is a necessary ingredient for improving the efficiency and quality of health care in the United States.”⁶ EHRs, for example, have the potential to reduce the ordering of duplicate or inappropriate diagnostic tests, avoid adverse drug events, expand the practice of evidence-based medicine, and increase the sharing of health information among a patient’s health care providers.⁷ In fact, the George W. Bush administration, as early as 2004, set the goal of developing a nationwide interoperable health information technology infrastructure that would achieve the following objectives:

- (a) Ensures that appropriate information to guide medical decisions is available at the time and place of care;
- (b) Improves health care quality, reduces medical errors, and advances the delivery of appropriate, evidence-based medical care;
- (c) Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information;
- (d) Promotes a more effective marketplace, greater competition, and increased choice through the wider availability of accurate information on health care costs, quality, and outcomes;
- (e) Improves the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health care information; and
- (f) Ensures that patients’ individually identifiable health information is secure and protected.⁸

⁴ *Id.* at div. A, tit. XIII, 123 Stat. at 226.

⁵ *Id.* at div. A, tit. IV, 123 Stat. at 467.

⁶ CONG. BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY, 3 (May 2008), *available at* www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf.

⁷ *See id.* at 11–16.

⁸ Exec. Order No. 13335, 69 Fed. Reg. 24059 (Apr. 30, 2004).

Recognizing the potential benefits of HIT, the HITECH Act includes key provisions to promote the adoption of EHRs by health care providers.⁹ The HITECH Act establishes an “EHR Incentive Program,” which includes financial incentives for health care providers that adopt and achieve meaningful use of certified EHR technology.¹⁰ The Centers for Medicare and Medicaid Services (“CMS”) estimate that approximately 624,000 providers will be eligible for incentives under the EHR Incentive Program,¹¹ resulting in a dramatically increased demand for EHR products and related services. This new, government-subsidized demand for EHR products is designed to, and likely will, motivate HIT vendors and developers to enter, or expand their presence in, the EHR market.

This Article, which explores the ways in which the protections and motivations inherent in United States intellectual property laws, combined with the various incentives offered by the HITECH Act, serve (and will continue to serve) as a driving impetus for the development of an expanded market for HIT, (i) provides in Section I an overview of the legislative and regulatory history of the HITECH Act; (ii) discusses in Section II some of the fundamental principles for securing, maintaining, and protecting intellectual property rights in the United States; (iii) addresses in Section III the impact of the HITECH Act on the HIT market, including the role of intellectual property protections in the development of EHR products; and (iv) analyzes in Section IV several of the legal issues that health care providers face while implementing EHR systems, particularly those arising in negotiating an EHR software license agreement.

I. LEGISLATIVE AND REGULATORY HISTORY

The HITECH Act was passed by the House of Representatives on January 28, 2009,¹² and by the Senate on February 10, 2009.¹³ The

⁹ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, div. B, tit. IV, 123 Stat. 115, 467.

¹⁰ *Id.*

¹¹ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 1844, 1974 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. pts. 412–13, 422, 495) (explaining that this number of providers includes hospitals, physician practices, medical doctors, dentists, podiatrists, optometrists, and chiropractors. CMS further estimates that of the 624,000 health care providers eligible for financial incentives, 94.71% will be physicians and other individual healthcare practitioners, 0.8% will be hospitals, and 4.47% will be hospitals or physicians that participate in a Medicare Advantage organization).

¹² H.R. 1, 111th Cong. (2009), 155 Cong. Rec. D83-01.

HITECH Act was then signed into law by President Obama on February 17, 2009.¹⁴ In supporting the bill, Congress noted that the HITECH Act would “modernize the health care system, save billions of dollars, reduce medical errors, and improve quality.”¹⁵ In addition, supporters of the bill argued that the HITECH Act would spur innovation in the health care industry, leading to growth and development comparable to other sectors of the American economy.¹⁶ Perhaps one of the most persuasive arguments in support of the bill was articulated by Senator Sheldon Whitehouse of Rhode Island:

The last few decades have seen enormous innovation in this country -- new communications platforms, the Internet and mobile phones, new sources of energy. This technological revolution is transforming the way we live and work, as the rail system did and the highway system did in decades and centuries past. And as the Federal Government helped build the railways and highways, the bricks and mortar infrastructure of the 20th century, today this recovery bill will support the digital infrastructure of the 21st century. It is a dual benefit: jobs today and a platform for growth tomorrow.

To me, one of the most vital parts of our Nation’s infrastructure in this 21st century will be the development of a national health information network to improve the quality and efficiency of health care, to save money, and to save lives. But today this network is growing at the speed of mud. Health care is frighteningly behind the rest of American industry in its development and implementation of information technology. Why? Because of economics, the strange, bizarre, twisted economics of our health care system that fails to reward doctors and hospitals when they invest in health information infrastructure.

If we can solve the health information network problem, private industry will develop technology to allow doctors to prescribe drugs electronically and help remind you to take them. Technology will help doctors update your vital information in real time and cross-

¹³ S. 1, 111th Cong. (2009), 155 Cong. Rec. D131-02.

¹⁴ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

¹⁵ 155 Cong. Rec. H717 (daily ed. Jan. 28, 2009).

¹⁶ See 155 Cong. Rec. S1511 (daily ed. Feb. 4, 2009).

reference your health issues with the best illness prevention and treatment strategies. And technology promises decision support programs implementing best medical practices which will help health care providers avoid costly, life-threatening, and completely unnecessary medical errors that now bedevil our health care system.

Look at what private technology and innovation have already done with the Internet—Google, e-Bay, Amazon, YouTube, Facebook. Whose life has not been changed?

Imagine what can happen in health care. Wonderful opportunities beckon, both in the near term, because funding this infrastructure will create jobs in the information technology sector, and in the long term to help us bring down the spiraling health care costs that threaten to engulf our economy.¹⁷

In order to spur innovation and investment in HIT, the HITECH Act created the EHR Incentive Program, which provides not only significant financial incentives for both hospitals and individual health care providers that adopt and achieve “meaningful use” of “certified” EHR technology, but also corresponding penalties for providers that fail to achieve meaningful use.¹⁸ The HITECH Act does not expressly define the term “meaningful use,” but instead states that, in order to qualify for incentive payments, health care providers must demonstrate to the satisfaction of the Secretary of the Department of Health and Human Services (“HHS”) that the provider is “using certified EHR technology in a meaningful manner.”¹⁹ Similarly, the HITECH Act does not include specifications or criteria for what constitutes “certified” EHR technology; rather, the HITECH Act grants rulemaking authority to HHS to issue such certification criteria.²⁰

On January 13, 2010, nearly one year after passage of the HITECH Act, HHS promulgated two much-anticipated rules implementing the EHR Incentive Program.²¹ The first rule, issued by

¹⁷ *Id.* at S1510–11.

¹⁸ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, div. B, tit. IV, subtit. A, 123 Stat. 115, 467.

¹⁹ *Id.* at § 4102(a) (codified at 42 U.S.C. § 1395ww(n)(3)(A)(i)).

²⁰ *See id.* at § 13101 (codified at 42 U.S.C. § 300jj(1)).

²¹ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 1844 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R.

CMS, proposed a definition of the term “meaningful use” (hereinafter, the “Meaningful Use Rule”).²² The Meaningful Use Rule also provided guidance regarding eligibility requirements for the EHR Incentive Program,²³ along with methods for calculating incentive payments and penalties under the EHR Incentive Program.²⁴ The second rule, issued by the Office of the National Coordinator for Health Information Technology (“ONC”), set forth the initial set of standards, implementation specifications, and certification criteria for “certified” EHR technology (hereinafter, the “Certification Rule”).²⁵ On July 28, 2010, after a six-month comment period, CMS and ONC finalized their respective regulations.²⁶

The Meaningful Use Rule includes highly detailed criteria for achieving meaningful use of EHR technology. CMS chose to implement the meaningful use criteria in three progressive stages, with Stage 1 beginning in 2011.²⁷ CMS is expected to establish Stage 2 and Stage 3 criteria in future rulemaking.²⁸ The Stage 1 criteria focus on electronically capturing health information, communicating such information for care coordination purposes, implementing clinical decision support tools, and reporting clinical quality measures.²⁹ The Meaningful Use Rule includes twenty-five discrete objectives for physicians, and twenty-four objectives for hospitals, divided into a “core” group and a “menu” set of objectives.³⁰ The core group includes the following fifteen required objectives for physicians, and fourteen required objectives for hospitals:

pts. 412–13, 422, 495); Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170).

²² See Medicare and Medicaid Programs: Electronic Health Record Incentive Program, 75 Fed. Reg. at 1844, 1854–70.

²³ *Id.* at 1907, 1911.

²⁴ *Id.* at 1908, 1911–16.

²⁵ Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170).

²⁶ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314 (July 28, 2010) (to be codified at 45 C.F.R. pts. 412–13, 422, 495); Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590 (July 28, 2010).

²⁷ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,321–24 (July 28, 2010).

²⁸ *Id.*

²⁹ *Id.*

³⁰ 42 C.F.R. § 495.6 (2010).

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- Use computerized provider order entry for medication orders;
 - Generate and transmit prescriptions electronically (physicians only);
 - Report ambulatory clinical quality measures to CMS;
 - Implement one clinical decision support rule;
 - Provide patients with an electronic copy of their health information, upon request;
 - Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request (hospitals only);
 - Provide clinical summaries for patients for each office visit (physicians only);
 - Implement drug-drug and drug-allergy interaction checks;
 - Record patient demographics;
 - Maintain up-to-date problem list of current and active diagnoses;
 - Maintain active medication list;
 - Maintain active medication allergy list;
 - Record and chart changes in patient vital signs;
 - Record smoking status for patients age 13 and older;
 - Capability to exchange key clinical information among providers of care and patient-authorized entities electronically; and
 - Protect electronic health information through the implementation of appropriate technical capabilities.³¹

The menu set includes each of the following ten objectives for physicians and hospitals:

- Implement drug-formulary checks;
- Incorporate clinical lab test results as structured data;
- Generate lists of patients by specific conditions;
- Send reminders to patients per patient preference for preventive/follow-up care (physicians only);
- Provide patients with timely electronic access to their health information (physicians only);

³¹ *Id.*

- Use certified EHR technology to identify patient-specific education resources;
- Perform medication reconciliation;
- Provide summary of care record for transitions of care and referrals;
- Record advanced directives for patients age 65 and older (hospitals only);
- Capability to submit reportable lab results to public health agencies (hospitals only);
- Capability to submit electronic data to immunization registries; and
- Capability to provide electronic syndromic surveillance data to public health agencies.³²

Providers must meet all of the core objectives and five of the menu set objectives to demonstrate meaningful use and thus qualify for financial incentives.³³ Physicians that fail to demonstrate meaningful use by 2015 will face reductions in their Medicare reimbursement rates, receiving 99% of the Medicare Physician Fee Schedule rates in 2015, 98% in 2016, and 97% in 2017 and subsequent years,³⁴ while hospitals will face reductions in their annual Medicare Inpatient Prospective Payment System market basket update.³⁵

The Certification Rule sets forth the initial certification criteria for “certified” EHR technology.³⁶ Each certification criterion adopted by ONC is aligned with one of the Stage 1 meaningful use objectives set forth above. The certification criteria establish the required capabilities that certified EHR technology will need to include in order to facilitate achievement of meaningful use by physicians and hospitals under the EHR Incentive Program.³⁷

The Certification Rule allows EHRs to be certified as either “Complete EHRs” or “EHR Modules.”³⁸ A Complete EHR is EHR technology that has been developed to meet all applicable certification

³² *Id.*

³³ *Id.*

³⁴ 42 C.F.R. § 495.102(d) (2010).

³⁵ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44, 3460 (July 28, 2010) (to be codified at 45 C.F.R. pts. 412–13, 422, 495).

³⁶ 45 C.F.R. § 170.300 (2010).

³⁷ Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590, 44,590 (July 28, 2010) (to be codified at 45 C.F.R. pt. 170).

³⁸ *See* 45 C.F.R. § 170.102 (2010).

criteria adopted under the Certification Rule.³⁹ In contrast, an EHR Module is any component that can meet the requirements of at least one certification criterion under the Certification Rule.⁴⁰ For example, an EHR Module may be designed specifically as a clinical decision support rules engine, or solely to submit public health information to public health authorities.⁴¹ In order to qualify as “Certified EHR Technology,” the EHR must be either a Complete EHR or a combination of EHR Modules that meets all of the requirements under the Certification Rule.⁴²

In allowing combinations of EHR Modules to qualify as certified EHR technology, the ONC Final Rule aims to spur innovation and creativity in the EHR marketplace by offering health care providers flexibility in their choice of EHR products. According to ONC:

An innovative and competitive HIT marketplace needs to exist much like the marketplace for consumer electronics, where, for the purpose of setting up a home theater, a television, DVD player, and stereo system can be purchased from three different manufacturers, from a single manufacturer, or as a complete system from one manufacturer. To that end, we believe that it will be common in the near future for Certified EHR Technology to be assembled from several replaceable and swappable EHR Modules As long as each EHR Module has been separately tested and certified[,] . . . a proper combination of certified EHR Modules could meet the definition of Certified EHR Technology.⁴³

ONC believed that this “modular” approach would “lead to a more competitive marketplace and allow those who adopt HIT to choose from a variety of offerings.”⁴⁴

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2014, 2022 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170).

⁴² 45 C.F.R. § 170.102 (2010).

⁴³ Health Information Technology: Initial Set of Standards, Implementation, Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. at 2023.

⁴⁴ *Id.*

II. INTELLECTUAL PROPERTY PROTECTION IN THE UNITED STATES

How could Senator Whitehouse so confidently and enthusiastically predict that private industry in the United States *will* develop the technological advancements necessary to undergird and spearhead health care reform?⁴⁵ Moreover, what convinced CMS and ONC that private industry in the United States would be sufficiently motivated to develop technology compliant with the highly detailed criteria set forth in the Meaningful Use Rule?⁴⁶ After all, economic incentives under the EHR Incentive Program are directed to health care providers, not developers of EHR technology.⁴⁷

The authors submit that the answer to these questions implicates much more than just the law of supply and demand – *i.e.*, “create a new market with certain economic incentives and they will come.” On the contrary, at the heart of the confidence, enthusiasm and conviction of the legislators, who drafted, debated, and ultimately enacted the HITECH Act, and the federal agencies that implemented that legislation, is a deeply-rooted belief in the role of intellectual property law in the United States as a force for motivating and rewarding the creative, inventive, and innovative spirit and commitment needed for technology to keep pace with improvements in all aspects of health care.

A. What is “Intellectual Property” and Why Protect It?

“Intellectual property,” reduced to its elemental components, comprises (i) an intangible *intellectual* act of an individual that produces certain subject matter followed by (ii) a tangible overt act upon which certain *property*-related rights in such subject matter vest, either in that individual or, in certain circumstances explained more fully below, in another party.⁴⁸ This overt act requirement arises

⁴⁵ See *supra* note 16 at S1510–11 and accompanying text (“[P]rivate industry *will* develop technology to allow doctors to prescribe drugs electronically and help remind you to take them. Technology *will* . . . update your vital information in real time and cross-reference your health issues . . . [a]nd *promises* decision support programs implementing best medical practices” (emphases added)).

⁴⁶ See *supra* p. 5 and accompanying notes (“The Meaningful Use Rule includes highly detailed criteria for achieving meaningful use of EHR technology”).

⁴⁷ See *supra* p. 2 and note 12.

⁴⁸ See generally Brian M. Hoffstadt, *Dispossession, Intellectual Property, and the Sin of Theoretical Homogeneity*, 80 S. CAL. L. REV. 909, 929–37 (2007).

primarily from the need to provide public notice of the subject matter described in clause (i), which, prior to such notice, resides solely in the mind of the individual. Intellectual property in the United States typically constitutes either copyrightable, patentable, trademark, or trade secret subject matter, all of which are discussed in more detail below.

Intellectual property laws in the United States relating to copyrightable and patentable subject matter are designed with the following general purpose in mind: To protect individuals' creative and inventive contributions for a limited period of time in an effort to incentivize the development of such contributions and allow those individuals to recoup their economic and other investments in such development with a view to thereafter releasing those contributions to the public for its ongoing use and benefit.⁴⁹

Similarly, by and through Congress' power to regulate interstate commerce,⁵⁰ it established a statutory framework⁵¹ for protecting trademarks, service marks, and trade dress, comprising terms, logos, symbols, and the like, that an individual or entity uses in interstate commerce to distinguish its goods and services from those offered by others.⁵² Although protection for marks derives in part

⁴⁹ See U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."); see also *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

⁵⁰ U.S. CONST. art. I, § 8, cl. 3 ("The Congress shall have power . . . To regulate Commerce with foreign Nations, and among the several States . . ."). As a result, a threshold requirement for seeking and securing federal registration of a mark under the Lanham Act is bona fide use (as opposed to token use) of that mark in interstate commerce – *i.e.*, commerce involving at least two (2) states or any state and a foreign nation – in connection with the relevant goods and/or services.

⁵¹ See The Lanham Act, 15 U.S.C. §§ 1051–1141 (2006). The Lanham Act and jurisprudence interpreting the various provisions of the Act comprise the primary basis for the federal protection of marks in the United States. In addition, for marks that are not used in interstate commerce, many, if not all, states have enacted statutory provisions not only for registering such marks at the state level but also for bringing state actions against infringers of such registered marks, most often on a deceptive or unfair trade practice basis; see also, *e.g.*, N.C. Gen. Stat. §§ 80–1 to 80–14 (2011).

⁵² See The Lanham Act, 15 U.S.C. §§ 1051–52, 1127 (providing a system for federal registration of marks (i) that are "in use in commerce" (§ 1051) or (ii) for which the registration applicant has a "bona fide intention to use the mark in commerce" as of the filing date of the registration application (§ 1052), wherein "commerce" is defined as "all commerce which may lawfully be regulated by Congress" (§ 1127)).

from the same conceptual framework as does protection for copyrightable and patentable subject matter, the primary purpose of U.S. trademark law is to prevent any use of a mark in connection with goods or services that (i) is likely to cause confusion, mistake, or deception among consumers in the marketplace as to (1) the source of such goods or services;⁵³ (2) the affiliation, connection, or association of one individual or entity with another individual or entity; or (3) the origin, sponsorship, or approval of an individual's or entity's goods or services by another individual or entity or (ii) is likely to cause dilution of the value of a famous mark.⁵⁴

Finally, through a combination of state statutes and interpretive case law, individual states have established protective schemes for subject matter comprising trade secrets.⁵⁵

Although United States intellectual property laws provide protection for certain works of authorship, inventions, marks, and trade secrets in an effort to establish an environment that stimulates the development of such intellectual properties, those same laws are designed also to promote the public good by not depriving the public of unfettered access to and use of such properties, if and when it becomes clear, often through some act or omission of the intellectual property owner, that the owner no longer desires, or otherwise is entitled to enjoy, the benefits of such protections.

⁵³ *Star Fin. Servs., Inc. v. AASTAR Mortg.*, 89 F.3d 5, 9 (1st Cir. 1996) (citing *DeCosta v. Viacom Int'l, Inc.*, 981 F.2d 602 (1st Cir. 1992), cert. denied, 509 U.S. 923 (1993)). See The Lanham Act, 15 U.S.C. §§ 1052(d), 1114 (providing (1) that confusingly similar marks cannot be registered and (2) allowing a cause of action for use of a mark "in connection with the sale, offering for sale, distribution, or advertising of any goods or services" in a manner that "is likely to cause confusion, or to cause mistake, or to deceive").

⁵⁴ *Decosta*, 981 F.2d at 605. See The Lanham Act, 15 U.S.C. § 1125(a), (c) (providing causes of action for use of a mark on or in connection with goods or services in a manner that "is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association . . . origin, sponsorship, or approval" or is "likely to cause dilution").

⁵⁵ All states in the United States (as well as the District of Columbia) have enacted statutes that protect trade secrets. See David P. Hathaway, *Is the North Carolina Trade Secrets Protection Act Itself a Secret, and Is the Act Worth Protecting?*, 77 N.C. L. Rev. 2149, 2150 (1999). For example, the State of North Carolina has enacted the North Carolina Trade Secrets Protection Act, codified at N.C. Gen. Stat. §§ 66–152 to 162 (2011), which, among other things, (i) defines "trade secret" as any "business or technical information that . . . [d]erives independent actual or potential commercial value from not being generally known or readily ascertainable . . . and . . . [i]s the subject of efforts that are reasonable under the circumstances to maintain its secrecy," (ii) provides a civil cause of action for any misappropriation of a trade secret, and (iii) provides legal and injunctive relief to a prevailing trade secret owner. *Id.* at §§ 66–152(3), 153, 154(a), (b).

Following is a discussion of some of the more important principles of United States intellectual property law directed to establishing and maintaining rights in, and protecting, intellectual property, with a particular focus on various items of EHR technology, such as computer software, scanning hardware, and systems and methods for communicating encrypted information, all of which are key to satisfying Meaningful Use Rule and Certification Rule criteria.⁵⁶

*B. Copyrightable Subject Matter*⁵⁷

1. Creation and Fixation

The *intellectual* act giving rise to copyrightable subject matter is known as “creation,” which comprises a contribution by the creator (*i.e.*, the “author”) of more than a trivial amount of originality resulting in an original work of authorship that is fixed in a copy for the first time.⁵⁸ The threshold of originality required to give rise to copyrightable subject matter is somewhat lower than the threshold of novelty and non-obviousness necessary to result in patentable subject matter.⁵⁹

The overt act giving rise to *property*-related rights in copyrightable subject matter is fixation of the original work of authorship in a tangible medium of expression that is sufficiently permanent to permit the work to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration (*i.e.*, “fixation”), at which time ownership of copyright rights in that work vest in the author of the work.⁶⁰

2. Categories of Copyrightable Subject Matter

Examples of original works of authorship subject to copyright protection in the United States include the following:

- literary works (books);
- visual works (paintings);
- audio works (sound recordings);

⁵⁶ See *supra*, text accompanying notes 27-42.

⁵⁷ The U.S. Copyright Act, codified at 17 U.S.C. §§ 101–1332 (2011) (“Copyright Act”), and federal jurisprudence interpreting the Copyright Act, comprise the primary basis for copyright protection in the United States.

⁵⁸ 17 U.S.C. § 101 (2011) (noting the definition of “created”).

⁵⁹ Compare 17 U.S.C. § 102(a) (2006) with 35 U.S.C. §§ 102–103 (2006).

⁶⁰ *Id.* (noting the definition of “fixed”).

- audiovisual works (motion pictures);
- architectural works (building designs);
- pictorial (photos), graphic (designs, schematics, drawings, flow charts, etc.), and sculptural works (models, prototypes, statues, etc.); and
- compilations and derivative works of any of the foregoing original works.⁶¹

It is important to note that copyright protection extends only to the creative or expressive elements of the work of authorship and not to any (i) ideas or words; or (ii) concepts, principles, systems, procedures, methods, or other utilitarian or functional aspects explained, illustrated, or embodied in the work,⁶² all of which may be subject to patent protection. However, copyright protection does extend to (i) the creative or expressive manner in which words, ideas, concepts, or principles are joined together (*e.g.*, in a novel or a flowchart) and (ii) the creative or expressive manner in which data are arranged, structured, or presented (*e.g.*, in a database or data chart).

a. Computer Software Code as a Copyrightable Literary Work

As discussed in more detail in the other sections of this Article, computer software comprises an integral component of the EHR technology required for providers to transition from paper to electronic health records. Computer software source code comprises the set of human-readable instructions developed by a computer programmer to specify actions that the computer must take to achieve the objectives of the program.⁶³ Computer software object code, on the other hand, is source code that has been compiled into a machine-readable format for execution by a computer.⁶⁴

The Copyright Act provides protection for “original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.”⁶⁵ Works of authorship include . . . literary works⁶⁶ In

⁶¹ *Id.* §§ 102(a), 103.

⁶² *Id.* § 102(b).

⁶³ LAWRENCE ROSEN, OPEN SOURCE LICENSING – SOFTWARE FREEDOM AND INTELLECTUAL PROPERTY LAW 2 (2005); H. WARD CLASSEN, A PRACTICAL GUIDE TO SOFTWARE LICENSING FOR LICENSEES AND LICENSORS 34 (3d ed. 2008).

⁶⁴ CLASSEN, *supra* note 62, at 34.

⁶⁵ 17 U.S.C. § 102.

⁶⁶ “Literary works” are “works, other than audiovisual works, expressed in words, numbers, or other verbal or numerical symbols or indicia, regardless of the

addition, the Copyright Act defines a “computer program” as “a set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result.”⁶⁷

Although the Copyright Act does not expressly provide that computer programs constitute original works of authorship susceptible to protection under the Act, it is well-established that computer programs do indeed constitute copyrightable subject matter in the form of literary works.⁶⁸ Both the source code and the object code underlying a computer program are protectable under U.S. copyright law.⁶⁹

While computer software code is protectable under copyright law as a literary work of authorship, certain business methods embodied within computer software are subject to protection under patent law.⁷⁰

3. Exclusive Rights of Copyright

Upon creation and fixation of the copyrighted work, the author of the work has the exclusive right to do and authorize others to do any of the following:

nature of the material objects, such as books, periodicals, manuscripts, phonorecords, film, tapes, disks, or cards, in which they are embodied.” *Id.* § 101.

⁶⁷ *Id.* § 101. The definition of “computer program” was added to the Copyright Act via amendment in 1980. *Apple Computer, Inc. v. Franklin Computer Corp.*, 714 F.2d 1240, 1247 (3d Cir. 1983) (citing relevant legislative history).

⁶⁸ *Apple Computer*, 714 F.2d at 1247 (citing legislative history of the 1976 Copyright Act, which states that the term “literary works” as used in that statute “includes . . . computer programs”); *Williams Elecs., Inc. v. Arctic Int’l, Inc.*, 685 F.2d 870, 875–77, nn.4–8 (3d Cir. 1982) (holding that “the copyrightability of computer programs is firmly established after the 1980 amendment to the Copyright Act [of 1976]”).

⁶⁹ *Apple Computer*, 714 F.2d at 1249 (stating that “a computer program, whether in object code or source code, is a ‘literary work’ and is protected from unauthorized copying, whether in its object or source code version”); ROSEN, *supra* note 62, at 20 (“The source code that defines a computer program is copyrightable, as is the translated object code that actually executes on the computer.”). The expressive elements of computer databases also constitute copyrightable subject matter. 1 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 2.04[C][1], at 2–49 & 2–50 (80th rel. 2009) [hereinafter NIMMER ON COPYRIGHT] (citing relevant legislative history, which states that the definition of “literary works” in the Copyright Act “includes computer data bases”).

⁷⁰ See T. Robert Rehm, Jr., *Navigating the Open Source Minefield: What’s a Business to Do?*, 10 WAKE FOREST INTELL. PROP. L. J. 289, 291 n.5 (2010). For a detailed discussion of intellectual property rights in computer software and distinctions between open source software and software licensed pursuant to the closed source model, see *id.* 289–321.

- *reproduce* the copyrighted work in copies;
- *prepare derivative works* based upon the copyrighted works;
- *distribute copies* of the copyrighted work to the public;
- *perform* the copyrighted work publicly; and
- *display* the copyrighted work publicly.⁷¹

b. Derivative Works and Compilations

Derivative works and compilations are examples of copyrightable subject matter that arise out of pre-existing works of authorship.⁷² A derivative work is based on one or more pre-existing works that are recast, transformed, or adapted in such a way that the resulting work, as a whole, constitutes an original work of authorship.⁷³ For example, an original screen play is a derivative work of the novel on which it is based.

A compilation is a collection of pre-existing works that are arranged in such a way that the resulting work of authorship, as a whole, constitutes an original work of authorship.⁷⁴ For example, an original collection of critiques by individual art critics on the paintings of a certain artist is a compilation of those critiques.

Copyright rights in a derivative work or compilation exist separate and distinct from copyright rights in the pre-existing works from which the derivative work or compilation arise. Nonetheless, due to the fundamental and substantial reliance of a derivative work or compilation on such pre-existing work(s), copyright rights in a derivative work or compilation cannot be exercised by the copyright owner thereof without permission of the owner of copyright rights in those pre-existing works.

4. Prosecuting a Copyright Registration Application

In addition to the foregoing exclusive rights of the copyright owner, timely registration of the copyrighted work with the United States Copyright Office (“Copyright Office”), although not necessary, is often advisable, because it provides the copyright owner certain procedural advantages and remedies, which are not otherwise

⁷¹ 17 U.S.C. § 106 (2006).

⁷² *Id.* § 101.

⁷³ *Id.*

⁷⁴ *Id.*

available absent such registration, in connection with enforcing such rights against infringers. Prosecuting a copyright registration application is relatively straightforward compared to prosecuting a patent application or an application to register a mark. A copyright registration application includes the following items: (i) a completed Copyright Office cover sheet; (ii) a deposit of the work for which registration is sought; and (iii) the applicable filing fee.⁷⁵

a. Benefits of Copyright Registration

Failure to timely register a copyrighted work may adversely affect a copyright owner's rights (or related remedies) in connection with that work in at least the following ways:

(i) A copyright owner may not institute an action to enforce its rights in the copyrighted work unless and until that work has been registered at the Copyright Office. U.S. copyright law is somewhat muddled on this point, however, because some courts have held that merely having a copyright registration on file at the U.S. Copyright Office is sufficient to file an infringement action, provided that the U.S. Copyright Office is served a copy of the underlying complaint and any subsequent pleadings.⁷⁶ In any event, copyright owners may seek expedited registration of copyrighted works in the event that the infringed copyrightable subject matter is not registered at the time that infringement commences.⁷⁷

(ii) In addition to enjoining the accused infringer's unlawful activities, copyright owners may seek to recover either *actual* damages or *statutory* damages from an accused infringer.⁷⁸ To recover *actual* damages, the copyright owner is required to prove the infringer's gross revenues arising out of the infringing activity, which in many cases is difficult to do.⁷⁹ On the other hand, in order to recover *statutory* damages, which are fixed by statute at amounts between (1) \$200 per infringed work (for innocent infringement) and (2) \$150,000 per infringed work (for willful infringement), the copyright owner is not required to shoulder this difficult burden of proof.⁸⁰

As an incentive to seek registration of copyrighted works, U.S. copyright law does not permit a copyright owner to seek recovery of *statutory* damages for (1) infringement of any unpublished work that

⁷⁵ 5 NIMMER ON COPYRIGHT § 21.03.

⁷⁶ See *Reed Elsevier, Inc. v. Muchnick*, 130 S.C. 1237, 1239 (2010).

⁷⁷ United States Copyright Office, *Special Handling* (Circular 10.0510).

⁷⁸ 17 U.S.C. § 504(a)(1)–(2) (2006).

⁷⁹ 17 U.S.C. § 504(b) (2006); see also 4 NIMMER ON COPYRIGHT § 14.03.

⁸⁰ 17 U.S.C. § 504(c)(2) (2006).

commenced before the effective date of its registration or (2) infringement of any published work that commenced before the effective date of its registration, unless such registration is made within three (3) months after first publication of such work.⁸¹

5. Notice of Copyright

The author of a copyrighted work can provide public notice of its ownership of such exclusive rights of copyright in that work by affixing notice, comprising the following elements, to visually perceptible copies of the copyrighted work in a manner reasonably calculated to put a potential infringer on notice of such ownership: (i) copyright symbol (“©” or “Copyright” or “Copr.”); (ii) year of first publication of the work; and (iii) name of copyright owner.⁸² Such notice serves to cut off any “innocent infringer” defense that an alleged infringer may assert and to otherwise maximize the scope of damages potentially recoverable by the copyright owner in any suit brought to enforce its rights in the copyrightable subject matter.⁸³

6. Transfer of Ownership of Copyright Rights

A transfer of ownership of copyright rights in a work of authorship may occur either (i) by operation of law or (ii) by written agreement. Oral transfers of copyright ownership are unenforceable and of no force or effect.⁸⁴

a. Transfer by Operation of Law

In general, ownership of copyright rights may be transferred by operation of law in connection with any business consolidation or combination (*e.g.*, a merger) for which applicable law provides for transfer of all right, title, and interest in and to the intangible assets (such as intellectual property rights) of the individual business entities into the consolidated or combined business entity.⁸⁵ In addition, ownership of copyright rights may be transferred by operation of law in connection with the “work made for hire” relationship described below.

i. Work Made for Hire

⁸¹ 17 U.S.C. § 412 (2006).

⁸² 8–6 NIMMER ON COPYRIGHT § 19.

⁸³ *See* 17 U.S.C. § 401 (2006).

⁸⁴ *See* 3–10 NIMMER ON COPYRIGHT § 10.03 [A][1].

⁸⁵ *See* 2 WILLIAM F. PATRY, PATRY ON COPYRIGHT § 5:116 (2011).

As discussed above, ownership of copyright rights in a work of authorship initially vests in the author of that work upon fixation of the work in a tangible medium of expression.⁸⁶ An exception to this general rule, however, occurs in the context of an employee, who creates a work of authorship within the scope of that employee's employment.⁸⁷ In this case, ownership of the work of authorship and all copyright rights therein vest, by operation of law, in the employee's employer, not in the employee.⁸⁸

In other words, the law views the employer, not the employee, as the author of the work for copyright purposes.⁸⁹ A work of the type described in the immediately preceding paragraph is a "work made for hire," which U.S. copyright law views differently from works created pursuant to an independent contractor arrangement.

Other than the foregoing exception, in order for ownership rights in a work of authorship, and any copyright rights therein, to vest in any party other than the author of that work, the author must execute a written document assigning all those rights to that other party.

Except in only a few limited cases, copyright rights in such independent contractor works do not transfer by operation of law to the individual or entity that commissions the work – as discussed below, such copyright rights can transfer to the commissioning party only via a written agreement signed by the independent contractor.⁹⁰

b. Transfer by Written Agreement

If ownership of copyright rights does not transfer by operation of law pursuant to the principles described above, such ownership may be transferred only by a written agreement signed by the transferring party.⁹¹ This serves to highlight a common misconception – *i.e.*, that merely paying a third party to develop copyrightable subject matter (except in a work made for hire situation) results in all cases in transfer to the paying party of all right, title, and interest in and to all copyright rights in such subject matter. On the contrary, such payment merely results in transfer to the paying party of title to the tangible

⁸⁶ See *supra* note 58.

⁸⁷ See 17 U.S.C. § 201(b) (2006).

⁸⁸ See 1–5 NIMMER ON COPYRIGHT § 5.03 [A].

⁸⁹ *Id.*

⁹⁰ *Cmty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 741 (1989).

⁹¹ See 17 U.S.C. § 202 (2006).

item embodying such copyrightable subject matter, not the underlying copyright rights therein.⁹²

7. Recordation of Transfers of Ownership of Copyright Rights

A less-than-forthright transferor of ownership of copyright rights may attempt to transfer by written agreement the same intellectual property rights twice – *i.e.*, initially to the rightful transferee and later to another transferee. Therefore, in order to protect itself against a later-executed, conflicting transfer of copyright rights to a later transferee that would otherwise be a bona fide purchaser for value without actual notice of the initial transfer, the rightful transferee must, within one month after execution of the underlying transfer document or at any time prior to recordation of a later-executed conflicting transfer, have any such transfer of ownership rights recorded at the Copyright Office along with a copy of the transfer document.⁹³ Although acknowledgement (*i.e.*, notarization) of the executed transfer document is not required for its validity, it does constitute prima facie evidence of the execution of the transfer.⁹⁴

8. Activities That Can Result in Loss of Copyright Rights

Because securing intellectual property rights, including copyright rights, often is a laborious, time-consuming, and expensive undertaking, owners of such rights owe it to themselves to become informed about and remain mindful of the ways in which those rights can be either irretrievably lost or rendered unenforceable for some period of time. In general, any act or omission by or on behalf of an owner of intellectual property rights that would provide a credible basis for a defense against infringement or misappropriation of such rights can lead to a loss of, or inability to enforce, such rights and corresponding remedies available in connection with challenging the infringement or misappropriation of those rights.⁹⁵

For example, in order to prevail in a copyright infringement action, the copyright owner must prove that (i) it owns valid and enforceable copyright rights in the infringed work and has standing to bring the action, all consistent with applicable legal requirements and (ii) the accused infringer has usurped one or more of the copyright

⁹² *See id.*

⁹³ 17 U.S.C. § 205 (2006).

⁹⁴ 17 U.S.C. § 204(b) (2006).

⁹⁵ *See* 4 NIMMER ON COPYRIGHT §§ 13.06–13.09.

owner's exclusive rights with respect to that work (most often, the infringer copies and/or distributes copyrighted materials without plaintiff's authorization).⁹⁶ The second element of a copyright infringement action often is difficult to prove by direct evidence of actual copying. As a result, most often the copyright owner must prove unauthorized copying by evidence of (1) access to the copyrighted work and (2) substantial similarity between the copyrighted subject matter in the infringing work and the copyrighted subject matter in the copyrighted work.⁹⁷ Therefore, any act or omission by or on behalf of the copyright owner that bars proof of any of the foregoing elements of a copyright infringement action can result in loss of, or inability to enforce, the owner's copyright rights in the infringed work.

Following are some of the ways in which copyright rights in a work of authorship can be lost or rendered temporarily unenforceable:

a. First Sale

The first authorized sale of, or other disposition that passes title in or to, a tangible item embodying copyrighted subject matter (*e.g.*, the sale of a compact disc on which a copyrighted computer program is recorded) exhausts the copyright owner's exclusive right to distribute, or otherwise control distribution of, that item.⁹⁸ It is important to note, however, the following limitations on any exhaustion of copyright rights in this situation: (i) title passes only as to the tangible item and not to the copyrighted subject matter or underlying copyright rights embodied therein and (ii) the following exclusive rights of the owner in that copyrighted subject matter remain intact and in full force and effect: (1) all the exclusive rights granted under U.S. copyright law (other than the distribution right) with respect to that item and (2) all such exclusive rights (including the distribution right) in connection with all other such items that have not been sold or otherwise disposed of in the manner described above.⁹⁹ While the first sale of a tangible item embodying a copyrighted work is not, in and of itself, a bad thing – in fact, it is a routine part of many commercial transactions – it is important to note that, after such a sale,

⁹⁶ 4 *id.* § 13.01.

⁹⁷ *Id.*

⁹⁸ Christian H. Nandan, *Software Licensing in the 21st Century: Are Software "Licenses" Really Sales, and How Will the Software Industry Respond?*, 1035 PRACTISING LAW INST. 619, 628 (2011).

⁹⁹ Vivian Wang, *Sale or License?* UMG v. Augusto, Vernor v. Autodesk, and the First Sale Doctrine, 19 TEX. INTELL. PROP. L.J. 1, 2 (2010).

certain exclusive rights of copyright as to the sold item, as described above, are no longer available to the owner of that copyrighted work.¹⁰⁰

b. Failure to Provide Notice of Copyright

In addition to the possible forfeiture of copyright rights discussed in Section II.B.8.(c) below, failure of the copyright owner to affix proper notice of copyright to the copyrighted work opens the door for assertion of an innocent infringer defense by an accused infringer of copyright rights in the work.¹⁰¹ This defense, which in and of itself, generally will not shield an accused infringer from liability, but may impact the amount of statutory damages available to the copyright owner, is not available if proper copyright notice appears on the copy of the infringed work accessed by the infringer. In addition, the defense is not available to the extent that the copyright owner can demonstrate that the infringer otherwise had actual knowledge of the owner's copyright rights – a showing that is often difficult to make.¹⁰² Therefore, it is important to require, especially in agreements in which rights in a copyrighted work are licensed to another party, that all copies of a copyrighted work clearly and prominently display the proper notice of copyright.

c. Abandonment

A copyright owner may abandon its copyright rights in a work by any overt act or pattern of behavior that indicates the copyright owner's intention to permanently disclaim such copyright rights.¹⁰³ For example, repeatedly permitting publication of the copyrighted work (or affixation of notice of copyright) in someone else's name could result in abandonment of copyright rights in the work. Forfeiture of copyright rights, which is another example of abandonment, arises out of prolonged or repeated failure to use proper notice of copyright on a copyrighted work.¹⁰⁴ Similarly, a copyright owner's repeated failure to enforce its rights in the copyrighted work against known infringements of that work can result in a loss of copyright rights in the work through acquiescence.¹⁰⁵

¹⁰⁰ Nadan, *supra* note 98, at 628.

¹⁰¹ See 2–7 NIMMER ON COPYRIGHT § 7.14(B).

¹⁰² See *id.* § 7.14(B)(1)(b)(iii) (citing 17 U.S.C. § 405(b)).

¹⁰³ See 4–13 *id.* § 13.06 (describing “abandonment”).

¹⁰⁴ See *id.* (distinguishing between “abandonment” and “forfeiture”).

¹⁰⁵ See *id.* § 13.07 (citing *Kraft v. Cohen*, 32 F. Supp. 821 (E.D. Pa. 1940), *rev'd on other grounds*, 117 F.2d 579 (3d Cir. 1941)) (describing “acquiescence”).

d. Implied License

Owners of copyright rights may elect to share such rights with other individuals or entities through written license agreements designed to expressly set out the scope of such licensed rights and any related restrictions and prohibitions.¹⁰⁶ However, in some cases, either improvidently drafted license terms or certain conduct by the licensor and/or licensee may serve as a basis for an implied license in certain copyright rights that was not intended by the licensor.¹⁰⁷

For example, an express license under certain copyright rights may be useless to the licensee unless rights under certain other copyright rights are also granted.¹⁰⁸ In such cases, the licensee may successfully assert that an implied license has been created in those other copyright rights. To avoid such an outcome, care should be taken to draft license terms that not only are appropriately tailored to the scope of copyright rights that the licensor intends to license but also expressly state all applicable restrictions and disclaim all licenses under those copyright rights other than those expressly stated in the relevant agreement.¹⁰⁹

Unlike assignments of or exclusive licenses under copyright rights, non-exclusive copyright licenses do not necessarily need to be in writing in order to be enforceable under federal copyright law.¹¹⁰ Therefore, oral statements or certain conduct evidencing an understanding by and between a licensor and its non-exclusive licensee as to the licensee's rights in copyrightable subject matter may give rise to a non-exclusive implied license in such subject matter that was not intended by the licensor.¹¹¹ As a result, licensors should be careful that their comments and actions do not provide a supportable basis for such an implied license.

e. Laches

Laches in a copyright context typically arises due to an inexcusable and unreasonable delay by the copyright owner in enforcing its copyright rights against a known infringer of such rights.¹¹² Such conduct may render the copyright rights

¹⁰⁶ *Id.* § 10.03 [A][1] (2010).

¹⁰⁷ *Id.* § [A][7].

¹⁰⁸ *Id.* § [A][2].

¹⁰⁹ *Id.*

¹¹⁰ *Id.* § [A][6].

¹¹¹ *Id.* § [A][5].

¹¹² 3–12 *id.* § 12.06(B).

unenforceable.¹¹³ The unenforceability of copyright rights due to laches highlights an important point with respect to all intellectual property rights – *i.e.*, once intellectual property rights are created, in order to maintain the ongoing viability of such rights, the owner must remain vigilant against violations of such rights and promptly take affirmative action to challenge such violations.¹¹⁴

f. Copyright Misuse

If a copyright owner exploits its exclusive rights of copyright beyond the scope of such rights granted by law to the copyright owner with an overall anticompetitive effect, the owner may be guilty of copyright misuse.¹¹⁵ For any infringement action brought by a copyright owner guilty of such misuse in which the misuse directly relates to the copyright rights at issue in such action, the alleged infringer may have grounds for asserting a defense based on copyright misuse.¹¹⁶ The underlying copyright rights in such situations are unenforceable until all the misuse and its related consequences are purged.¹¹⁷

g. Fair Use

Unlike the foregoing activities that may result in loss of copyright rights, all of which derive primarily from some act or omission by or on behalf of the copyright owner, “fair use” of copyrighted subject matter is a restriction on copyright rights that has evolved from a judicial attempt to forgo strict application of the U.S. Copyright Act in certain situations where it would be contrary to the fundamental purpose of the copyright laws to do so.¹¹⁸ Such situations may include the use of copyrighted subject matter for purposes of criticism, comment, news reporting, teaching, scholarship, and research.¹¹⁹

In determining whether use of copyrighted subject matter constitutes fair use, the following factors, among others, are typically taken into account: (i) the purpose and character of the use, including whether such use is of a commercial nature or is for non-profit educational purposes; (ii) the nature of the copyrighted work; (iii) the

¹¹³ *Id.* § 12.06(A).

¹¹⁴ *Id.* § 12.06(B)(4).

¹¹⁵ 4–13 *id.* § 13.09(A)(2).

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Harper & Row Publ'ers, Inc. v. Nation Enters.*, 471 U.S. 539, 549 n.3 (1985) (quoting *Iowa State Univ. Research Found., Inc. v. Am. Broad.*, 621 F.2d 57, 60 (2d Cir. 1980)).

¹¹⁹ 17 U.S.C. § 107 (2006).

amount and substantiality of the portion of the copyrighted work used relative to the copyrighted work as a whole; and (iv) the effect of the use of the copyrighted work on the potential market for or value of the copyrighted work.¹²⁰ While none of these factors alone is dispositive of the fair use analysis in any given case, one or more of the factors may be given additional weight depending on the particular circumstances.¹²¹

C. *Patentable Subject Matter*¹²²

1. Conception and Disclosure

The *intellectual* act giving rise to patentable subject matter is known as “conception,” which comprises the mental formulation by an individual (*i.e.*, the “inventor”) of a novel, non-obvious, and useful invention (*e.g.*, a product, process, method, system, etc.) in sufficient detail to allow for the requisite disclosure described in the immediately following paragraph.¹²³

The overt act giving rise to *property*-related rights in a patent context is “disclosure” of the invention in sufficient detail, and in a manner that permits appropriate corroboration, so as to enable one of ordinary skill in the pertinent art to reduce the invention to practice either (i) actually, by constructing a physical embodiment of the invention that can be demonstrated to work for its intended purpose or (ii) constructively, by filing a patent application that claims such invention and complies with the other legal requirements for such an application.¹²⁴

Once an invention is conceived, the inventor must exercise reasonable diligence in reducing the invention to practice to ensure that any patent-related rights in that invention vest in the inventor.¹²⁵

In contrast with copyrightable subject matter for which the vesting of substantive rights is a one-step process that occurs upon

¹²⁰ *Id.*; see 4 NIMMER ON COPYRIGHT § 13.05[A][5][a].

¹²¹ *Id.*

¹²² The U.S. Patent Statute, codified at 35 U.S.C. §§ 1–376 (2011) (“Patent Statute”), and federal jurisprudence interpreting the Patent Statute, comprise the primary basis for patent protection in the United States.

¹²³ 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1-GLOS (Matthew Bender, 2011) [hereinafter CHISUM ON PATENTS]; see 35 U.S.C. §§ 101–103 (2006).

¹²⁴ 3A CHISUM ON PATENTS §§ 10.04–10.06; BLACK’S LAW DICTIONARY 532 (9th ed. 2009).

¹²⁵ See 3A CHISUM ON PATENTS §10.03.

fixation of the work in a tangible medium of expression, vesting of substantive patent rights involves a two-step process as follows:

First, conception and disclosure in the manner just described vest in the inventor (or its transferee) nothing more than the right to pursue patent protection for the invention in the United States.¹²⁶ That right, however, is subject to the rights of any other individual, who (1) can demonstrate prior conception of the invention or (2) first reduces the invention to practice, but only to the extent that the inventor who first conceived the invention fails to comply with the reasonably diligent reduction to practice described above, all in accordance with certain statutory requirements and rules and regulations.¹²⁷

Second, once the inventor (or its transferee) exercises its right to file a patent application claiming the applicable invention, the claimed invention must comply with the requirements of U.S. patent law, which are discussed in more detail below, before a patent will issue for that invention.¹²⁸ If and when such a patent issues, the exclusionary rights described below vest in the inventor (or its transferee) upon issuance of that patent.¹²⁹

2. Types of Patentable Subject Matter

Patentable subject matter involved in technology commercialization most often is protectable under what are known as “utility” patents (as opposed to other types of patents dealing with certain ornamental designs (*i.e.*, “design” patents) and new and distinct varieties of plants (*i.e.*, “plant” patents)). Inventions subject to utility patent protection in the United States include the following:

- Products:
 - apparatus (electronic scanning device)
 - composition of matter (chemical compound)
 - product of nature (genetically engineered material); and
 - manufacture (any product-related subject matter not included in the foregoing categories)

- Processes:
 - methods/procedures (encryption of electronic communications) and

¹²⁶ *See id.*

¹²⁷ *See id.*

¹²⁸ *See* 35 U.S.C. § 1, *et. seq.* (2010).

¹²⁹ *See* 35 U.S.C. § 154 (2010).

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- systems (communications network).¹³⁰

Utility patent protection extends only to the utilitarian or functional aspects of a product or process and not to any creative or expressive aspects of such products or processes, all of which may be subject to copyright protection as discussed above.

3. Exclusionary Rights Arising From an Issued Patent

Upon conception and disclosure of the relevant invention in the manner described above and issuance by the United States Patent and Trademark Office (“USPTO”) of a patent that claims that invention, the inventor of the claimed invention has the right to exclude others (i) from making, using, offering for sale, and selling the patented invention throughout the United States and from importing the patented invention into the United States and (ii) for patented inventions comprising a process, to exclude others from importing into the United States any products made by that process.¹³¹

It is important to note that rights granted under a patent are rights of exclusion rather than rights to affirmatively engage in any of the activities that are the subject of such exclusionary rights. Said another way, a patent covering the invention claimed therein merely gives the patent holder (*i.e.*, patentee) the right to exclude all others from exercising the rights described in clauses (i) and (ii) of the immediately preceding paragraph with respect to that invention; it does not grant the patentee the affirmative right to engage in any of those activities with respect to the invention.¹³² Therefore, a license under patent rights is more appropriately characterized as a patentee’s “covenant not to sue” its licensee for exercising any of the rights that the patent grant permits the patentee to exclude others from exercising.¹³³

For example, in the situation where a patented invention, which comprises claim elements A, B, C, and D, is an improvement of an earlier patented invention, which comprises claim elements A, B, and C, the patentee’s rights under the earlier patent to exclude the practice of any invention comprising the elements A, B, and C would “block” the patentee of the later patent from affirmatively exercising any of the exclusionary rights under that later patent with respect to

¹³⁰ 1 CHISUM ON PATENTS §§ 1.02–03.

¹³¹ 35 U.S.C. § 154 (2010); 5 CHISUM ON PATENTS § 16.02.

¹³² 5 CHISUM ON PATENTS § 16.02(1).

¹³³ *Id.* § 16.02(1) n.1.

the invention comprising claim elements A, B, C, and D, but only to the extent that any such exercise of rights requires the practice of the earlier patented elements A, B, and C.

This “blocking” situation does not arise very often, primarily because the patentee of the earlier patent often is also the patentee of the later patent. This is so because improvements to earlier patented inventions are, in most cases, set out in the disclosure of the earlier filed application, which reserves to the patentee of the earlier patent the right to file subsequent patent applications (generally called “continuation” applications) claiming such improvements.¹³⁴ In situations where “blocking” poses problems, the patentee of the later filed patent can either secure a license from the patentee of the earlier patent or substitute for one or more of elements A, B, and C (in the example above) certain non-equivalent element(s) so that there would be no violation of any of the exclusionary rights of the patentee of the earlier patent.

4. Prosecuting a Patent Application

a. Non-Provisional Patent Application Requirements

Utility patent applications in the United States are of two (2) basic types: (i) non-provisional and (ii) provisional. A non-provisional patent application, which is subject to substantive review by the USPTO, typically includes the following items, at a minimum: (1) one or more claims; (2) specification; (3) inventor’s oath or declaration; and (4) filing fee.¹³⁵ In addition, a non-provisional application may include drawings, if required to describe the claimed invention, and information disclosure statements, which are discussed in more detail below. Finally, for most, if not all, non-provisional applications filed in an employment context, the application includes an assignment of the patent application and inventions claimed therein from the employee-inventor to the employer-assignee.

If, in connection with preparing the patent application, the inventor, its assignee, or their patent attorney uncovers any patents, documents, references, or other information that may be material to the patentability of any of the subject matter claimed in the application, those materials should be identified in an information disclosure statement and copies thereof provided as part of the application.¹³⁶ In addition, if the subject matter claimed in the non-provisional application is properly supported by the disclosure (*i.e.*,

¹³⁴ 4A *id.* § 13.01.

¹³⁵ 4 *id.* § 11.02.

¹³⁶ *Id.* § 11.03(4)(c)(ii).

satisfies the Disclosure Requirements discussed below) set forth in any earlier-filed patent application, that subject matter can claim priority back to the earliest filed of such applications in an effort to overcome any Prior Art (defined below) that might undermine the patentability of that subject matter.¹³⁷

For example, a non-provisional application can rely for priority on the provisional application from which it derives so long as the provisional application meets all the statutory requirements for such an application and the non-provisional application is filed no later than twelve (12) months after the filing date of the corresponding provisional application. Although such a claim of priority may help to overcome troublesome Prior Art, it is important to note that, depending on the filing date of a non-provisional application that claims such priority, the term of any patent issuing from that non-provisional application possibly would be deemed to commence on the filing date of the earliest-filed application from which priority is claimed rather than on the filing date of the non-provisional application.¹³⁸

The claims define the scope of the patented invention. For a patent application to issue into a patent, the invention claimed in that application must be novel and non-obvious.¹³⁹ In order to be “novel,” at least one element of the claimed invention must be newly conceived by the inventor – in other words, all elements of the claimed invention cannot be disclosed within a single reference in the Prior Art.¹⁴⁰ The “Prior Art” essentially comprises all patents, documents, references, and other information that relate to the invention for which patent protection is sought and are available to or accessible by the inventor on the date on which conception of that invention commences.¹⁴¹

In order to be “non-obvious,” all elements of the claimed invention cannot be disclosed within multiple references in the Prior Art for which it would have been obvious to a person of ordinary skill in the art of the claimed invention, whether through any suggestion, motivation, or teaching included in the Prior Art or through the ordinary skill of such a person or common sense, to combine the teachings of those references to bring about the claimed invention.¹⁴²

¹³⁷ *Id.* § 11.03(2)(c)(v).

¹³⁸ *Id.* § 11.03(2)(b)(vi)(A).

¹³⁹ *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1061–62 (Fed. Cir. 1992).

¹⁴⁰ 1 CHISUM ON PATENTS § 3.01.

¹⁴¹ *Id.*

¹⁴² *Id.*

The specification and drawings included with a non-provisional application, which, collectively, comprise the “disclosure” of the application, must set forth (1) a clear, reasonably detailed, and accurate written description of the claimed invention (the “Written Description Requirement”); (2) sufficient to enable a person of ordinary skill in the art to which that invention pertains to make and use the claimed invention (the “Enablement Requirement”); and (3) the best mode for carrying out the claimed invention (the “Best Mode Requirement”) (the foregoing requirements in (1)-(3), collectively, the “Disclosure Requirements”).¹⁴³ A patent cannot issue from a patent application unless and until the USPTO determines that the disclosure satisfies the Disclosure Requirements.

Patent infringement analysis is directed to the invention as claimed in the infringed patent and is informed by, among other things, the patent’s disclosure and its “prosecution history,” which is discussed in more detail in Section II.C.4.(c) below.

b. Provisional Patent Application Requirements

A provisional patent application, which is not subject to substantive review by the USPTO, is an abbreviated version of a non-provisional patent application in that it need not include any claims or an inventor’s oath or declaration and cannot include any information disclosure statements.¹⁴⁴ However, a provisional application must include a completed USPTO cover sheet that clearly identifies the application as provisional.¹⁴⁵

A provisional patent application is similar in effect to an intent-to-use registration application for a mark, which is discussed in more detail in Section II.D.4.(b) below, in that a provisional application allows an applicant to establish an earlier priority date for purposes of determining patentability of any invention that is ultimately claimed in a later filed non-provisional application that relies for priority on that provisional application. However, in order to claim such priority, the disclosure of the provisional application must comply with the Disclosure Requirements and the corresponding non-provisional application must be filed no later than twelve (12) months after the filing date of the provisional application.¹⁴⁶

¹⁴³ 3 *id.* § 7.01.

¹⁴⁴ 4 *id.* § 11.02(1)(g)(i).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* § 11.02(1)(g)(iii).

c. USPTO Examination

After examining a non-provisional patent application, the USPTO typically issues an office action directed primarily at identifying issues arising from (i) any failure of the disclosure of the application to comply with the Disclosure Requirements and/or (ii) any Prior Art that renders the claims of the application unpatentable.¹⁴⁷ Additional office actions may be required to address other issues as they arise. USPTO office actions in connection with patent prosecution generally result in a narrowing of the claim scope initially sought by the applicant in order to overcome any Prior Art asserted by the USPTO examiner.¹⁴⁸ These office actions, the applicant's responses thereto, and any other correspondence or other information exchanged by the USPTO examiner and the applicant in connection with prosecuting the patent, which, collectively, are known as the "prosecution history" of the application, ultimately result in (1) issuance of a patent having claim scope deemed acceptable by the USPTO; or (2) a final ruling by the USPTO that the claims of the application are unpatentable, whereupon the applicant either (a) appeals the adverse ruling to a federal court or a higher authority within the USPTO or (b) abandons the application.¹⁴⁹

5. Notice of Patent

A patentee can provide public notice of the exclusionary rights granted under a patent by affixing notice comprising the following elements to the patented article or, when that is not possible, affixing a label bearing such notice to the patented article or its packaging: (i) the word "patent" or abbreviation "pat." together with (ii) the number of the patent.¹⁵⁰

Providing such notice, which is known as "marking," serves to maximize the scope of damages potentially recoverable by the patent owner in any suit brought to enforce its rights in the patented subject matter.¹⁵¹

6. Transfer of Ownership of Patent Rights

As with transfers of ownership of copyright rights, a transfer of ownership of patent rights may occur either (i) by operation of law or

¹⁴⁷ *Id.* § 11.03(1)(c).

¹⁴⁸ *Id.* § 11.03(1)(c)(v).

¹⁴⁹ 37 C.F.R. § 1.113 (2010).

¹⁵⁰ 35 U.S.C. § 287(a) (2006).

¹⁵¹ *Id.*

(ii) by written agreement.¹⁵² Oral transfers of ownership of patent rights are unenforceable and of no force or effect.¹⁵³

a. Transfer by Operation of Law

Ownership of patent rights may be transferred by operation of law in connection with any business consolidation or combination (e.g., a merger) for which applicable law provides for transfer of all right, title, and interest in and to the intangible assets (such as intellectual property rights) of the individual business entities into the consolidated or combined business entity.¹⁵⁴ In addition, ownership of patent rights may be transferred by operation of law in connection with the relationship described below.¹⁵⁵

i. Hired-to-Invent Employment

As discussed above, rights in patentable subject matter initially vest in the inventor of such subject matter once the requisite disclosure is made.¹⁵⁶ An exception to this general rule, however, occurs in the context of an employee, who is hired for the express purpose of inventing the process, method, product, etc. that the employee conceives and that ultimately becomes a patented invention.¹⁵⁷ In order to be enforceable against the employee-inventor, the terms and conditions of any such hired-to-invent arrangement must be evidenced by a written agreement between the employer and employee or, alternatively, by an implied-in-fact contract arising out of and indicating a tacit understanding between those parties followed by conduct in furtherance of and in accordance with that understanding.¹⁵⁸ Whether such an implied-in-fact contract exists is determined by the contract law of the respective state in each case.¹⁵⁹

In the hired-to-invent arrangement described above, ownership of the resulting subject matter and all patent rights therein vest, by operation of law, in the inventor's employer, not in the inventor. In other words, the law views the employer, not the employee, as the inventor of the patentable subject matter for patent protection

¹⁵² *Pointer v. Six Wheel Corp.*, 177 F.2d 153, 157 (9th Cir. 1949) (citing *Agawam Co. v. Jordan*, 74 U.S. 583, 602 (1868)).

¹⁵³ 3 JOHN GLADSTONE MILLS, III, ET AL., PAT. L. FUNDAMENTALS § 19:4 (2d ed. 2011).

¹⁵⁴ 8 CHISUM ON PATENTS § 22.01.

¹⁵⁵ 8 *id.* § 22.03(2).

¹⁵⁶ 3 *id.* § 7.01.

¹⁵⁷ 8 *id.* § 22.03(2).

¹⁵⁸ 19 RICHARD A. LORD, WILLISTON ON CONTRACTS § 54:20 (4th ed. 2010).

¹⁵⁹ 8 CHISUM ON PATENTS § 22.03(5).

purposes.¹⁶⁰ Other than the foregoing exception, in order for ownership rights in patentable subject matter and any patent rights therein to vest in any party other than the inventor of that subject matter, the inventor must execute a written document transferring ownership of all those rights to that other party.¹⁶¹

Even in employment contexts that do not rise to the level of the hired-to-invent arrangement described above, certain license rights in patentable subject matter developed by an employee in connection with his or her employment may pass by operation of law to the respective employer.¹⁶² Such license rights, known as “shop rights,” arise out of principles of equity and fairness and are designed to recognize the contributions that an employer makes in connection with development of such patentable subject matter.¹⁶³

Typically, shop rights in patentable subject matter permit the employer to use such subject matter on a non-exclusive basis in connection with the employer’s business without fear of reprisal by the employee. An analysis of whether shop rights arise from inventive activity in connection with an employment relationship typically takes account of the full nature of the parties’ relationship, including the following factors: (i) the extent to which the employee utilized the employer’s resources (time, materials, wages, workplace, etc.) in connection with such development; (ii) the extent to which the employee induced or acquiesced in the employer’s use of that subject matter; and (iii) the extent to which the employee assisted in any such use.¹⁶⁴

Similar to the case of “shop rights” arising out of inventive activity in an employment context, certain license rights in patentable subject matter can pass by operation of law, such as in cases where inventive activity is funded by the U.S. Government.¹⁶⁵ However, in virtually every case in which that occurs, the inventor is required to enter into written agreements with the U.S. Government that incorporate certain governmental regulations, policies, and procedures

¹⁶⁰ *Banks v. Unisys Corp.*, 228 F.3d 1357, 1359 (Fed. Cir. 2000).

¹⁶¹ 35 U.S.C. § 261 (2006); *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000) (stating that proper assignment requires a written assignment).

¹⁶² See *McElmurry v. Ark. Power & Light Co.*, 995 F.2d 1576, 1580 (Fed. Cir. 1993); 8 CHISUM ON PATENTS § 22.03.

¹⁶³ See *McElmurry*, 995 F.2d at 1580; 8 CHISUM ON PATENTS § 22.03(a).

¹⁶⁴ See *McElmurry v. Arkansas Power & Light Co.*, B-C-90-41, 1992 WL 521752 (E.D. Ark. Feb. 10, 1992) *aff’d*, 995 F.2d 1576 (Fed. Cir. 1993).

¹⁶⁵ See generally 35 U.S.C. §§ 200–212 (2006) (codifying the Bayh-Dole Act to clarify government contracting of patent rights); 37 C.F.R. § 401 (2011).

providing such license rights to the U.S. Government.¹⁶⁶ Such license rights, known as “march-in rights,” are designed to recognize the contributions made by the U.S. Government in connection with developing the patentable subject matter and to give the U.S. Government the right to “march in” to develop and commercialize patentable technology to which it has financially contributed in the event that the inventor is unable or unwilling to do so.¹⁶⁷ In addition, the U.S. Government receives a “non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced each subjective invention . . . by or on behalf” of the U.S. Government.¹⁶⁸

b. Transfer by Written Agreement

If ownership of patent rights does not transfer by operation of law pursuant to the principles described above, such rights may be transferred only by a written agreement signed by the party transferring such rights.¹⁶⁹ This serves to highlight a common misconception – *i.e.*, that merely paying a third party to develop patentable subject matter (except in a hired-to-invent situation) results in all cases in transfer to the paying party of all right, title, and interest in and to all patent rights in such subject matter.¹⁷⁰ On the contrary, such payment merely results in transfer to the paying party of title to the tangible item embodying such patentable subject matter, not the underlying patent rights therein.¹⁷¹

¹⁶⁶ 35 U.S.C. § 202(a) (2006) (providing for the Government’s retention of the invention by claiming any of four circumstances in the funding agreement).

¹⁶⁷ See generally 3 MILLS, III, ET AL., *supra* note 151, § 18:7; and 35 U.S.C. § 203 (2006).

¹⁶⁸ 37 C.F.R. § 401.14(a); 48 C.F.R. § 52.227-13(c)(1)(i) (2011).

¹⁶⁹ 35 U.S.C. § 261 (2006). The patentee is not necessarily required to execute the assignment in every case, so long as someone authorized by applicable law to execute on behalf of the patentee does so. See, e.g., *Cookson v. Louis Marx & Co.*, 23 F. Supp. 615, 617 (S.D.N.Y. 1938) (“On creditor’s bill a court of equity may appoint a trustee to make an assignment of a debtor’s patent right in case the debtor himself does not make the required assignment, and an assignment executed by the trustee will pass title to a purchaser.” (citing *Ager v. Murray*, 105 U.S. 126 (1881))).

¹⁷⁰ See generally 8 CHISUM ON PATENTS § 22.03(2). An assignment provision often is required to be expressly stated in present terms rather than a future promise of assignment. Compare *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000) (holding an assignment provision that “hereby conveys, transfers and assigns” as a present assignment), with *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574 (Fed. Cir. 1991) (holding an assignment provision agreeing that the invention “will be assigned” as not a present assignment).

¹⁷¹ 8 CHISUM ON PATENTS § 22.01 (“[A]bsent some effective transfer or other obligation to assign patent rights, the individual inventor owns the right to apply for and obtain a patent.”).

7. Recordation of Transfers of Ownership of Patent Rights

In order to protect itself against a later-executed, conflicting transfer of patent rights to a later transferee that would otherwise be a bona fide purchaser for value without actual notice of the initial transfer, a rightful transferee of ownership in patent rights must, within three (3) months after execution of the underlying transfer document or prior to the date of the later transfer, have any such transfer of ownership recorded at the USPTO along with a copy of the transfer document.¹⁷² Although acknowledgement (*i.e.*, notarization) of the executed transfer document is not required for its validity, it does constitute prima facie evidence of the execution of the transfer.¹⁷³

8. Activities That Can Result in Loss of Patent Rights

In order to prevail in a patent infringement action, the patent owner must prove that (i) it owns valid and enforceable rights in the patented invention, consistent with applicable legal requirements,¹⁷⁴ and (ii) the accused infringer has usurped one or more of the patent owner's exclusionary rights with respect to that invention.¹⁷⁵ With regard to the second element of proof, the patent owner must prove that each and every element recited in at least one of the claims of the infringed patent is found in the infringing device, method, or process.¹⁷⁶ Therefore, any act or omission by or on behalf of the patent owner that bars proof of either or both of the foregoing elements of a patent infringement action can result in loss of, or inability to enforce, the owner's rights in the infringed patent.¹⁷⁷

Following are some of the ways in which patent rights can be lost or rendered temporarily unenforceable:

¹⁷² 35 U.S.C. § 261 (2006).

¹⁷³ *Id.*

¹⁷⁴ Patent infringement suits must satisfy the Supreme Court's three-part framework in order to form a justiciable controversy under Article III of the Constitution, including standing, ripeness, and lack of mootness. *Caraco Pharm. Labs., Ltd. v. Forest Labs.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (standing); *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967) (ripeness); *U.S. Parole Comm'n v. Geraghty*, 445 U.S. 388, 397 (1980) (mootness).

¹⁷⁵ 4 MILLS, III, ET AL., *supra* note 151, § 20:3.

¹⁷⁶ *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1582 (Fed. Cir. 1988).

¹⁷⁷ 5B CHISUM ON PATENTS § 18.06(1)(a).

a. Patent Exhaustion

Similar to the “first sale” restriction on a copyright owner’s exclusive right to distribute copyrighted subject matter, an unconditional, authorized sale of, or other disposition that passes title in or to, a tangible item embodying a patented invention exhausts the patent holder’s right to exclude (or otherwise control) use or further sale or disposition of that tangible item.¹⁷⁸ However, exhaustion of patent rights in this situation is subject to the same limitations described above in Section II.B.8.(a) with respect to loss of copyright rights.¹⁷⁹ In addition, any conditions placed on the sale or other disposition of the item will pass on to the transferee.¹⁸⁰

b. Failure to Mark

Failure to provide public notice of patent rights in the manner described in the “Notice of Patent” section above will bar the patent holder from recovering any damages in a patent infringement action initiated to enforce such rights, except to the extent that the infringer was notified of such patent rights and continued to infringe thereafter.¹⁸¹ Any damages recovery pursuant to the foregoing exception will be limited only to infringements occurring after such notification is given.¹⁸²

c. Failure to Timely File a Patent Application

An inventor is statutorily barred from patenting any invention for which an embodiment thereof is on sale or in public use for more than one (1) year prior to filing a patent application claiming that invention.¹⁸³ The “on sale” bar includes not only sales of, but also offers to sell, an embodiment of the applicable invention.¹⁸⁴ The “public use” bar includes any uses of the applicable invention by a person other than the inventor, who is under no limitation, restriction, or obligations of secrecy to the inventor.¹⁸⁵ It is important to note that “public use” of an embodiment of an invention can occur in a non-public setting so long as the requirements of the immediately preceding sentence are satisfied.¹⁸⁶ Both the “on sale” and “public

¹⁷⁸ 5 *id.* § 16.03(2)(a).

¹⁷⁹ See *supra* text accompanying note 98.

¹⁸⁰ 5 CHISUM ON PATENTS § 16.03(2).

¹⁸¹ 7 CHISUM ON PATENTS § 20.03(7)(c).

¹⁸² *Id.*

¹⁸³ 35 U.S.C. § 102(b) (2006).

¹⁸⁴ *In re Brigrance*, 792 F.2d 1103, 1107 (Fed. Cir. 1986).

¹⁸⁵ *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

¹⁸⁶ *New Railhead Mfg. v. Vermeer Mfg.*, 298 F.3d 1290, 1297 (Fed. Cir.

use” bars may be subject to an “experimental use” exception that may apply in certain limited circumstances in which the subject invention is used exclusively for experimental purposes directed to further development and refinement of that invention.¹⁸⁷

d. Failure to Satisfy Statutory Requirements for Obtaining a Patent

As discussed in the Section II.C.4. above, (i) the disclosure included in a patent application must comply with the Disclosure Requirements and (ii) the invention claimed in that application must be novel and non-obvious. Otherwise, the USPTO will not grant a patent on the application. It is important to note that issuance of a patent does not prevent the validity of that patent from later being challenged by an accused infringer or other third parties on lack of novelty or obviousness grounds or for failure to meet any of the Disclosure Requirements.¹⁸⁸ In reviewing the merits of any such challenge, a court will give some degree of deference to the USPTO’s determination (during prosecution of the application issuing into that patent) that all the statutory requirements for patentability were indeed satisfied.¹⁸⁹

e. Abandonment

Abandonment of rights in connection with patentable subject matter can occur in at least the following ways:

First, an inventor who conceives and reduces to practice an invention may abandon that invention in the event that, thereafter, he indicates an intent to so abandon by failing to diligently commercialize, or file a patent application claiming, that invention.¹⁹⁰ Such abandonment constitutes a loss of the inventor’s proprietary rights in the invention, and such rights may accrue in another party that files a patent application on the same invention during the inventor’s dilatory period.¹⁹¹ Whether such a loss of rights occurs typically depends on evidence of the inventor’s intent to abandon, which may be inferred from the length of the inventor’s delay and the

¹⁸⁷ See *T.P. Lab. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir.), cert. denied, 469 U.S. 826 (1984) (holding experimental use is a negation of the public use bar, not an exception). However, since *TP Laboratories* the Federal Circuit has continued to refer to experimental use as an “exception.” See *In re Brigrance*, 792 F.2d at 1109.

¹⁸⁸ 35 U.S.C. §§ 102–03, 112 (2006).

¹⁸⁹ See 1 CHISUM ON PATENTS § 5.06[2][b][i][C].

¹⁹⁰ See *id.* § 6.03.

¹⁹¹ *Id.*

extent and nature of any activities undertaken by the inventor during that delay period with respect to the invention at issue.¹⁹²

Second, a patent application may go abandoned (*i.e.*, expire) for applicant's failure to prosecute the application in accordance with rules and regulations established by the USPTO.

Finally, a patent may go abandoned for the patentee's failure to pay certain fees required to maintain the patent in effect.

f. Fraud and Inequitable Conduct Before the USPTO

Patent applicants and their patent counsel have a duty to prosecute patent applications before the USPTO with candor, good faith, and honesty. Therefore, a patent may be invalidated or rendered unenforceable due to any breach of this duty that constitutes fraud or inequitable conduct before the USPTO in connection with prosecuting the application that issues into that patent.¹⁹³ Inequitable conduct includes any affirmative misrepresentation as to, failure to disclose, or submission of false information that is material to patentability with the intent to deceive or mislead the patent examiner into issuing the patent.¹⁹⁴ Inequitable conduct constitutes fraud in situations where, but for such inequitable conduct, the applicable patent would not have issued. The consequences of inequitable conduct, which render a patent unenforceable, and fraud, which invalidates a patent, may extend to other patents that are related to the patent at issue.¹⁹⁵ It is also important to note that enforcement of a patent known by the patentee to be fraudulently procured may give rise to antitrust liability where all the other elements of an antitrust violation can be proved.¹⁹⁶

g. Patent Misuse

If a patentee exploits its patent rights beyond the scope of the exclusionary rights granted by law to the patentee with an overall anticompetitive effect, the patentee may be guilty of patent misuse.¹⁹⁷ For any infringement action brought by a patentee guilty of such misuse in which the misuse directly relates to the patent rights at issue in such action, the alleged infringer may have grounds for asserting a defense based on patent misuse.¹⁹⁸ When patent misuse arises, it is often in connection with licensing arrangements, such as covenants not to deal, discriminatory royalty rates, territorial and field of use

¹⁹² *See id.*

¹⁹³ 6 *id.* § 19.03.

¹⁹⁴ 6 *id.* §§ 19.03, 19.03[2] (2005).

¹⁹⁵ *Id.* § 19.03[6].

¹⁹⁶ *Id.*

¹⁹⁷ *See id.* § 19.04.

¹⁹⁸ *Id.*

restrictions, concerted refusals to deal, and tying of licenses under patented products to licenses under non-patented products, all of which attempt to expand the scope of the licensed patent rights beyond its legally permissible contours.¹⁹⁹ The underlying patent rights in such situations are unenforceable until all the misuse and its related consequences are purged.²⁰⁰

h. Prosecution History Estoppel

During prosecution of a patent application, the applicant may be required to narrow the scope of (*i.e.*, reduce the amount of subject matter covered by) one or more of the claims in the application in order for those claims to be patentable – *i.e.*, to not be anticipated or rendered obvious by the Prior Art.²⁰¹ The surrendered claim scope then becomes part of the prosecution history of the application. If a patent issues on the narrowed claim(s), the patentee is precluded from trying to resurrect and assert the surrendered claim scope in any action subsequently brought to enforce the patentee’s rights in the patent.²⁰² In this situation, the patentee is said to be “estopped” from asserting the surrendered claim scope according to the doctrine of “prosecution history estoppel” or “file wrapper estoppel.”

i. Other Activities to Avoid

The discussion above in Sections II.B.(d)-(e) with respect to loss of copyright rights under theories of implied license and laches applies with equal force and effect to rights in patentable subject matter.

D. Trademarks and Service Marks

1. “Use” of -- the Keystone for Acquiring Rights in a Trademark or a Service Mark

The *intellectual act* in a trademark/service mark context is an individual or entity’s “formation of the requisite intent” to use a term, logo, symbol, or other potential indicator in commerce as a “mark” – *i.e.*, with the intent that potential consumers of the goods or services

¹⁹⁹ *Id.* § 19.04[3].

²⁰⁰ *Id.* § 19.04.

²⁰¹ See 2 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 14:1 (2011).

²⁰² *Id.*

offered by that individual or entity associate the term, logo, or symbol with the individual or entity as the source of not only those goods or services but also the quality thereof.²⁰³ Such use constitutes use as a trademark (in connection with goods) or as a service mark (in connection with services). Both trademarks and service marks will hereinafter be referred to as “marks.”

Marks subject to protection in the United States under the Lanham Act and related jurisprudence include virtually any term, logo, symbol, or potential indicator that is used as a mark.²⁰⁴ However, in order to register a mark at the USPTO, which is discussed in more detail below, the mark, among other things, (i) must be inherently distinctive, or, through use in commerce, have become distinctive, of the mark owner’s goods or services and (ii) must not so closely resemble another mark registered or previously in use in the United States as to be likely to cause confusion among potential consumers of those goods or services.²⁰⁵

The *overt act* in the context of a mark is “use” of the mark in commerce in connection with the relevant goods or services in furtherance of and accordance with the requisite intent described above, because only upon such use can the goodwill symbolized by that mark come about.

2. Categories of Marks

In addition to trademarks and service marks, any visual appearance of a product or its packaging or of a structural design (*e.g.*, the color scheme and other visual aspects of a building exterior) that serves as an indicator to potential consumers of the source of certain goods or services may constitute a mark under the name of “trade dress.”²⁰⁶ Simply put, any term, logo, symbol, or other potential indicator used as a source indicator may qualify as a mark.

It is important to distinguish use of a word or term as a “trade name,” which is directed solely to identifying the applicable business organization, from use of that word or term as a “mark,” which *may* serve to identify the mark owner’s business but which primarily (and most importantly) also *must* perform a source indicator function.²⁰⁷

²⁰³ See generally 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 2:1 (4th ed. 2011) [hereinafter MCCARTHY ON TRADEMARKS].

²⁰⁴ See 5 MCCARTHY ON TRADEMARKS § 27:18.

²⁰⁵ See 15 U.S.C.A. § 1127 (2011); 1 MCCARTHY ON TRADEMARKS § 3:1.

²⁰⁶ 1 MCCARTHY ON TRADEMARKS § 8:4.

²⁰⁷ 1 *id.* § 4:13.

3. Rights in Marks

Upon formation of the requisite intent and use of the mark in furtherance thereof, a common law priority of right to use that mark in connection with those goods or services within the geographical area where such use occurs (*i.e.*, “priority of right”) vests in the user thereof (or its licensor).²⁰⁸ However, any such priority of right is subject to the priority of right of any prior users of the same or a substantially similar mark in connection with related goods or services within that area. Such prior users possess a prevailing priority of right, because, as a general rule at common law, (i) use of a mark in connection with certain goods or services within a certain geographical area establishes a priority of right in the user, as of the date of such use (*i.e.*, the “priority date”), as against future uses of that same or a substantially similar mark in connection with related goods or services within that area and (ii) a user with an earlier priority date (*i.e.*, a “senior user”) prevails over a user with a later priority date (*i.e.*, a “junior user”).²⁰⁹

Trademark protection for a term, logo, symbol, or other potential source indicator applies only to the extent that the potential source indicator functions as a mark and not to (i) any aspects thereof that are solely creative or expressive in nature, all of which may be subject to copyright protection as discussed in Section II.B. above or (ii) any utilitarian or functional aspects of the potential source indicator, all of which may be subject to patent protection as discussed in Section II.C. above.

4. Prosecuting an Application to Register a Mark at the USPTO

Although it is not necessary to register a mark with the USPTO in order to accrue common law rights in that mark (and its associated goodwill) through use of the mark in commerce, federal registration does carry with it certain benefits, some of which are described in Section II.D.4.(c) below.²¹⁰ For unregistered marks, the *overt act* requirement discussed above is satisfied through actual use of the mark in any commercial context, and any priority of right that arises out of such use is traceable to the date of such actual use, which constitutes the user’s priority date.²¹¹ However, in the case of a mark

²⁰⁸ See 2 *id.* § 16:1.

²⁰⁹ *Id.*; 2 *id.* § 16:18.50.

²¹⁰ See 3 *id.* § 19:8.

²¹¹ See 2 *id.* § 16:1.

for which the owner pursues and secures federal registration at the USPTO, the *overt act* requirement, which necessarily implicates use in interstate commerce,²¹² may be satisfied not only on the actual use basis just described but also on a “constructive use” basis prior to commencement of such actual use, which, as explained in Section II.D.4.(b) below, may result in an earlier priority date.²¹³

a. Use-Based Applications

In the event that a mark owner is using its mark in interstate commerce in connection with certain goods and/or services and desires to pursue a federal registration for that mark in connection with such goods and services, the owner would file a use-based registration application with the USPTO. In such cases, the USPTO generally will look to, among other things, the owner’s date of first actual use of the applied-for mark in interstate commerce in connection with those goods and/or services, as stated in the registration application, in determining the mark owner’s priority of right vis-à-vis other applicants that seek registration of the same or similar mark in connection with goods and/or services related to those of the mark owner.²¹⁴

b. Intent-to-Use Applications

The constructive use process commences by filing with the USPTO an intent-to-use application to register the mark, which is filed before actual use of the mark commences and wherein the applicant declares a bona fide intent, as of the filing date of the application, to use the mark in interstate commerce in connection with the relevant goods or services.²¹⁵ However, a priority of right to use the applied-for mark will not vest, and a registration for the mark will not issue, unless and until, among other things, the applicant commences actual use of the mark in interstate commerce within the prescribed time period.²¹⁶ Upon commencement of such actual use and issuance of a

²¹² See 3 *id.* § 19:104.

²¹³ 2 *id.* § 16:1.

²¹⁴ See *id.*

²¹⁵ 2 *id.* § 16:2.

²¹⁶ 15 U.S.C. § 1051(d)(1) (2011). Once the USPTO issues a Notice of Allowance on an intent-to-use application, which indicates that the application has satisfied the relevant requirements for registration, the applicant nonetheless must commence use of the applied-for mark in interstate commerce in connection with the relevant goods and/or services within six (6) months thereafter in order for a registration to issue. *Id.* The applicant can petition the USPTO for up to five consecutive 6-month extensions of the period within which to commence such use; however, in the event such use does not commence within 36 months after issuance

registration for the mark, the applicant's priority date is deemed to be the filing date of the intent-to-use application rather than the date of first actual use of the mark.²¹⁷ It is important to note that as long as a mark is the subject of a registration application having an intent-to-use filing basis, no goodwill is established in that mark, which, as discussed in Section II.D.6. below, has significant consequences in connection with any proposed assignment of that mark or its associated registration application.²¹⁸

c. USPTO Examination

After examining a use-based or intent-to-use registration application for a mark, the USPTO typically issues an office action directed primarily at identifying any (i) registration "refusals" due to the applicant's failure to comply with the Lanham Act's statutory requirements for registration or (ii) registration "objections" due to the applicant's failure to comply with the USPTO's administrative requirements for registration.²¹⁹ In order to put the application in a condition for approval by the USPTO, the applicant must overcome all such refusals and objections.²²⁰ Additional office actions from the USPTO and applicant responses thereto, may be required to address other issues as they arise. In the event that the applicant cannot overcome all such refusals and objections after the USPTO makes its determinations final, the applicant may either (a) appeal the adverse determinations to the USPTO's Trademark Trial and Appeal Board ("TTAB") or a federal court or (b) abandon the application.²²¹

If and when the application passes muster at the USPTO, it is published for opposition in order to give any third party an opportunity to oppose registration of the applied-for mark on the grounds that such registration would cause damage to that party.²²² Any opposition to registration is conducted pursuant to a proceeding before the TTAB, and prosecution of the registration application is suspended pending the outcome of that proceeding. Absent any such opposition, or in cases where the applicant prevails in an opposition proceeding, (i) if the application is use-based, a registration thereafter in the normal

of the Notice of Allowance, the application goes irretrievably abandoned. *Id.* § 1051(d)(2), (4).

²¹⁷ See 15 U.S.C. § 1057(c) (2011).

²¹⁸ See *infra* notes 230–38 and accompanying text.

²¹⁹ 15 U.S.C. § 1062(b) (2011).

²²⁰ See *id.*

²²¹ See *id.*

²²² 15 U.S.C. § 1062–63 (2011).

course or (ii) if the application is intent-to-use based, the USPTO will issue a Notice of Allowance, which starts a three-year period within which the applicant must commence use in interstate commerce of the applied-for mark in connection with the relevant goods and/or services in order for a registration ultimately to issue.²²³

d. Benefits of Federal Registration

Federal registration of a mark for use in interstate commerce in connection with certain goods and/or services provides the registrant with a priority of right throughout the entire United States to use the same or any substantially similar mark in connection with the same or related goods and/or services.²²⁴ However, in accordance with the general rule stated in Section II.D.3.above, such nationwide priority of right is subject to the rights of any senior users within the geographical area of use by such senior users as of the filing date of the registration application. Moreover, this priority of right is predominately evidentiary in nature.²²⁵

It is important to note that, unlike unregistered marks in which the priority of right to use the mark is limited to the geographical area of use, the priority of right to use a federally registered mark is nationwide (subject to rights of senior users as described above) even if, for example, that mark has not been used in all fifty (50) states.²²⁶ However, in order to qualify for federal registration, such use must occur, at a minimum, in interstate commerce.²²⁷ In addition to the foregoing priority of right, as with registration of a copyrighted work, federal registration of a mark provides certain procedural advantages and remedies, which are not otherwise available absent such registration, in connection with enforcing that priority of right against infringers.²²⁸

²²³ The Lanham Act also provides a means whereby a party may petition to cancel a federal registration on the grounds that it causes damage to that party. 15 U.S.C. § 1064 (2011).

²²⁴ See 15 U.S.C. § 1052 (2011).

²²⁵ See *id.* § 1057(b) (2011) (“A certificate of registration of a mark upon the principal register . . . shall be prima facie evidence of the validity of the registered mark and of the registration of the mark, of the owner’s ownership of the mark, and of the owner’s exclusive right to use the registered mark in commerce on or in connection with the goods or services specified in the certificate, subject to any conditions or limitations stated in the certificate.”)

²²⁶ *Id.*, see also *Du Barry of Hollywood, Inc. v. Richard Hudnut*, 323 F.2d 986, 988–89 (9th Cir. 1963).

²²⁷ See *supra* note 50.

²²⁸ See 3 MCCARTHY ON TRADEMARKS § 19:8.

5. Notice of Registration

A registrant can provide public notice of federal registration of a mark by affixing notice including one of the following elements immediately adjacent to the mark: (i) the words “Registered in the U.S. Patent and Trademark Office”; (ii) abbreviation “Reg. U.S. Pat. & Tm. Off.”; or (iii) the letter “R” enclosed within a circle (*i.e.*, “®”).²²⁹ Such notice serves to enhance the scope of damages potentially recoverable by the mark owner in any suit brought to enforce its rights in the mark.²³⁰

6. Transfer of Ownership Rights in Federally Registered and Applied-for Marks

Ownership of rights in federally-registered marks and marks that are the subject of pending federal registration applications (collectively, “Federal Marks”) and goodwill associated with such marks initially inure in the party that either actually or constructively uses the Federal Mark in commerce on or in connection with the relevant goods or services, and such rights vest upon such actual use.²³¹ In order for ownership rights in a Federal Mark and any associated goodwill therein, which arises out of use of that mark, to vest in any party other than the user of the mark, the user must execute a written document transferring all those rights to that other party.²³²

Such a case arises when the owner of a Federal Mark relies on licensees to make use of that mark in connection with some commercial activity involving the relevant goods or services.²³³ This situation typically arises when the owner of the Federal Mark is a manufacturer that relies on distributors or other such third-party licensees to market and sell the manufacturer’s branded products.²³⁴ To protect against any unintended vesting in such licensees of any rights in the Federal Mark or associated goodwill, the licensee’s marketing and sales activities should be governed by a written license agreement that transfers all such rights to the owner of the Federal Mark and states that all uses of that mark by the licensee, and all

²²⁹ 15 U.S.C. § 1111 (2011).

²³⁰ 3 MCCARTHY ON TRADEMARKS § 19:144.

²³¹ *Id.* § 16:35.

²³² 15 U.S.C. § 1060 (2011); 3 MCCARTHY ON TRADEMARKS § 18:1 (defining assignment of a mark as “an outright sale of all rights in that mark”).

²³³ See 3 MCCARTHY ON TRADEMARKS, § 18:40–43 (stating that owners of a mark may license the use of the mark to other parties, even though it is not specifically allowed in the Federal Lanham Act).

²³⁴ 3 *id.* § 16:48.

goodwill arising therefrom, inures to the sole and exclusive benefit of the owner.²³⁵

Trademarks and service marks used in connection with a mark owner's business are merely symbols of the goodwill in that business that arises out of such use.²³⁶ As a result, (i) trademarks and service marks have no significance independent and apart from the goodwill they symbolize; (ii) a mark and the good will that it symbolizes are inseparable; and (iii) any goodwill symbolized by a mark cannot materialize unless and until that mark is used in commerce in connection with the relevant goods or services.²³⁷

The foregoing principles give rise to the following facts regarding transfers of ownership rights in marks: (1) any transfer of ownership rights in a mark without transfer of its associated goodwill constitutes an assignment-in-gross that is null and void and of no force or effect for purposes of transferring the associated goodwill and (2) marks that have not yet been used have no associated goodwill and, therefore, ownership rights therein cannot be transferred.²³⁸

As a corollary to the foregoing in clause (2), as long as a mark is the subject of a registration application having an intent-to-use filing basis, neither that registration application nor the applied-for mark can be transferred to an individual or entity other than a successor to the mark owner's business (or portion thereof to which the mark pertains) that intends to continue operating that business (or portion thereof) after the transfer takes effect.²³⁹

As with transfers of ownership of copyright and patent rights, a transfer of ownership of rights in a Federal Mark may occur either (i) by operation of law or (ii) by written agreement. Oral transfers of ownership of such rights are unenforceable and of no force or effect.²⁴⁰

a. Transfer by Operation of Law

Ownership of rights in a Federal Mark may be transferred by operation of law in connection with any business consolidation or combination (*e.g.*, a merger) for which applicable law provides for transfer of all right, title, and interest in, and to the intangible assets

²³⁵ 3 *id.* § 18:45.50.

²³⁶ 1 *id.* § 2:15.

²³⁷ *United Drug Co. v. Theodore Rectanus Co.*, 248 U.S. 90, 97 (1918); 3 MCCARTHY ON TRADEMARKS § 18:2.

²³⁸ 3 MCCARTHY ON TRADEMARKS § 18:3.

²³⁹ *The Clorox Co. v. Chemical Bank*, 40 U.S.P.Q. 2d 1098, 1104 (Trademark Tr. & App. Bd., 1996); *see* 15 U.S.C. § 1060(a)(1).

²⁴⁰ 15 U.S.C. § 1060(a)(3).

(such as intellectual property rights) of, the individual business entities into the consolidated or combined business entity.²⁴¹

b. Transfer by Written Agreement

If ownership of rights in a Federal Mark do not transfer by operation of law pursuant to the principles described in the immediately preceding paragraph, such rights may be transferred only by a written agreement signed by the party transferring such rights.²⁴²

7. Recordation of Transfers of Ownership of Rights in Federally Registered and Applied-for Marks

In order to protect itself against a later-executed, conflicting transfer of rights in a Federal Mark to a later transferee that would otherwise be a bona fide purchaser for value without actual notice of the initial transfer, a rightful transferee of ownership in such rights must, within three months after the date of the initial transfer or prior to the later transfer, have any such transfer of ownership of such rights recorded at the USPTO along with a copy of the transfer document.²⁴³ Although acknowledgement (*i.e.*, notarization) of the executed transfer document is not required for its validity, it does constitute prima facie evidence of the execution of the transfer.²⁴⁴

8. Activities That Can Result in Loss of Rights in a Mark

In order to prevail in a federal infringement or dilution action to enforce rights in a mark, the mark owner must prove that (i) it owns valid and enforceable rights in the mark and has standing to bring the action, all consistent with applicable legal requirements and (ii) the accused party has usurped the mark owner's exclusive right to use the infringed or diluted mark in connection with the applicable goods or services free of other confusingly similar or dilutive marks. With regard to the second element of proof, the mark owner must prove that the accused party's unauthorized use of the mark at issue is likely to cause (1) confusion or mistake in the marketplace with respect to the source of the mark owner's and/or the infringer's goods or services; (2) confusion, or to cause mistake, or to deceive consumers as to an affiliation, connection, or association by and between the mark owner and the infringer that does not, in fact, exist; or (3) dilution of the

²⁴¹ 15 U.S.C. § 1060(a)(1).

²⁴² *Id.* § 1060(a)(3).

²⁴³ *Id.* § 1060(a)(4).

²⁴⁴ *Id.* § 1060(a)(3).

value of a famous mark by blurring or tarnishment.²⁴⁵ Therefore, any act or omission by or on behalf of the mark owner that bars proof of either or both of the foregoing elements can result in loss of, or inability to enforce, the mark owner's rights in the infringed or diluted mark.²⁴⁶

Following are some of the ways in which rights in marks can be lost or rendered temporarily unenforceable:

a. Abandonment

As with patent rights, abandonment in connection with rights in marks can occur in several ways.

First, a mark owner may abandon the mark itself as follows:

i. Non-Use

Because use of a mark is the linchpin from which all rights in that mark derive, any prolonged non-use of a mark that is coupled with the intent to not resume use of the mark, will result in abandonment of, and loss of rights in, the mark.²⁴⁷ Non-use of a mark for a period of three (3) consecutive years creates a rebuttable presumption of abandonment of the mark.²⁴⁸ Intent not to resume use of a mark may be inferred from the circumstances surrounding such non-use.

ii. Failure to Control Quality

Any failure of the mark owner to establish and implement appropriate control measures over (i) the quality of the goods and services in connection with which the applicable mark is used and (ii) the manner in which that mark is used may result in abandonment of the mark due to failure of the mark to continue serving as a consistent indicator of the quality of the associated goods or services.²⁴⁹

iii. Assignment Without Goodwill

Transfer of ownership rights in a mark without contemporaneous transfer of the goodwill associated with that mark

²⁴⁵ 15 U.S.C. § 1125(a)(1)(A) (2006) (stating civil action requirements pertaining to confusion in the marketplace and/or affiliation); *id.* § 1125(c) (stating injunctive relief remedies for dilution of famous mark by blurring or tarnishment).

²⁴⁶ *See* 15 U.S.C. §§ 1114, 1125(a); *see, e.g.*, *Fisons Horticulture, Inc. v. Vigoro Indus., Inc.*, 30 F.3d 466, 472 (3d Cir. 1994).

²⁴⁷ *See* 15 U.S.C. § 1127.

²⁴⁸ *Id.*

²⁴⁹ *See Sheila's Shine Prods., Inc. v. Sheila Shine, Inc.*, 486 F.2d 114, 124 (5th Cir.1973).

completely undermines the source indicator function of the applicable mark thereby resulting in its abandonment.²⁵⁰

iv. Genericness

Failure of the mark owner to vigilantly monitor for unauthorized uses of its mark and to vigorously enforce its rights in such marks against potential infringers may cause the applicable mark to lose its source indicator characteristics and ultimately become generic, which is a form of abandonment.²⁵¹

Second, a trademark or service mark registration application may go abandoned for applicant's failure to prosecute the application in accordance with rules and regulations established by the USPTO.²⁵²

Finally, a trademark or service mark registration may go abandoned (*i.e.*, expire) for registrant's failure to file certain documentation and pay certain fees required to maintain the registration in effect.²⁵³

b. Assignment of an Intent-to-Use Registration Application

Except under the very limited circumstances described in Section II.D.6. above, a registration application for a mark filed on an intent-to-use basis cannot be assigned prior to converting to a use-based application without jeopardizing the validity and enforceability of any registration that might issue from that application.²⁵⁴

c. Failure to Provide Notice of Registration

The Lanham Act generally provides that a mark owner may recover (i) the infringer's profits and the mark owner's damages resulting from the infringement, and (ii) costs of the infringement action.²⁵⁵ Monetary relief under the Lanham Act is available for (1) infringement of the mark owner's rights or dilution of the mark's value under federal law that occurs after the mark is registered and (2) pursuant to § 1125 of the Lanham Act, violations of the mark owner's rights under common law that occur prior to such registration.²⁵⁶

²⁵⁰ See 15 U.S.C. § 1060(a)(1); *see, e.g.*, *Defiance Button Mach. Co. v. C & C Metal Prods.*, 759 F.2d 1053 (2d Cir. 1985).

²⁵¹ 15 U.S.C. § 1127 (2006).

²⁵² 37 C.F.R. § 2.65 (2010).

²⁵³ *Id.* §§ 2.182–2.183.

²⁵⁴ 3 MCCARTHY ON TRADEMARKS § 19:61.

²⁵⁵ 15 U.S.C. § 1117 (2006).

²⁵⁶ *Id.* § 1125.

While failure to provide proper notice of registration of a mark does not preclude liability in an infringement action, it does have a bearing on the amount of monetary relief awarded.²⁵⁷ For example, § 1111 of the Lanham Act precludes recovery of profits and damages if the mark owner fails to provide notice of the mark's registration in accordance with the provisions of the Lanham Act, unless the infringer had actual notice of such registration.²⁵⁸ Thus, the mark owner's remedies in such a situation are limited to recovery of the costs of the infringement action and an injunction against further infringing activity.²⁵⁹

Furthermore, § 1114 of the Lanham Act precludes recovery of profits and damages from a contributory infringer (*i.e.*, one who assists, but does not directly participate in, an act of direct infringement of a trademark) unless the contributory infringer acts with knowledge that its conduct is intended to be used to cause confusion or mistake, or to deceive.²⁶⁰ Once again, the trademark owner's remedies in such a situation are limited to recovery of the costs of the infringement action and an injunction against further infringing activity.²⁶¹

d. Misuse of Marks

If a mark owner exploits its rights in a mark beyond the scope of the exclusive rights granted by law to the mark owner with an overall anticompetitive effect, the mark owner may be guilty of misuse of the mark.²⁶² For any infringement action brought by a mark owner guilty of such misuse in which the misuse directly relates to the mark at issue in such action, the alleged infringer may have grounds for asserting a defense based on misuse of the mark.²⁶³ As is the case with copyright and patent misuse, when misuse of a mark arises, it is often in connection with licensing arrangements that attempt to expand the scope of the exclusive rights attendant to licensed marks beyond its legally permissible boundaries.²⁶⁴ All such rights in the mark are

²⁵⁷ See *id.* § 1111 “[A] registrant of a mark . . . may give notice that his mark is registered . . . and in any suit for infringement under this chapter by such a registrant failing to give such notice of registration, no profits and no damages shall be recovered . . . unless the defendant had actual notice of the registration.” (emphasis added).

²⁵⁸ *Id.*

²⁵⁹ See *id.*

²⁶⁰ *Id.* § 1114(1), (2)(A).

²⁶¹ *Id.* §§ 1114(2)(A–B).

²⁶² 6 MCCARTHY ON TRADEMARKS § 31:91.

²⁶³ *Id.*

²⁶⁴ *Id.*

rendered unenforceable until all the misuse and its related consequences are purged.²⁶⁵

e. Fraud and Inequitable Conduct before the USPTO

As with patent applications prosecuted before the USPTO, applicants seeking registration of marks and their counsel have a duty to prosecute registration applications before the USPTO in good faith and with candor and honesty.²⁶⁶ However, there are a number of fundamental differences between prosecuting patent applications and registration applications for marks that give rise to a somewhat less stringent duty of candor in connection with the process for registering marks.²⁶⁷ Two of those differences are as follows:

First, unlike patent applications, which are prosecuted before the USPTO on a confidential, *ex parte* basis without any opportunity for third party input during the prosecution process, prosecution of registration applications for marks provides a publicly available record of the entire proceeding and includes an opposition period (discussed in Section II.D.4.C. above) after substantive examination, during which third parties may oppose registration of the applicable mark on grounds that such registration would cause damage to that third party.²⁶⁸

Second, unlike patent rights in an invention, which do not fully vest in the applicant unless and until a patent issues on the invention, initial rights in marks vest upon use of the mark and are not contingent on securing a registration for the mark.²⁶⁹ Said another way, grant of a patent creates rights while issuance of a registration for a mark merely broadens the geographical scope, and further reinforces the validity and enforceability, of already existing rights by establishing corresponding evidentiary presumptions in favor of the registrant.²⁷⁰

²⁶⁵ *Id.* quoting *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 298 F. Supp. 1309 (S.D.N.Y. 1969), *modified*, 433 F.2d 686 (2d Cir. 1970), *cert. denied*, 403 U.S. 905 (1971).

²⁶⁶ *See* 37 C.F.R. § 1.56 (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office.”). *See, e.g., Aromatique, Inc. v. Gold Seal, Inc.*, 28 F.3d 863, 877 (8th Cir. 1994) (“Aromatique defended its actions in part by asserting that an applicant for a trademark owes no duty of candor to the PTO. This is plainly wrong.”).

²⁶⁷ 6 MCCARTHY ON TRADEMARKS § 31:65.

²⁶⁸ 3 *id.* § 19:130; 15 U.S.C. § 1063 (2006).

²⁶⁹ 2 MCCARTHY ON TRADEMARKS § 16:1.

²⁷⁰ *See supra* note 225.

The foregoing differences highlight the need for a more stringent duty of candor in the patent application context for the following reason: Because the exclusionary effects of patent rights are more far-reaching than similar effects arising from registration of a mark, closer and more demanding scrutiny is warranted in connection with prosecuting patents in order to ensure that each patent grant rewards true technological innovation without unnecessarily constraining the public's use of technology that otherwise should be freely available.

As in the patent context, fraudulent and inequitable conduct in connection with prosecuting registrations for marks typically involves material misrepresentations and false statements and failure to disclose information material to the registrability of the applicable mark with the intent to deceive and mislead the examiner into issuing a registration.²⁷¹ However, notwithstanding that fraudulent or inequitable conduct in prosecuting a registration application for a mark will invalidate or preclude issuance of a registration for the underlying mark, such conduct will not render invalid or unenforceable the common law rights in the underlying mark. That is so primarily because those rights are created upon use of the mark in commerce and are not dependent on a registration for their vitality.²⁷² Such a result seems reasonable and understandable from an infringement litigation perspective for the following reason: Rendering common law rights in a mark unenforceable due to the mark owner's fraudulent or inequitable conduct during prosecution of an application to register that mark would defy the objectives of trademark law by permitting the accused infringer to continue causing consumer confusion in the marketplace.²⁷³

f. Parody and Comparative Advertising

Similar to the balancing of competing interests that occurs in analyzing the fair use defense to copyright infringement, courts sometimes are called upon to balance free speech considerations with a mark owner's legitimate expectation to be free of confusingly similar and dilutive marks.²⁷⁴ Parody and comparative advertising are two contexts within which such balancing is required. Use of another's trademark or service mark in either context is not likely to cause

²⁷¹ 6 *id.* § 31:59–83.

²⁷² 6 *id.* § 31:60.

²⁷³ 6 *id.* § 31:60.

²⁷⁴ 6 *id.* §§ 31:144, 31:155; Cliff Notes, Inc. v. Bantam Doubleday Dell Publ'g Grp., Inc., 886 F.2d 490, 494–95 (2d Cir. 1989).

customer confusion, and therefore is not actionable, as long as certain requirements are met in each case.²⁷⁵

Parody typically involves a combination of criticism/critique and humor that employs some degree of imitation in order to achieve the desired effect.²⁷⁶ When the imitation involves use of another party's mark in order to catch the reader's attention, as long as the content of the parody is such that the reader quickly realizes that such use is actually a parody and not the "real thing," there is usually little likelihood that confusion will result. On the other hand, if the message of the parody is slow to develop or otherwise is likely to be missed altogether by the reader, actionable confusion may well result.²⁷⁷

Use by a party of another party's mark in comparative advertising typically attempts to tout the advantages and benefits of the using party's goods or services compared with those offered by the other party. As long as the advertising content is truthful and not confusing as to (i) the source of the goods or services being compared or (ii) any affiliation between the parties, such use is likely not objectionable.²⁷⁸ In order to minimize the chance of any such confusion, a disclaimer of association is sometimes included as part of the advertising.²⁷⁹

g. Fair Use

"Fair use" of a mark involves use of another party's mark that is legal (*i.e.*, non-infringing), because it does not give rise to a likelihood of confusion. There are two types of fair use in connection with marks: (i) classic fair use and (ii) nominative fair use.

i. Classic Fair Use

Classic fair use is use of another party's mark, or a mark substantially similar thereto, merely to describe something about the user's goods or services, rather than use in a trademark sense (*i.e.*, as an indicator of the source of the user's goods or services).²⁸⁰ Likelihood of confusion is precluded in such cases because the other party's mark is not being used as a source indicator.²⁸¹ This type of fair use most often occurs in connection with marks that are

²⁷⁵ 4 MCCARTHY ON TRADEMARKS § 23:11.

²⁷⁶ *Id.*

²⁷⁷ 6 *id.* § 31:154.

²⁷⁸ 4 *id.* § 25:52.

²⁷⁹ *Id.*

²⁸⁰ 2 *id.* § 11:45.

²⁸¹ *Id.*

descriptive in nature – *i.e.*, marks to which trademark law affords very little protection.²⁸²

ii. Nominative Fair Use

Nominative fair use is use of another party's mark to identify the mark owner's goods and/or services, not the user's goods and/or services.²⁸³ Such use typically is not confusing to consumers because it identifies the actual owner of the mark at issue.²⁸⁴ Use of another's mark in comparative advertising is an example of nominative fair use.²⁸⁵ Use of a mark constitutes nominative fair use if (i) the mark owner's goods and/or services are readily identifiable to consumers only through use of the mark; (ii) the mark is used only to the extent reasonably necessary to identify the mark owner; and (iii) the mark is not used in a way that states or suggests any sponsorship or endorsement by the mark owner.²⁸⁶

h. Other Activities to Avoid

The discussion above in Sections II(B)(8)(d)-(e) and II(C) with respect to loss of copyright rights under theories of implied license and laches applies with equal force and effect to rights in marks.²⁸⁷

E. Trade Secrets

The *intellectual* act in a trade secret context involves (i) creation, conception, or other similar mental act by an individual giving rise to certain subject matter, whether or not copyrightable or patentable, that (1) is readily distinguishable from generalized knowledge and skill; (2) is secret (*i.e.*, not generally known or easily compiled); and (3) derives independent economic value from its secret status coupled with (ii) "formation of the requisite intent" to maintain the secrecy of such subject matter.²⁸⁸

The overt act giving rise to *property*-related rights in a trade secret context involves taking steps reasonably necessary to maintain the secrecy of the foregoing subject matter in furtherance of the intent described in clause (ii) above. Although secrecy is at the heart of the overt act requirement in a trade secret context, the tangible measures

²⁸² *Id.*

²⁸³ *Id.* § 23:11.

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ *Id.* (citing *New Kids on the Block v. News Am. Pub., Inc.*, 971 F.2d 302, 308 (9th Cir. 1992)).

²⁸⁷ See generally 3 MCCARTHY ON TRADEMARKS §§ 18:43.50, 31:1.

²⁸⁸ See ROGER M. MILGRIM, MILGRIM ON TRADE SECRETS § 1.01 (2010).

that a trade secret owner adopts and implements in order to maintain that secrecy (*e.g.*, confidentiality agreements, security procedures, etc.) serve the public notice function described at the beginning of this chapter.²⁸⁹ In some cases, owners of patentable subject matter elect to treat such subject matter as a trade secret, as opposed to filing for patent protection, due to the disclosure required in connection with seeking patent rights in such subject matter and the uncertainty in ultimately securing such rights.²⁹⁰

Any act or omission by or on behalf of a trade secret owner that results in a loss of trade secret status will diminish, if not eradicate, the value of the trade secret.²⁹¹ Examples include (i) providing access to trade secrets without first implementing and enforcing reasonable confidentiality obligations and restrictions and (ii) failure to institute reasonable security measures to control access to and dissemination of trade secrets.²⁹²

Unlike issues involving copyrightable or patentable subject matter, all of which are governed primarily, if not exclusively, by federal law, issues involving trade secrets are subject to the laws of the respective states in each case.²⁹³

III. IMPACT OF THE HITECH ACT: CREATING A NEW MARKET FOR HIT

This Section III will explore the ways in which the HITECH Act has created a dramatically expanded market for HIT products, and how our existing intellectual property legal structures provide a key ingredient necessary to facilitate and sustain this new HIT market.

As a result of the HITECH Act, health care providers now have a tangible and easily quantifiable financial motivation to purchase and implement EHR systems. Under the HITECH Act's EHR Incentive Program, physicians can receive up to \$44,000 in financial incentives for adopting and achieving meaningful use of certified EHR systems;²⁹⁴ physicians that have an average Medicaid patient population of 30% or more can receive up to \$63,750 in incentives.²⁹⁵

²⁸⁹ *See id.* § 1.04.

²⁹⁰ *See id.* § 1.06.

²⁹¹ *See id.* § 1.05.

²⁹² *See id.*

²⁹³ *See id.* § 1.01.

²⁹⁴ 42 C.F.R. § 495.102(b) (2010).

²⁹⁵ *Id.* §§ 495.304, 495.310(a)(3).

Hospitals will stand to receive even greater incentive amounts, easily reaching into the millions of dollars.²⁹⁶

Accompanying the “carrot” of financial incentives for providers that demonstrate meaningful use, however, is the “stick” of financial penalties for providers that fail to do so: physicians that fail to demonstrate meaningful use by 2015 will face reductions in their Medicare reimbursement rates of up to 1%,²⁹⁷ while hospitals will face reductions in their annual Medicare Inpatient Prospective Payment System market basket update.²⁹⁸

In addition to the potential financial incentives (and penalties) under the EHR Incentive Program, the HITECH Act may also create certain intangible benefits for those providers that implement EHR systems. As set forth in the Meaningful Use Rule, CMS will maintain and make publicly available (through its website) a list of all health care providers that have adequately demonstrated meaningful use of EHR technology.²⁹⁹ As EHRs become pervasive among health care providers, patients likely will come to understand and appreciate the many health care benefits of EHRs, and may eventually begin to seek out providers that have met the meaningful use criteria, and avoid providers that have not. The HITECH Act thereby creates a valuable resource for patients to easily identify those providers that have adopted and are using EHRs in a meaningful manner. As a result, providers that wish to successfully attract and retain patients will have further incentive to adopt and embrace EHR technology and related systems.

Considering both the tangible and intangible incentives for providers under the HITECH Act, it is likely that the demand for EHR products will significantly increase in the coming years. In fact, CMS estimates that approximately 624,000 providers will be eligible for incentives under the EHR Incentive Program.³⁰⁰ The influx of federal funds under the HITECH Act will help subsidize the purchase and license of EHR technology for many providers that otherwise may not have been able to afford an EHR system, in effect, drawing new purchasers into the HIT market. Providers who already own or license EHR systems may seek to use HITECH Act incentive payments to upgrade or expand their EHR capabilities. In either case, the vast

²⁹⁶ See *id.* §§ 495.104, 495.310(f).

²⁹⁷ *Id.* § 495.102(d).

²⁹⁸ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 42 C.F.R. §§ 412, 413, 422, & 495.

²⁹⁹ 42 C.F.R. § 495.108(a).

³⁰⁰ Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 1844, 1974 (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, 495).

number of providers eligible for incentives under the HITECH Act will increase the demand for EHR products, and this increase in demand will result in a significant opportunity for EHR vendors to enter or expand their presence in the HIT market.

While the increase in demand for EHR products will be a key motivator for EHR vendors, there are additional factors that will further incentivize EHR developers to create or expand their EHR product offerings. One such factor is the process developed under the HITECH Act for the certification of EHR products. As discussed in more detail in Section I above, in order to qualify for incentive payments under the EHR Incentive Program, providers must adopt and implement “certified” EHR technology.³⁰¹ ONC has established a process whereby EHR vendors may test and certify their EHR products.³⁰² Under the certification program, ONC will designate certain private entities as “ONC-Authorized Testing and Certification Bodies” (“ONC-ATCBs”).³⁰³ Currently, six organizations have been authorized as ONC-ATCBs: Drummond Group, Inc.; Certification Commission for Health Information Technology (“CCHIT”); InfoGard Laboratories, Inc.; SLI Global Solutions; ICSA Labs; and Surescripts LLC.³⁰⁴

ONC-ATCBs are authorized to test and certify both Complete EHRs and EHR Modules.³⁰⁵ EHR vendors will be required to demonstrate, in accordance with the applicable ONC-ATCB’s procedures, that the applicable vendor’s EHR technologies provide all of the capabilities required to allow providers to meet the Stage 1 meaningful use criteria.³⁰⁶ Once certified, the ONC-ATCB will report to ONC information about the certified EHR technology, including the specific meaningful use criteria that have been demonstrated by the EHR vendor.³⁰⁷

As a key component of the certification process, ONC will maintain and publish an updated list of all EHR technology that has

³⁰¹ 42 C.F.R. § 495.8(a)(1)(A) (2010).

³⁰² See generally Establishment of the Temporary Certification Program for Health Information Technology, 75 Fed. Reg. 36158 (proposed June 24, 2010) (to be codified at 45 C.F.R. pt. 170).

³⁰³ 45 C.F.R. § 170.401 (2010).

³⁰⁴ See *ONC-Authorized Testing and Certification Bodies*, THE OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3120> (last updated Dec. 28, 2010).

³⁰⁵ 45 C.F.R. § 170.410 (2010).

³⁰⁶ See *id.* § 170.423(e).

³⁰⁷ *Id.* § 170.423(h).

been certified by an ONC-ATCB.³⁰⁸ This list will provide a detailed description of each of the certified EHR products, including the specific functionality that has been certified by the ONC-ATCB.³⁰⁹ The publication of certified EHR products by ONC is likely to be an important motivator for EHR vendors.

As health care providers seeking to demonstrate meaningful use begin to enter the EHR market, those providers will be required to implement certified EHR products. The publication of certified EHR products by ONC provides what is, in effect, a free advertising mechanism for EHR vendors. All potential EHR purchasers desiring to capitalize on the EHR Incentive Program will be highly motivated, if not required, to consult the list of certified EHR products before entering the EHR Incentive Program, and by having a product identified on the certified product list, EHR vendors can be assured that providers are aware of the vendors' potential product offerings. In addition, a provider will be able to evaluate and compare the entire spectrum of certified EHR products to find the product that most closely fits its particular needs. The certification process thereby creates a clearly defined marketplace for EHR technology, one which is easily accessible to potential purchasers.

Furthermore, ONC established the certification process in a manner that aims to reduce potential barriers to entry for EHR vendors seeking to enter the EHR market. As discussed in Section I above, the Certification Rule allows EHRs to be certified as either Complete EHRs or EHR Modules.³¹⁰ A Complete EHR is EHR technology that has been developed to meet *all* certification criteria adopted under the Certification Rule,³¹¹ whereas an EHR Module is any EHR component that can meet the requirements of at least *one* certification criterion under the Certification Rule.³¹² Permitting vendors to certify both Complete EHRs and EHR Modules is important because it allows a broad range of potential vendors to offer products in the certified EHR market. For example, if the Certification Rule only allowed certification of Complete EHRs, some EHR vendors would be precluded from offering certified EHR products, simply because they do not have the capacity to develop Complete EHRs. The Certification Rule is much more flexible, however. An EHR vendor only needs to show that the EHR technology can meet the

³⁰⁸ Establishment of the Temporary Certification Program for Health Information Technology, 75 Fed. Reg. 36158, 36170–71 (proposed June 24, 2010) (to be codified at 45 C.F.R. pt. 170).

³⁰⁹ *Id.*

³¹⁰ 45 C.F.R. § 170.102 (2010).

³¹¹ *Id.*

³¹² *Id.*

requirements of one of the Certification Rule's certification criterion, which is significantly less onerous than meeting the full array of certification criteria.

The effect of this flexible approach is two-fold: First, it allows a greater number of EHR vendors to offer certified EHR products to those providers that wish to receive incentives under the EHR Incentive Program. Second, by expanding the number of EHR vendors in the marketplace, providers will have a greater choice of EHR products. As a result, ONC's certification process benefits not only vendors, by establishing relatively low thresholds for entry into the EHR market, but also health care providers, by providing a greater variety of choices among certified EHR products.

Ultimately, ONC sought to use the flexible certification process for Complete EHRs and EHR Modules to spur innovation and creativity in the EHR marketplace in order to support the newly created demand for EHR technology.³¹³ While the success of ONC's certification process will not be fully realized for several years, it does appear that ONC has begun to meet its goal of spurring innovation in the HIT market, especially with respect to EHR products and related services. As of the writing of this Article, ONC-ATCBs have certified 413 EHR products.³¹⁴ Among those certified products, 245 have been certified as Complete EHRs and 168 as EHR Modules.³¹⁵ Although certified Complete EHRs do outnumber the certified EHR Modules, the number of certified EHR Modules is not insignificant. Certified EHR Modules comprise 41% of the certified EHR products.³¹⁶ Had ONC not permitted vendors to certify both Complete EHRs and EHR Modules, the number of available certified EHR products would have been substantially reduced.

The above paragraphs describe three factors important for motivating EHR vendors to enter the HIT market: (1) the increased demand for EHR products resulting from potential incentives and penalties under the EHR Incentive Program; (2) the defined market for EHR products created by the ONC certification process and facilitated by the publication of certified EHR products to potential purchasers; and (3) the flexible barriers to entry into the EHR market as a result of

³¹³ See Establishment of Temporary Certification Program for Health Information Technology, 75 Fed. Reg. 2014, 2023 (proposed June 24, 2010) (to be codified at 45 C.F.R. pt. 170).

³¹⁴ See CERTIFIED HEALTH IT PRODUCT LIST, <http://onc-chpl.force.com/ehrcert> (last visited Feb. 22, 2011).

³¹⁵ See *id.*

³¹⁶ See *id.*

certification for both Complete EHRs and EHR Modules. Each of these factors will help reshape the EHR market and create significant incentives for EHR vendors to continue to develop and produce EHR products.

While each of the foregoing factors is crucial to the success of the new market for EHR technology, the authors submit that those factors alone are not sufficient to ensure that EHR vendors become and remain adequately motivated to develop EHR products. In fact, another key ingredient necessary to ensure the success of the HITECH Act's EHR Incentive Program and the growing trend toward widespread adoption of EHRs is not part of the HITECH Act, but rather, is a product of our existing legal system; that ingredient is, of course, the legal protections afforded by our intellectual property legal structures.

The framework of intellectual property laws in the United States provides a vehicle whereby ownership of intellectual property rights in EHR technologies is allowed to ultimately vest in the appropriate party, such as EHR vendors that create, conceive, and otherwise develop such technologies, and are adequately protected against others who might try to infringe upon, misappropriate, or otherwise violate such rights. The HITECH Act certainly creates broad new opportunities for EHR vendors to develop and market their products, but without protection under the intellectual property laws, such product development would be futile; vendors will only be motivated to create and innovate to the extent their creations and innovations are and will remain protected. As such, intellectual property laws are a fundamental ingredient to ensuring the success and sustainability of the new EHR market envisioned under the HITECH Act.

As an illustration, several products and mechanisms have recently benefited from established intellectual property protections following passage of the HITECH Act. Since early 2009, the Copyright Office has issued copyright registrations to a number of computer software developers for software programmed to supply physicians' offices with ready-to-use electronic health record-keeping, managing, and transferring capabilities.³¹⁷ The USPTO registered multiple marks with "electronic health record,"³¹⁸ "EMR,"³¹⁹ or a

³¹⁷ U.S. COPYRIGHT OFF. PUBLIC CATALOG, <http://cocatalog.loc.gov> (search for "electronic health record" by "Keyword"; then follow "Begin Search" hyperlink) (last visited Apr. 1, 2011).

³¹⁸ TRADEMARK ELECTRONIC SEARCH SYSTEM (*TESS*), U.S. PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/trademarks/index.jsp> (follow "Search Marks" hyperlink; then follow "Basic Word Mark Search" hyperlink; then search for "electronic health record"; then follow "Submit Query" hyperlink).

similar phrasing in the title between 2009 and the present, and the USPTO continues to receive an increasing number of patent applications involving an electronic medical record component each month.³²⁰

For example, “EHR Everywhere,” a computer program offering patient information management, storage, and billing resources,³²¹ was created in 2009 and registered at the Copyright Office in 2010.³²² 360 EHR, a mark registered with the USPTO by Medaxis Corporation in November 2010, was first used in commerce in 2010, according to filing data.³²³ In addition, 360 EHR is identified on the list of certified EHR products, and includes clinical, office management, and billing features.³²⁴ Doctors’ Administrative Solutions, LLC filed a patent application with the USPTO on January 25, 2010 for a “computer-implemented method for tracking of clinical, demographic, financial and service metrics within a physician practice,”³²⁵ and numerous procedures related to electronic medical records have already obtained a patent.³²⁶ The authors submit that the number of EHR vendors benefiting from intellectual property law protection will only increase with the expansion of the EHR market under the HITECH Act.

³¹⁹ *Id.* (follow “Search Marks” hyperlink; then follow “Basic Word Mark Search” hyperlink; then search for “EMR”; then follow “Submit Query” hyperlink).

³²⁰ PAT. APPLICATION FULL TEXT & IMAGE DATABASE, <http://appft1.uspto.gov/netathtml/PTO/search-bool.html> (search “electronic medical record”; then follow “Search” hyperlink).

³²¹ *Clinical*, EHR EVERYWHERE, http://ehreverywhere.com/EHR_Clinical.aspx (last visited Apr. 1, 2011).

³²² U.S. COPYRIGHT OFF. PUBLIC CATALOG, <http://cocatalog.loc.gov> (search for “EHR Everywhere” by “Keyword”; then follow “Begin Search” hyperlink) (last visited Apr. 1, 2011).

³²³ TRADEMARK ELECTRONIC SEARCH SYS., <http://www.uspto.gov/trademarks/index.jsp> (follow “Search Marks” hyperlink; then follow “Basic Word Mark Search” hyperlink; then search for “360 EHR”; then follow “Submit Query” hyperlink) (last visited Apr. 1, 2011).

³²⁴ *Medaxis Products and Services*, MEDAXIS, <http://www.medaxis.com/ProductsAndServices/360EHR/> (last visited Apr. 1, 2011).

³²⁵ PAT. APPLICATION FULL TEXT & IMAGE DATABASE, <http://appft1.uspto.gov/netathtml/PTO/search-bool.html> (search “Doctors’ Administrative Solutions”; then follow “Search” hyperlink) (last visited Apr. 1, 2011).

³²⁶ PAT. FULL TEXT & IMAGE DATABASE, <http://patft.uspto.gov/netathtml/PTO/search-bool.html> (search “electronic medical record”; then follow “Search” hyperlink) (last visited Apr. 1, 2011).

IV. NAVIGATING THE EHR SOFTWARE LICENSE AGREEMENT

Assuming that the HITECH Act accomplishes its intended goal of motivating health care providers to adopt and implement EHR systems, many providers will be forced to confront certain legal challenges surrounding the adoption of EHR technology for the first time; one such challenge is understanding and negotiating an EHR software license agreement (“SLA”). Providers transitioning from paper health records to an EHR will need an SLA that affords the provider all the rights it needs, and imposes on the EHR software vendor all the obligations necessary to make that transition, without exposing the provider to unnecessary or unreasonable liability. This Section IV will address several issues likely to be faced by providers as they identify a suitable vendor and negotiate the vendor’s SLA.

First, the provider will need to select an EHR software vendor that is willing to work with the provider and the provider’s information technology (“IT”) department (or IT service provider) to assess the provider’s EHR needs and provide an EHR software solution that meets those needs. Virtually every software vendor uses its own form of SLA, which, to no one’s surprise, is drafted in favor of the vendor. It is important for the provider to know upfront how amenable a vendor is to modifying its form SLA to address the provider’s concerns. Some vendors are more willing than others to do that – in fact, certain terms and conditions in a vendor’s form SLA may be non-negotiable due to company policy or other reasons. Therefore, it is imperative for the provider to inquire about these points during the vendor selection process, not after negotiations have commenced.

Once the provider has selected an EHR vendor, the next step will be to negotiate the SLA. The provider will need to consider the following factors when reviewing the vendor’s form SLA. Does the SLA clearly identify all the hardware, software, and related services that the vendor is required to provide to ensure a smooth transition to EHR? Just as importantly, does the SLA clearly specify the provider’s responsibilities in order to accommodate the vendor’s EHR software system? In order to attract business, vendors likely will submit proposals that include representations and assurances about their EHR software that inexplicably do not find their way into the vendor’s form SLA. The best way to ensure that the SLA obligates the vendor to deliver on the representations and assurances made in the proposal is to incorporate the proposal by reference into the SLA, making clear that all such representations and assurances will constitute duties and obligations of the vendor. The provider also will need to ensure that

the SLA includes an acceptance testing procedure for determining whether the EHR software operates in accordance with its specifications and other documentation (“Documentation”). Also, if the software can’t be made to conform to its Documentation during implementation, is the vendor willing to refund all amounts the provider paid upfront for the software?

Next, will the EHR software, and the provider’s health care and other data used in connection with the software, reside on the provider’s own servers or be hosted externally, either on the vendor’s servers or at a third-party hosting facility? External hosting introduces additional issues with respect to data security, integrity and availability, and the accountability of the third-party hosting entity, all of which need to be addressed in the SLA. Furthermore, does the licensed software include software that is owned by an entity other than the EHR software vendor (“Third-Party Software”)? All Third-Party Software should be identified as such in the SLA, because the vendor is usually not willing to stand behind Third-Party Software to the same extent as software the vendor owns. In such cases, the provider should require the vendor, at a minimum, to pass through to the provider any and all Third-Party Software warranties that are available.

Managing potential liability exposure is always important for health care providers; this is especially true in connection with transitioning to EHR. As a result, providers should make sure that the SLA includes a liability cap, consequential damages disclaimer, and indemnification provisions that reasonably allocate potential liability under the SLA between the vendor and the provider. Also, it goes without saying that maintaining the confidentiality of patient and other information is a top priority, and potential source of liability, for health care providers, especially with the advent of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its privacy and security requirements with respect to protected health information (“PHI”). The vendor’s likely access to PHI during EHR software installation and implementation will require execution of a business associate agreement between the provider and the vendor. Moreover, transitioning to EHR also introduces a number of other health information exchange issues, which may need to be addressed within the SLA.

In addition, the vendor should be willing to provide certain representations and warranties with respect to its EHR software that are designed to give the provider a comfort level about the condition of the EHR software as of the effective date, and during the term, of

the SLA. For example, at a minimum, the vendor should represent and warrant the following for each item of EHR software provided to or accessed by the provider: (i) the EHR software and the provider's use of that software does not and will not infringe or misappropriate the intellectual property rights of any third party; (ii) the EHR software will operate in accordance with its Documentation during the applicable warranty period; and (iii) upon delivery to or access by the provider, the EHR software is free of any viruses or other disabling code that could damage the provider's computer systems or networks.

The vendor should provide maintenance (software error corrections) and support (software upgrades and enhancements) as part of its EHR software product offering. The vendor should be required to promptly respond to and correct (or provide appropriate workarounds for) software errors that have a material adverse impact on the provider's use of the software. Providers will need to look for remedies in the form of service credits for any breach by the vendor of its maintenance and support obligations under the agreement. Furthermore, for externally hosted applications, it is important to require a near-100% system availability and ensure that system availability is calculated in a reasonable manner. Providers should be particularly mindful of provisions requiring the provider to implement software upgrades, new releases, and versions made available by the vendor in order to remain eligible to receive maintenance and support. Complying with such requirements may necessitate a costly and unanticipated (and, therefore, non-budgeted) upgrade of the provider's software systems and related hardware.

As discussed above, in order for providers to qualify for incentives under the EHR Incentive Program, the provider must implement *certified* EHR technology. Furthermore, separate and distinct from the EHR certification standards, providers must meet all of the applicable meaningful use criteria. To ensure that providers will be able to comply with the meaningful use criteria, the provider will want to make sure that the SLA requires the vendor to maintain certification for its EHR software, and to cooperate with the provider's efforts to comply with all applicable meaningful use criteria.

Once the EHR software is installed and implemented, it will become one of the provider's most important assets. Ensuring the ongoing viability of that asset will rely in large part on the effectiveness of the vendor's maintenance and support services, none of which can be performed without access to the source code of the EHR software. As a result, the SLA should provide a contingency plan, in the form of a source code escrow agreement, in the event that the vendor is unwilling or unable to provide such services. Requiring the vendor to establish and maintain such an agreement with a

reputable source code escrow agent will allow the provider access to the EHR software source code in the event of, for example, the vendor's insolvency or failure to provide maintenance and support services for any other reason.

Finally, assume the provider makes a one-time, upfront payment for a perpetual license to use the EHR software. What happens if the vendor cannot correct errors in the EHR software or breaches the SLA in a manner that leaves the provider no choice but to terminate the SLA? Shouldn't the vendor be required to refund some, if not all, of the upfront payment due to the provider's limited use of the EHR software? Also, it seems only fair that the vendor should be obligated to help the provider quickly transition to another EHR software vendor. Further, shouldn't the vendor be required to promptly return all confidential information that it received from the provider? These examples highlight the importance of providing for possible termination of the SLA and its aftereffects by including exit strategies within the SLA designed to return the provider to some semblance of normalcy after the SLA terminates.

V. CONCLUSION

While the full effect of the HITECH Act will not be known for several years, the authors contend that the HITECH Act has already served, and will continue to serve, as a powerful motivator for healthcare providers to adopt and implement EHR systems, and for vendors to develop products to meet this new demand. Fundamental to the success of the HITECH Act, however, will be the protections and motivations inherent in United States intellectual property laws. These protections, combined with significant financial incentives available under the HITECH Act, will position our country's healthcare system to ultimately develop a nationwide interoperable health information technology infrastructure, a crucial element for improving the quality and efficiency of health care in the United States.

